

# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/45/22	22.06.2021	5,400,000 Capsules of	11.05.2021	Rs. 20,000/= +
	at 9.00 a.m.	Tacrolimus capsule 1mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/45/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01205602	Tacrolimus capsule 1mg	5,400,000	2,000,000
		Capsules	Capsules –
	Tacrolimus capsule 1mg		February 2022
	Each capsule to contain 1mg of Tacrolimus		
			2,000,000
	Note:		Capsules – June
	01. The shelf life of the product should be		2022
	minimum of 24 months		
			1,400,000
	Packing: 10 Capsules in a strip		Capsules –
	10 strips in a box		October 2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,374,840.00 or USD 6,889.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

# **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

# **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

# **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

# **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the

conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).

The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.

- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

# (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

# **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

# Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

# FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

			AN	NEX – 1		
	D./BID REFERENCE : ER NO.)					
DATE (	OF ISSUE :					
CLOSI	NG DATE & TIME :					
(SRI L	ANKAN TIME) :					
	LIST NO. :			_		
SR No.	Item Description/Specifications	Quantity	Delivery Schedule			
	Description, opecifications			$\neg$		
	Nos of Representative sa	mples for th	ne item to be submitted fo	or the		
Amour	it of Bid Bond : LKR	or USD	to be submitted along w	ith the		
Bid						
Bid Bo	Bid Bond valid till (date)					
Bid val	Bid validity period : Bid should be valid till (date)					
Bid Do	cument Fee :					
(should	be paid in cash to SPC for each	:h set of Bid Do	ocuments).			

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

# **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/95/22	23.06.2021	60,000,000 Tablets of	12.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Nifedipine Tablet 20mg S.R.		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/95/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

# ORDER LIST NO.: 2022/SPC/N/R/P/00016

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00203501	Nifedipine tablet 20mg S.R.	60,000,000	30,000,000
		Tablets	Tablets – May
	Nifedipine Extended release tablet USP 20mg.		2022
	Each film coated tablet to contain 20mg of		00 000 000
	Nifedipine USP in slow release form		30,000,000
			Tablets –
	Note:		September 2022
	01. The shelf life of the product should be		
	Minimum of 24 months		
	Packing: 500 Tablets in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 480,960.00 or USD 2,410.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

# **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

# **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

# **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

# **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

# **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

# **Documents & Information**

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)
  - If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

# (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# **Sufficient quantity of Samples should be forwarded for evaluation**

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

# FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					ANNEX – 1	
	D./BID REFERENCE ER NO.)	:				
DATE (	OF ISSUE	:				
	NG DATE & TIME	:				
(SRI LA	ANKAN TIME)	:				
ORDER	LIST NO. :					
SR No.	Item		Quantity	Delivery Schedule		
	Description/Specific	cations				
		_				
	Nos of Representat Ition as tender samp		nples for th	ne item to be submitted	for the	
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	with the	
Bid						
Bid Bo	Bid Bond valid till (date)					
Bid validity period: Bid should be valid till (date)						
Bid Do	cument Fee :					
(should	be paid in cash to SPC	for eacl	h set of Bid Do	ocuments).		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

# **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/94/22	23.06.2021 at 9.00 a.m.	400,000 Tablets of Bosentan Tablet 62.5mg	12.05.2021	Rs. 12,500/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/94/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

# ORDER LIST NO.: 2022/SPC/N/R/P/00016

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00202102	Bosentan tablet 62.5mg	400,000 Tablets	200,000 Tablets - January 2022
	Bosentan tablet 62.5mg Each tablet to contain 62.5mg of Bosentan		200,000 Tablets – May 2022
	Note: 01. The shelf life of the product should be minimum of 24 months.		
	Packing : 200 Tablets in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 257,120.00 or USD 1,289.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

# **CONDITIONS OF SUPPLY**

# (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

# **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the

information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.
  - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

# **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. <  $25\,^{\circ}$ C,  $2-25\,^{\circ}$ C,  $15-20\,^{\circ}$ C /30 °C,  $2-8\,^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

# **Documents & Information**

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

# (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

# **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be

compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

# FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					ANNEX – 1	
	D./BID REFERENCE ER NO.)	:				
DATE (	OF ISSUE	:				
	NG DATE & TIME	:				
(SRI LA	ANKAN TIME)	:				
ORDER	LIST NO. :					
SR No.	Item		Quantity	Delivery Schedule		
	Description/Specific	cations				
		_				
	Nos of Representat Ition as tender samp		nples for th	ne item to be submitted	for the	
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	with the	
Bid						
Bid Bo	Bid Bond valid till (date)					
Bid validity period: Bid should be valid till (date)						
Bid Do	cument Fee :					
(should	be paid in cash to SPC	for eacl	h set of Bid Do	ocuments).		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

# **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/93/22	23.06.2021	3,000 Ampoules of	12.05.2021	Rs. $12,500/= +$
	at 9.00 a.m.	Isoprenaline HCI Injection		Taxes
		2mg/2ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/93/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

# ORDER LIST NO.: 2022/SPC/N/R/P/00016

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00204101	Isoprenaline HCl Injection 2mg/2ml	3,000	3,000
		Ampoules	Ampoules –
	Isoprenaline Injection BP 2mg/2ml		August 2022
	Each 2ml amber coloured ampoules to contain 2 mg of		
	Isoprenaline Hydrochloride BP for intravenous infusion. OR		
	Isoproterenol Hydrochloride injection USP 2mg/2ml		
	Each 2ml amber coloured ampoule to contain 2mg of		
	Isoproterenol Hydrochloride USP for intravenous		
	infusion.		
	Note:		
	1. The injection should be stable for a minimum of		
	24 months when stored at a temperature range of 28'C-32'C		
	2.Each ampoule should be labelled accordingly.		
	Packing: 10 Ampoules in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 827,227.00 or USD 4,145.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

# **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

# **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

# **Standards & Quality**

rejected.

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister

& strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. <  $25\,^{\circ}$ C,  $2-25\,^{\circ}$ C,  $15-20\,^{\circ}$ C /30 °C,  $2-8\,^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No.

26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their **Authorized Agent in the Supplier's Country.**
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

## Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

### **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows:

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

### 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/92/22	23.06.2021	5,700,000 Tablets of	12.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Methyldopa Tablet 250mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/92/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23<sup>RD</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO.: 2022/SPC/N/R/P/00016

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00202201	Methyldopa tablets 250mg	5,700,000	3,000,000
		Tablets	Tablets – March
	Methyldopa tablets BP,250mg		2022
	Each coated tablet to contain Methyldopa BP		
	equivalent to 250mg of anhydrous Methyldopa		2,700,000
	Tablet should also conform to dissolution test for		Tablets – July
	Methyldopa tablets as per USP		2022
	OR		
	Methyldopa tablets USP 250mg		
	Each film coated tablet to contain 250mg of		
	Methyldopa USP.		
	Note:		
	01. Tablets should be yellow in colour.		
	02. The shelf life of the product should be minimum		
	of 24 months		
	Packing : 500 Tablets in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 558,600.00 or USD 2,799.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

						ANNEX -	1
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSING DATE & TIME		:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item	cations	Quantity	Deliv	ery Schedule		
	Description/Specific	Cations				$\overline{}$	
evalua	Nos of Represental stion as tender samp at of Bid Bond : LKR	oles.	-				
Bid Bo	nd valid till	(	date)				
Bid va	lidity period: Bid sh	ould be y	valid till	(d	ate)		
		oulu bo			•		
Bid Do	cument Fee :			(4	•		
	cument Fee:				·		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

### 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/91/22	23.06.2021	50,000 Ampoules of	12.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Dopamine Injection		
		200mg/5ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

## Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/91/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO.: 2022/SPC/N/R/P/00016

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00204001	Dopamine injection 200mg/5ml	50,000	50,000
		Ampoules	Ampoules –
	Sterile Dopamine concentrate BP/Dopamine		August 2022
	Hydrochloride injection BP 200mg/5ml		
	Each 5ml amber coloured ampoule to contain 200mg		
	of Dopamine Hydrochloride BP in		
	water for injection BP/USP, to use as intravenous		
	Infusion after dilution with a suitable diluent.		
	OR		
	Dopamine Hydrochloride injection USP 200mg in 5ml		
	Each 5ml amber coloured ampoule to contain 200mg		
	of Dopamine Hydrochloride USP		
	in water for injection BP/USP, to use as intravenous		
	infusion after dilution with a suitable diluent.		
	Note:		
	1. This injection should be stable for a minimum		
	of 24 months when stored at a temperature		
	range of 28'C-32'C		
	2. Each ampoule should be labelled accordingly.		
	Packing: 10 Ampoules in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 123,230.00 or USD 618.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-

requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eq. In delivery; time, product
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### **Sufficient quantity of Samples should be forwarded for evaluation**

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

## Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

### 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/90/22	23.06.2021	13,300 Ampoules of	12.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Furosemide (Frusemide)		
		Injection 100mg/10ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

## Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/90/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00016

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00200303	Furosemide (Frusemide) Injection 100mg/10ml	13,300	13,300
		Ampoules	Ampoules
	Furosemide Injection BP/USP, 100mg/10ml		<ul><li>October</li></ul>
	OR		2022
	Frusemide Injection BP, 100mg/10ml		
	Each 10ml amber coloured ampoule to contain		
	Furosemide Sodium equivalent to 100mg of		
	Furosemide BP/USP or Frusemide BP for, slow		
	intravenous and intravenous infusion.		
	Note:		
	1. The injection should be stable for a minimum of		
	2 years when stored at a temperature range of 28'C-32'C		
	2. Each ampoule should be labelled accordingly.		
	Packing: 10 Ampoules in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 25,345.00 or USD 127.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.

3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding

- defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

## (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.

- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  Bid Bond should be submitted together with the Bid or to reach SPC on or before the
- closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.

  The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The
- amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				<u> </u>	ANNEX – 1	
	BID NO./BID REFERENCE : (TENDER NO.)					
DATE (	OF ISSUE	:				
	CLOSING DATE & TIME (SRI LANKAN TIME)					
ORDER	LIST NO. :					
SR No.	Item Description/Specification	tions	Quantity	Delivery Schedule		
	Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amoun	nt of Bid Bond : LKR .		or USD	to be submitted along	with the	
Bid						
Bid Bo	nd valid till	(	(date)			
Bid val	idity period: Bid shou	ld be	valid till	(date)		
Bid Do	cument Fee :					
(should	be paid in cash to SPC f	or eac	h set of Bid Do	ocuments).		
MSD CO	NDITIONS OF SUPPLY					
1.						

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping

Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/89/22	23.06.2021 at 9.00 a.m.	18,000 Vials of Glyceryl Trinitrate Injection 50mg/10ml	12.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/89/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00016

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00203002	Glyceryl trinitrate injection 50mg/10ml	18,000	9,000 Vials –
	Nitroglycorin Injection USD F0mg/10ml	Vials	August 2022
	Nitroglycerin Injection USP 50mg/10ml Each 10ml vial/ampoule to contain 50mg of		9,000 Vials –
	Nitroglycerin for preparing Intravenous		November
	infusion.		2022
	Note		
	Note:  1. This injection should be stable for a minimum of		
	24 months when stored at a temperature range		
	of 28'C-32'C		
	2.Each vial/ampoule should be labelled		
	accordingly.		
	Backing: 10 viola in a pack		
	Packing: 10 vials in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 159,012.00 or USD 797.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the

- Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					<u> ANNEX – 1</u>
	BID NO./BID REFERENCE : (TENDER NO.)				
DATE (	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specifica	ations	Quantity	Delivery Schedule	
	Везеприон/ эреспис	40115			
	Nos of Representati		nples for th	ne item to be submitted	for the
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period : Bid sho	uld be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eacl	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping

Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/88/22	23.06.2021	50,000 Vials of Insulin	12.05.2021	Rs. $12,500/= +$
	at 9.00 a.m.	Isophane (human) 1,000		Taxes
		IU/10ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/88/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00700701	Insulin Isophane (human) 1,000 IU/10ml	50,000	25,000 Vials
	Isophane Insulin injection BP (NPH Insulin) derived from human 1000IU in 10ml.  OR Isophane Insulin suspension USP (NPH Insulin) derived from human 1000 IU/10ml.  Each rubber capped multidose Vial to contain 1000 IU/10ml of sterile purified suspension of Isophane Insulin BP/USP derived from human.	Vials	- January 2022 25,000 Vials - June 2022
	<ul> <li>Note:</li> <li>1. This injection should be stable for a minimum of 24 months when stored within 2'C - 8'C.</li> <li>2. Do not allow to freeze.</li> <li>3. Each vial should be labelled accordingly.</li> <li>Packing: 10 Vials in a box</li> </ul>		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 630,980.00 or USD 3,162.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

rejected.

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the

- Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at  $25\,^{\circ}\text{C}$  +/-  $2\,^{\circ}\text{C}$  & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					<u> ANNEX – 1</u>
	BID NO./BID REFERENCE : (TENDER NO.)				
DATE (	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specifica	ations	Quantity	Delivery Schedule	
	Везеприон/ эреспис	40115			
	Nos of Representati		nples for th	ne item to be submitted	for the
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period : Bid sho	uld be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eacl	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping

Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.

- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/87/22	23.06.2021	13,000 Suppositories of	12.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Domperidone Suppository		
		10mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/87/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00800406	Domperidone Suppository 10mg	13,000	6,500
	Domperidone suppository 10mg Each suppository to contain Domperidone maleate BP, equivalant to 10mg of Domperidone in a suitable suppository base.  Note: 1.This suppository should be stable for a minimum of 24 months when stored at a temperature below 25'C.  2.Each suppository should be labelled accordingly  Packing: 10 Suppositories in a box	Suppositories	Suppositories - February 2022 6,500 Suppositories - July 2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 10,400.00 or USD 53.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
  - When the validity of the product/manufacturing licenses and registrations of NMRA (eg: manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 17. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 18. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

19. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

- 20. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 21. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 22. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

23. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 24. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 25. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 26. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 27. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 28. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 29. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

30. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

- 31. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 32. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 33. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 34. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 35. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be

#### compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

<u> ANNEX – 1</u>

BID NO./BID REFERENCE

(TENDER NO.)

DATE OF ISSUE :
CLOSING DATE & TIME :

(SRI LANKAN TIME)

#### **ORDER LIST NO. :**

SR No.	Item Description/Specifications	Quantity	Delivery Schedule

...... Nos of Representative samples for the item to be submitted for the evaluation as tender samples.

Amount of Bid Bond : LKR ..... or USD ..... to be submitted along with the

Bid

Bid Bond valid till ...... (date)

Bid validity period: Bid should be valid till ...... (date)

Bid Document Fee : .....

(should be paid in cash to SPC for each set of Bid Documents).

#### MSD CONDITIONS OF SUPPLY

1.

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

**BID FOR THE SUPPLY OF** 

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### <u>Amendment to Bidding Document under 'Conditions of Contract'</u>

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted

- in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/86/22	23.06.2021	2,100 Ampoules of	12.05.2021	Rs. 20,000/= +
	at 9.00 a.m.	Tetracosactrin Injection		Taxes
		250mcg/1ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/86/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

# ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00703001	Tetracosactrin Injection 250mcg/1ml	2,100	700 Ampoules
	Tetracosactrin (Tetracosactide) injection BP, 250mcg/1ml	Ampoules	- February 2022
	Each 1ml ampoule to contain 250mcg of Tetracosactide BP in water for injection BP/USP, for intramuscular or intravenous injection.		700 Ampoules - May 2022
	Note: 1. This injection should be stable for a minimum of 24 months when stored within a temperature range or 2'C - 8'C. Protect from light.		700 Ampoules - August 2022
	2. Each ampoule should be labelled accordingly		
	Packing: 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,209,449.00 or USD 6,060.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

# (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

## **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

# **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and

other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

# (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available

for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

# **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

<u> ANNEX – 1</u>

BID NO./BID REFERENCE

(TENDER NO.)

DATE OF ISSUE :
CLOSING DATE & TIME :

(SRI LANKAN TIME)

#### **ORDER LIST NO. :**

SR No.	Item Description/Specifications	Quantity	Delivery Schedule

...... Nos of Representative samples for the item to be submitted for the evaluation as tender samples.

Amount of Bid Bond : LKR ..... or USD ..... to be submitted along with the

Bid

Bid Bond valid till ...... (date)

Bid validity period: Bid should be valid till ...... (date)

Bid Document Fee : .....

(should be paid in cash to SPC for each set of Bid Documents).

#### MSD CONDITIONS OF SUPPLY

1.

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

**BID FOR THE SUPPLY OF** 

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### <u>Amendment to Bidding Document under 'Conditions of Contract'</u>

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted

- in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/85/22	23.06.2021	60,000 Tablets of	12.05.2021	Rs. 20,000/= +
	at 9.00 a.m.	Dinoprostone Vaginal Tablet		Taxes
		3mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/85/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	<b>Quantity</b>	<u>Delivery</u>
01300301	Dinoprostone Vaginal Tablet 3mg	60,000	20,000 Tablets
	Dinoprostone Vaginal Tablet, 3mg	Tablets	- May 2022
	Each tablet to contain 3mg of Dinoprostone BP/USP for vaginal use		20,000 Tablets - August 2022
	Note: 01.The shelf life of the product should be minimum of 24 months		20,000 Tablets - November
	Packing : One Tablet in a pack 10 packs in a box		2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,227,612.00 or USD 6,151.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

## (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

# **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
- specified in the specification.)

  17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister
  - & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

# **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. <  $25\,^{\circ}$ C,  $2-25\,^{\circ}$ C,  $15-20\,^{\circ}$ C /30 °C,  $2-8\,^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

# **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

## (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

# FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					ANNEX – 1		
	D./BID REFERENCE ER NO.)	:					
DATE (	OF ISSUE	:					
	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item Description/Specificati	ione	Quantity	Delivery Schedule			
	Description/Specificati	10115					
	Nos of Representative tion as tender samples		nples for th	ne item to be submitted	for the		
Amour	t of Bid Bond : LKR		. or USD	to be submitted along	g with the		
Bid							
Bid Bo	Bid Bond valid till (date)						
Bid validity period : Bid should be valid till (date)							
Bid Do	cument Fee :						
(should	be paid in cash to SPC fo	or eacl	h set of Bid Do	ocuments).			

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

# **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/84/22	23.06.2021	1,000,000 Ampoules of	12.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Oxytocin Injection 5 I.U./ 1ml		Taxes
		amp.		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

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GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA. TENDER NO. : DHS/P/WW/84/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

# ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01300202	Oxytocin Injection 5 I.U./ 1ml amp.	1,000,000	500,000
	Oxytocin Injection BP/USP, 5IU/1ml. Each 1ml ampoule to contain 5IU of synthetic Oxytocin BP/USP in water for injection BP/USP for subcutaneous, intramuscular, slow intravenous injection and intravenous infusion.  Note:  1.This injection should be stable for a minimum of 24	Ampoules	Ampoules - July 2022 500,000 Ampoules - October 2022
	months when stored with in the temperature range of 2'C - 15'C. Do not freeze.  2.Each ampoule should be pre-filed.  3.Each ampoule should be labelled accordingly  Packing: 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 456,600.00 or USD 2,288.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

# (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pac specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

# **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

# **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

# **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

# FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows:

					ANNEX – 1		
	D./BID REFERENCE ER NO.)	:					
DATE (	OF ISSUE	:					
	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item Description/Specificati	ione	Quantity	Delivery Schedule			
	Description/Specificati	10115					
	Nos of Representative tion as tender samples		nples for th	ne item to be submitted	for the		
Amour	t of Bid Bond : LKR		. or USD	to be submitted along	g with the		
Bid							
Bid Bo	Bid Bond valid till (date)						
Bid validity period : Bid should be valid till (date)							
Bid Do	cument Fee :						
(should	be paid in cash to SPC fo	or eacl	h set of Bid Do	ocuments).			

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

# **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/83/22	23.06.2021	250,000 Ampoules of	12.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Oxytocin Injection 2 I.U./ 2ml		Taxes
		amp.		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/83/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
<b>SR No.</b> 01300201	Item Description/ Specification  Oxytocin Injection 2 I.U./ 2ml amp.  Oxytocin Injection BP/USP, 2IU/2ml. Each 2ml ampoule to contain 2IU of synthetic Oxytocin BP/USP in water for injection BP/USP for subcutaneous, intramuscular, slow intravenous injection and intravenous infusion.  Note:  1.This injection should be stable for a minimum of 24 months when stored with in the temperature range of 2 'C - 15 'C. Do not freeze.  2.Each ampoule should be labelled accordingly	Quantity 250,000 Ampoules	90,000 Ampoules - January 2022  80,000 Ampoules - May 2022  80,000 Ampoules - September 2022
	Packing : 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 960,150.00 or USD 4,810.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

## (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

						ANNEX	<u>( – 1</u>
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSI	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item Description/Specific	rations	Quantity	Delive	ry Schedule		
	Description/Specific	ations					
	Nos of Representat Ition as tender samp		nples for th	ne item to b	e submitted	for t	the
Amour	nt of Bid Bond : LKR		. or USD	to be รเ	ıbmitted alonç	y with 1	the
Bid							
Bid Bo	nd valid till	(	date)				
Bid val	lidity period:Bid sho	ould be	valid till	(da	ite)		
Bid Do	cument Fee :						
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).			

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/82/22	23.06.2021	90,000 Vials of Insulin	12.05.2021	Rs. $12,500/= +$
	at 9.00 a.m.	Soluble (Hu) Injection 1,000		Taxes
		IU/10ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

## Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/82/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	<b>Quantity</b>	<u>Delivery</u>
00700801	Insulin Soluble (Hu) Injection 1,000 IU/10ml	90,000 Vials	45,000 Vials
	Insulin Injection BP (Soluble Insulin) 1000 I.U. in 10ml derived from human. Each rubber capped multidose vial to contain sterile neutral solution of 1000 I.U./10ml of human insulin BP. OR Insulin Injection USP (Soluble Insulin)1000IU in 10ml derived from human. Each rubber capped multidose vial to contain sterile neutral solution of 1000 IU/10ml of human Insulin USP.		- April 2022 45,000 Vials - August 2022
	1. This injection should be stable for a minimum of 24 months when stored within 2'C -8'C.		
	2. Do not allow to freeze.		
	3. Each vial should be labelled accordingly.		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 668,700.00 or USD 3,351.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

## (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

## **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

## (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

						ANNEX -	1
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSI	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item	cations	Quantity	Deliv	ery Schedule		
	Description/Specific	Cations				$\overline{}$	
evalua	Nos of Represental stion as tender samp at of Bid Bond : LKR	oles.	-				
Bid Bo	nd valid till	(	date)				
Bid va	lidity period: Bid sh	ould be y	valid till	(d	ate)		
		oulu bo			•		
Bid Do	cument Fee :			(4	•		
	cument Fee:				·		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/81/22	23.06.2021 at 9.00 a.m.	15,000 Ampoules of Ergometrine Maleate	12.05.2021	Rs. 3,000/= + Taxes
		Injection 500mcg/1ml amp.		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

## Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/81/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
01300102	Ergometrine Maleate Injection 500mcg/1ml amp.	15,000	15,000
	Ergometrine injection BP (2001) 500mcg/ml Each 1ml amber coloured ampoule to contain 500mcg of Ergometrine maleate BP in water for injection BP/USP for intramuscular or intravenous injection OR Ergonovine injection USP (25) 500mcg/ml Each amber coloured ampoule to contain 500mcg of Ergonovince maleate USP in water for injection BP/USP for intramuscular or intravenous injection.	Ampoules	Ampoules - October 2022
	Note: 1.This injection should be stable for a minimum of 24 months when stored with in the temperature range of 2'C - 8'C.  2.Each ampoule should be labelled accordingly.  Packing: 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 13,056.00 or USD 66.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

## **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

## (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

## Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

## 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI LA	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specifica	tions	Quantity	Delivery Schedule	
	Description/Specifica	LIUIIS			
	Nos of Representative tion as tender sample		nples for th	ne item to be submitte	d for the
Amour	t of Bid Bond : LKR .		. or USD	to be submitted alor	g with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid shou	ıld be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



## **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/80/22	23.06.2021	240,000 Suppositories of	12.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Bisacodyl Suppository 10mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

TENDER NO. : DHS/P/WW/80/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	<b>Quantity</b>	<u>Delivery</u>
00801203	Bisacodyl Suppository 10mg  Bisacodyl Suppository BP/USP 10mg (Adult). Each suppository to contain 10mg Bisacodyl BP/USP in a suitable suppository base to be used in a temperature range of 28'C-32'C.  Note:  1. This suppository should be stable for a Minimum of 24 months when stored at a temperature range of 28'C-32'C.  2. Each suppository should be labelled accordingly.  Packing: 10 Suppositories in a box	240,000 Suppositories	80,000 Suppositories - March 2022  80,000 Suppositories - July 2022  80,000 Suppositories - November 2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 70,704.00 or USD 355.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

## **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

specified in the specification.)

- Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					<u>ANNEX – 1</u>
	)./BID REFERENCE	:			
(TENDI	ER NO.)				
DATE (	OF ISSUE	:			
CLOSII	NG DATE & TIME	:			
(SRI LA	NKAN TIME)	:			
ORDER	<u>LIST NO. :</u>				
SR No.	Item		Quantity	Delivery Schedule	
	Description/Specification	ons			
	Nos of Representative	sar	nples for th	e item to be submitted	for the
evalua	tion as tender samples	<b>.</b>			
Amoun	t of Bid Bond : LKR		. or USD	to be submitted along	with the
Bid				•	,
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid should	d be v	/alid till	(date)	
Bid Do	cument Fee :		••		
(should	be paid in cash to SPC fo	r eacl	n set of Rid Do	cuments)	
Constitution of the state of th					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



## **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/79/22	23.06.2021	500 Vials of Glucagon	12.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Injection 1 I.U. vial		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/79/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00701001	Glucagon Injection 1 I.U. vial  Glucagon Hydrochloride Injection BP/USP 1IU vial.	500 Vials	250 Vials - May 2022
	Each vial to contain 1IU (1mg) of Glucagon Hydrochloride BP/USP as dry powder for reconstitution with water for injection BP/USP for subcutaneous, intramuscular or intravenous injection.		250 Vials - August 2022
	Note; 1.The product should be stable for minimum of 02 Years when stored under 2'C - 8'C.		
	2.Each vial should be labeled accordingly.		
	Packing : One vial in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 51,984.00 or USD 261.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

## **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

## Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME		:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/78/22	23.06.2021	16,500 Ampoules of	12.05.2021	Rs. $12,500/= +$
	at 9.00 a.m.	Vasopressin Injection 20 I.U./1ml ampoule		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

## Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/78/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
<b>SR No.</b> 00703401	Vasopressin Injection 20 I.U./1ml ampoule  Vasopressin Injection USP,20 IU in 1ml ampoule Each 1ml glass ampoule to contain 20IU of an aqueous solution of synthetic vasopressin USP for subcutaneous, intramuscular injection or intravenous infusion.  Note; 1. This Injection should be stable for a minimum of 24 months when stored with in the temperature range of 2'C - 8'C. Do not freeze.  2. Each ampoule should be labelled accordingly.	16,500 Ampoules	8,500 Ampoules - May 2022  8,000 Ampoules - September 2022
	Packing: 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 414,804.00 or USD 2,079.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

## (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

						ANNEX	<u>( – 1</u>
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSI	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item Description/Specific	rations	Quantity	Delive	ry Schedule		
	Description/Specific	ations					
	Nos of Representat Ition as tender samp		nples for th	ne item to b	e submitted	for t	the
Amour	nt of Bid Bond : LKR		. or USD	to be รเ	ıbmitted alonç	y with 1	the
Bid							
Bid Bo	nd valid till	(	date)				
Bid val	lidity period:Bid sho	ould be	valid till	(da	ite)		
Bid Do	cument Fee :						
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).			

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/77/22	23.06.2021	1,200,000 Suppositories of Diclofenac Sodium	12.05.2021	Rs. 12,500/= + Taxes
	at 9.00 a.m.	Suppository 100mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

## Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/77/22 DATE OF ISSUE : 12<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
01400306	Diclofenac Sodium Suppository 100mg	1,200,000	300,000
	Diclofenac Sodium suppository 100mg Each suppository to contain 100mg of Diclofenac Sodium BP/USP in a suitable suppository base.	Suppositories	Suppositories - February 2022
	Note: 1. This suppository should be stable for a minimum of 24 months when stored at a temperature bellow 30'C.		300,000 Suppositories - May 2022
	2. Each suppository should be labelled accordingly		300,000 Suppositories - August 2022
	Packing: 10 Suppositories in a box		300,000 Suppositories - November 2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 267,600.00 or USD 1,341.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					ANI	<u>NEX – 1</u>
_	D./BID REFERENCE ER NO.)	:				
DATE (	OF ISSUE	:				
	NG DATE & TIME	:				
(SRI LA	ANKAN TIME)	:				
ORDER	LIST NO. :					_
SR No.	Item Description/Specifica	tions	Quantity	Delivery S	chedule	
	Description, Specifical	CIOIIS				1
	Nos of Representative tion as tender sample		nples for th	e item to be	submitted fo	r the
Amour	nt of Bid Bond : LKR .		. or USD	to be subm	itted along wi	th the
Bid						
Bid Bo	nd valid till	(	date)			
Bid val	idity period: Bid shou	ld be	valid till	(date)		
Bid Do	cument Fee :					
(should	be paid in cash to SPC f	or eac	h set of Bid Do	ocuments).		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/76/22	23.06.2021 at 9.00 a.m.	55 Vials of Corticotropine Injection 200 I.U./5ml	12.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/76/22 DATE OF ISSUE :  $12^{TH}$  MAY 2021

CLOSING DATE & TIME : 23RD JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	<b>Quantity</b>	<u>Delivery</u>
00703002	Corticotropine Injection 200 I.U./5ml	55 Vials	30 Vials
	Corticotropine Zinc injection BP 200 IU/5ml		- April 2022
	Each 5ml ampoule /vial to contain Corticotropine adsorbed on to Zinc Hydroxide, equivalent to 200 IU		25 Vials
	of Corticotrophine for subcutaneous and		- August
	intramuscular injection. OR		2022
	Corticotrophine Zinc Hydroxide injectable		
	suspension USP Each 5ml ampoule/vial to contain Corticotrophine		
	adsorbed on to Zinc Hydroxide, equivalent to 200 IU		
	of Corticotrophine for subcutaneous and intramuscular injection.		
	Note:		
	1. This Injection should be stable for a minimum of 24 months when stored with in the temperature range of 2'C - 8'C.		
	2.Each ampoule/vial should be labelled accordingly.		
	Packing : One vial in a pack 10 Packs in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,002.00 or USD 6.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-

requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### Shelf life & Warrantees.

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg.  $< 25\,^{\circ}$ C, 2-25  $^{\circ}$ C, 15-20  $^{\circ}$ C /30  $^{\circ}$ C, 2-8  $^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30  $^{\circ}$ C +/- 2  $^{\circ}$ C & 75% +/- 5% RH for AC stored items and at 25  $^{\circ}$ C +/- 2  $^{\circ}$ C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eq. In delivery; time, product
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### **Sufficient quantity of Samples should be forwarded for evaluation**

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specificati	ione	Quantity	Delivery Schedule	
	Description/Specificati	10115			
	Nos of Representative tion as tender samples		nples for th	ne item to be submitted	for the
Amour	t of Bid Bond : LKR		. or USD	to be submitted along	g with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid shoul	d be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC fo	or eacl	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/75/22	23.06.2021	70,000 Vials of Anti Venom	12.05.2021	Rs. 35,000/= +
	at 9.00 a.m.	Serum Injection 10ml		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/75/22
DATE OF ISSUE : 12<sup>TH</sup> MAY 2021
CLOSING DATE & TIME : 23<sup>RD</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00602301	Anti Venom Serum Injection 10ml	70,000	25,000 Vials
	Snake Venom Antiserum IP (96) To Neutralise the Venoms of the Cobra (Naja Naja)*, Russelle's viper (vipera Russelli)* the Common Krait	Vials	- January 2022
	(Bungarus Caeruleus) * and saw scaled viper (Echiscarnatus Reg) * in a Lyophillised sterile powder form, to dilute with water for injections BP/USP/IP.		25,000 Vials - May 2022 20,000 Vials
	Each vial to contain sufficient powder to prepare 10ml of refined Globulin solution to meet the following conditions.		- October 2022
	Product should conform to potency test IP 1ml of reconstituted serum should neutralize not less than the following quantities of standard venoms when tested in white mice of NIH Strain and weight between 18 - 20g     Cobra (Naja Naja)0.6mg     Common Krait (Bangarus Caeruleus) 0.45mg, Russell's Viper (Viper Russelli) 0.6mg     Saw-scaled Viper(Echiscarnatus Reg)0.45mg     (Product should contain at least 10% of excess Potency at the time of supply)		
	<ul><li>2. Abnormal toxicity: test should conform to IP standard.</li><li>3. Shelf Life; 2 years when stored below 25'C</li></ul>		
	Note: The following documents should be submitted pre- shipment for each lot of serum despatched.		
	Summary protocols for production and quality testing (Including protocols for immunization, initial pool, final bulk and finished product ) based on WHO model summary protocols.		
	Lot release certificate from National Control     Laboratory of manufacturing country for that     particular batch.		
	3. Certificate of analysis of finished product.		
	4. Certificate of analysis of diluents, if applicable.		
	5. The package information leaflet.		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 2,076,606.00 or USD 10,405.00.

Bid Bond should be submitted with valid up to 19.01.2022 together with the bid Bid should be valid till 20.12.2021.

**Non refundable Bid Fee Rs. 35,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
  - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.
- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
  - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).
- 6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.

- (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

  The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
- (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.

- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. <  $25\,^{\circ}$ C,  $2-25\,^{\circ}$ C,  $15-20\,^{\circ}$ C /30 °C,  $2-8\,^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated

damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.

- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.

- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-

# Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows:

BID NO	)./BID REFERENCE		
	ER NO.)	•	
DATE (	OF ISSUE	:	
	NG DATE & TIME		
(SKI LA	ANKAN TIME)		
ORDER	LIST NO. :		
SR No.	Item	Quantity	Delivery Schedule
	Description/Specification	) IIS	
	Nos of Representative tion as tender samples	<u>-</u>	ne item to be submitted for t
evalua	tion as tender samples	-	
evalua Amoun Bid	tion as tender samples	or USD	ne item to be submitted for t
evalua Amoun Bid Bid Bo	tion as tender samples	or USD	to be submitted along with t
evalua Amoun Bid Bid Bo Bid val	tion as tender samples  It of Bid Bond : LKR  Ind valid till	or USD (date) be valid till	to be submitted along with t
evalua Amoun Bid Bid Bo Bid val Bid Do	tion as tender samples  It of Bid Bond : LKR  Ind valid till  Idity period : Bid should	or USD (date) be valid till	to be submitted along with t
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<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF	
BID NO./BID REFERENCE	

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

**Amendment to Bidding Document under 'Conditions of Contract'** 

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

#### **08 TERMS OF DELIVERY**

- 8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/74/22	22.06.2021 at 9.00 a.m.	4,500 Bottles of Fat emulsion Injection 20%, 100ml bottle	11.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/74/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/R/P/00007

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00402103	Fat emulsion injection 20% in 100ml bottle	4,500	4,500 Bottles
	Fat emulsion injection 20% in 100ml bottle Each 100ml bottle to contain in 20% w/v of soya oil for parenteral use BP, 1.2 - 1.5% w/v of Lecithin USNF 2.2 - 2.5% w/v of glycerol BP in a suitable vehicle.	Bottles	- August 2022
	Note: Alternative formulate may be acceptable, therefore tenderers should give detailed composition of product offered.		
	The bottle should be graduated to 100ml and be made of medicinal grade Polyethylene or Polypropylene. PVC is not acceptable.		
	2. The bottle should have a device for hanging.		
	3. To prevent leakage of fluid with insertion or withdrawal of spike or continuous use the site of the insertion of piercing spike should be covered with a sterile rubber disk or bung and the plastic cover of the disk or bung should be fused to neck of the bottle right round.		
	Each bottle should be packed individually in a protective polyethylene cover.		
	5. The product should be sterile and stable for a minimum of 24 months within a temperature range of 30'C - 35'C.		
	6. The bottle should be labelled accordingly.		
	Packing: 10 Bottles in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 48,462.00 or USD 243.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

(a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total

- rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.

- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their **Authorized Agent in the Supplier's Country.**
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  Bid Bond should be submitted together with the Bid or to reach SPC on or before the
  - closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNEX – 1
	D./BID REFERENCE ER NO.)	:		
DATE (	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER I	LIST NO. :			<del>-</del>
SR No.	Item		Quantity	D.P. C.L.II.
		ations	Qualitity	Delivery Schedule
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Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column

NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

#### 08 TERMS OF DELIVERY

- All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/73/22	22.06.2021	7,000 Vials of Cytarabine	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Injection 1g in 10ml vial		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/73/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00048

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01201703	Cytarabine Injection 1g in 10ml vial	7,000	3,500 Vials
	Cytarabine Injection BP 1g/10ml, (Not for intrathecal use)	Vials	- January 2022
	Each 10ml vial to contain 1g of Cytarabine BP in		3,500 Vials
	water for injection BP/USP OR		- June 2022
	Cytarabine for Injection USP 1g, (Not for intrathecal use)		
	Each vial to contain 1g of Cytarabine BP/USP as sterile dry powder for reconstitution with water for injection BP/USP before use for intravenous and subcutaneous use.		
	Note: 1.This injection should be stable for 24 months when stored at a temperature within 28'C-32'C.		
	2.Each vial should be labelled accordingly		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 152,476.00 or USD 764.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

# **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complete/false, the grace
  - period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

# **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

**Terms and Conditions of Bid/Instructions to Bidders** 

#### Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNEX – 1
_	D./BID REFERENCE : ER NO.)			
DATE	OF ISSUE :			
	NG DATE & TIME : ANKAN TIME) :			
ORDER	LIST NO. :			
SR No.	Item Description/Specification	Quantity	Delivery Schedule	
	Nos of Representative tion as tender samples.	samples for th	ne item to be submitted	for the
Amour	nt of Bid Bond : LKR	or USD	to be submitted along	with the
Bid				
Bid Bo	nd valid till	(date)		
Bid val	lidity period : Bid should	oe valid till	(date)	
Bid Do	cument Fee :			
(should	be paid in cash to SPC for	each set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID FOR THE SUPPLY OF
BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/72/22	22.06.2021	23,000 Vials of Mesna	11.05.2021	Rs. $12,500/= +$
	at 9.00 a.m.	Injection 200mg in 2ml		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/72/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00048

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
O1210101	Mesna Injection 200mg in 2ml  Mesna injection 200mg in 2ml  Each vial to contain aqueous solution of mesna (sodium 2-mercapto-ethanesulphonate) 200 mg in 2 ml intravenous injection  Note:  1. The injection should be stable for a minimum of 24 months when stored below 30'C  2. This injection should be protected from light.  3. Each vial should be labelled accordingly.	23,000 Vials	13,000 Vials - June 2022 10,000 Vials - October 2022
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 296,263.00 or USD 1,485.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.

- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

specified in the specification.)

- Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD
  - and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. <  $25\,^{\circ}$ C,  $2-25\,^{\circ}$ C,  $15-20\,^{\circ}$ C /30 °C,  $2-8\,^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

## **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

						ANNEX -	1
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSI	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item	cations	Quantity	Deliv	ery Schedule		
	Description/Specific	Cations				$\overline{}$	
evalua	Nos of Represental stion as tender samp at of Bid Bond : LKR	oles.	-				
Bid Bo	nd valid till	(	date)				
Bid va	lidity period : Bid sh	ould be y	valid till	(d	ate)		
		oulu bo			•		
Bid Do	cument Fee :			(4	•		
	cument Fee:				·		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/71/22	22.06.2021	2,300 Ampoules of	11.05.2021	Rs. $12,500/= +$
	at 9.00 a.m.	Papaverine HCI Injection		Taxes
		20mg/1ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/71/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00048

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00207001	Papaverine HCI Injection 20mg/1ml	2,300	1,300
	Papaverine Hydrochloride Injection USP, 20mg in 1ml	Ampoules	Ampoules - January 2022
	Each ampoule to contain sterile solution of Papaverine Hydrochloride 20mg/1ml, in water for injection BP/USP for slow intramuscular or intravenous injection.		1,000 Ampoules - July 2022
	Note: 1. The injection should be stable for a minimum of 2 years when stored at at a temperature range of 28'C-32'C		
	2. Each ampoule should be labelled accordingly.		
	Packing: 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 703,507.00 or USD 3,525.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD. Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.
- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets

and DOM & DOE shall consist of at least the year & month.

- (b). printed in case of capsules
- Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

						ANNEX -	1
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSI	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item	cations	Quantity	Deliv	ery Schedule		
	Description/Specific	Cations				$\overline{}$	
evalua	Nos of Represental stion as tender samp at of Bid Bond : LKR	oles.	-				
Bid Bo	nd valid till	(	date)				
Bid va	lidity period : Bid sh	ould be y	valid till	(d	ate)		
		oulu bo			•		
Bid Do	cument Fee :			(4	•		
	cument Fee:				·		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/70/22	22.06.2021	450,000 Vials of Cefuroxime	11.05.2021	Rs. 20,000/= +
	at 9.00 a.m.	Injection 250mg vial		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

TENDER NO. : DHS/P/WW/70/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22ND JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO.: 2022/SPC/N/R/P/00036

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00101405	Cefuroxime Injection 250mg vial	450,000	150,000 Vials
	Cefuroxime Sodium injection BP, 250mg OR Cefuroxime Sodium injection USP, 250mg	Vials	- February 2022
	Columbian Colling		150,000 Vials
	Each vial to contain Cefuroxime Sodium BP/USP, equivalent to 250 mg of Cefuroxime as sterile, dry,		- May 2022
	free flowing powder for reconstitution with water		150,000 Vials
	for injection BP/USP before use. The reconstituted preparation should be suitable		- September
	for slow Intravenous injection, Intravenous infusion and Intra-muscular injection.		2022
	Note:		
	01. The product should be stable for a minimum of two years when stored at a temperature range of 25 °C -30 °C		
	02. Each vial should be labeled accordingly.		
	Packing : 50 Vials in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,287,990.00 or USD 6,454.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

# (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

## **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

## **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding

- defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO. (applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

## (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.

- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

## Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

## Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

## **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows:

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/69/22	22.06.2021	200,000 Vials of Ceftriaxone	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Injection 1g		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/69/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00036

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00101704	Ceftriaxone Injection 1g  Ceftriaxone for injection USP 1g Each vial to contain sterile Ceftriaxone sodium USP equivalent to 1g of Ceftriaxone as sterile dry powder for reconstitution with water for injection BP/USP for intravenous injection  Note:  1.The product should conform to bio equivalence criteria Of the WHO.  2.This injection should be stable for a minimum of 02 years when stored under temperature not exceeding 30'C  3.Each vial should be labelled accordingly  Packing: 10 Vials in a pack	200,000 Vials	200,000 Vials - July 2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 185,560.00 or USD 930.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer

covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

## **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eq. In delivery; time, product
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)
  - If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

## Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

## **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows:

					ANNEX – 1	
	)./BID REFERENCE ER NO.)	:				
DATE (	OF ISSUE	:				
CLOSII	NG DATE & TIME	:				
(SRI LA	NKAN TIME)	:				
	LIST NO. :					
SR No.	Item Description/Specific	ations	Quantity	Delivery Schedule		
	Description/specific	acions				
	Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amoun	t of Bid Bond : LKR		. or USD	to be submitted along	g with the	
Bid						
Bid Bo	nd valid till	(	date)			
Bid val	idity period: Bid sho	ould be	valid till	(date)		
Bid Do	cument Fee :		···			
(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).		
•	•			•		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/68/22	22.06.2021	40,000,000 Tablets of	11.05.2021	Rs. 20,000/= +
	at 9.00 a.m.	Nicorandil Tablet 10mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/68/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00018

Item Description/ Specification	Quantity	<u>Delivery</u>
Nicorandil Tablet 10mg	40,000,000	20,000,000
Nicorandil tablet 10mg Each tablet to contain 10mg of Nicorandil	Tablets	Tablets - February 2022
Note: 01.The shelf life of the product should be minimum of 24 months  Packing: 100 Tablets in a pack		20,000,000 Tablets - July 2022
	Nicorandil Tablet 10mg  Nicorandil tablet 10mg  Each tablet to contain 10mg of Nicorandil  Note:  01.The shelf life of the product should be minimum of 24 months	Nicorandil Tablet 10mg Nicorandil tablet 10mg Each tablet to contain 10mg of Nicorandil  Note: 01.The shelf life of the product should be minimum of 24 months

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,536,000.00 or USD 7,696.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

## **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

## **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

## Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC) Terms and Conditions of Bid/Instructions to Bidders

## Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specificati	ione	Quantity	Delivery Schedule	
	Description/Specificati	10115			
	Nos of Representative tion as tender samples		nples for th	ne item to be submitted	for the
Amour	t of Bid Bond : LKR		. or USD	to be submitted along	g with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid shoul	d be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC fo	or eacl	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

## **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit. Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/67/22	22.06.2021	90,000,000 Tablets of Aspirin	11.05.2021	Rs. 20,000/= +
	at 9.00 a.m.	enteric coated tablet 75mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

TENDER NO. : DHS/P/WW/67/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22ND JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00018

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00205404	Aspirin enteric coated tablet 75mg	90,000,000	90,000,000
	Aspirin enteric coated tablets BP, 75 mg blister pack Each Gastro-resistant tablet to contain 75mg of Aspirin BP OR Aspirin delayed-release tablets USP 75mg blister pack Each tablet to contain 75mg of Aspirin USP.	Tablets	Tablets - August 2022
	Note: 01.The shelf life of the product should be minimum of 24 months  Packing: 100 Tablets in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,404,000.00 or USD 7,035.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

## **CONDITIONS OF SUPPLY**

## (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer

covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eq. In delivery; time, product
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grass
  - If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

### **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows:

					ANNEX – 1	
	D./BID REFERENCE ER NO.)	:				
DATE	OF ISSUE	:				
	NG DATE & TIME	:				
(SRI L	ANKAN TIME)	:				
ORDER	LIST NO. :					
SR No.			Quantity	Delivery Schedule		
	Description/Specific	ations				
	Nos of Representation as tender samp		nples for tr	ne item to be submitted	for the	
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	y with the	
Bid						
Bid Bond valid till (date)						
Bid validity period : Bid should be valid till (date)						
Bid Do	cument Fee :					
(should	I be paid in cash to SPC	for each	h set of Bid Do	ocuments).		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/66/22	22.06.2021	1,050,000 Ampoules of	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Atropine Sulphate Injection 600mcg/1ml ampoule		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/66/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00018

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01500801	Atropine Sulphate Injection 600mcg/1ml ampoule	1,050,000	550,000
	Atropine Injection BP 600mcg in 1ml Ampoule. Each 1ml ampoule to contain 600mcg of Atropine Sulphate BP in water for injection BP/USP for subcutaneous, intramuscular or intravenous use OR Atropine Sulphae injection USP 600mcg in 1ml Ampoule. Each 1ml ampoule to contain 600mcg of Atropine Sulphate USP in water for injection BP/USP for subcutaneous, intramuscular or intravenous use.  Note:  1.This injection should be stable for 24 months when stored at a temperature range of 28'C-32'C  2.Each ampoule should be labelled accordingly.  3.Ampoule should be scored or one point cut ampoule.  Packing: 10 Ampoules in a pack	Ampoules	Ampoules - February 2022 500,000 Ampoules - June 2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 437,010.00 or USD 2,190.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.

- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
  - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.
- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.
  - All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).
- 6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding

- defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.

- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  Bid Bond should be submitted together with the Bid or to reach SPC on or before the
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows:

						ANNEX -	1
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSING DATE & TIME :		:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item	cations	Quantity	Deliv	ery Schedule		
	Description/Specific	Cations				$\overline{}$	
Nos of Representative samples for the item to be submitted for the evaluation as tender samples.  Amount of Bid Bond: LKR							
Bid Bo	nd valid till	(	date)				
Bid validity period : Bid should be valid till (date)							
		oulu bo			•		
Bid Do	cument Fee :			(4	•		
	cument Fee:				·		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/65/22	22.06.2021	460,000 Ampoules of	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Tranexamic Acid Injection		Taxes
		500mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/65/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/R/P/00018

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00205903	Tranexamic Acid Injection 500mg	460,000	230,000
00203903	Tranexamic acid injection BP 500mg in 5ml. Each 5ml ampoule to contain 500mg of Tranexamic Acid BP in water for injection BP/USP for slow intravenous injection.  Note:  1.This injection should be stable for a minimum of 24 months when stored at a temperature range of 28'C-32'C  2.Each ampoule should be labelled accordingly.	Ampoules	Ampoules - February 2022 230,000 Ampoules - July 2022
	Packing: 10 Ampoules in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 274,620.00 or USD 1,376.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

# (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
  - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO

will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be

compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

				ANNEX –	1
_	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :	,			
SR No.	Item Description/Specification	tions	Quantity	Delivery Schedule	
evalua	tion as tender sample	es.	-	ne item to be submitted for th	
	nt of Bid Bond : LKR .		or USD	to be submitted along with th	е
Bid					
Bid Bo	nd valid till		(date)		
Bid val	lidity period: Bid shou	ld be	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC f	or eac	h set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/64/22	22.06.2021	1,100,000 Capsules of	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Tranexamic Acid Capsule		Taxes
		500mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/64/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/R/P/00018

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00205901	Tranexamic Acid Capsule 500mg  Tranexamic Acid Capsule 500mg.  Each capsule to contain 500mg of Tranexamic Acid BP.	1,100,000 Capsules	1,100,000 Capsules – May 2022
	Note: 01.The shelf life of the product should be minimum of 24 months.  Packing: 100 Capsules in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 238,260.00 or USD 1,194.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

supply.

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the

conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).

The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.

- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their **Authorized Agent in the Supplier's Country.**
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI LA	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item		Quantity	Delivery Schedule	
	Description/Specific	cations			
		_			
	Nos of Representat Ition as tender samp		nples for th	ne item to be submitted	for the
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period : Bid sho	ould be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eacl	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

## STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/63/22	22.06.2021	16,500 Ampoules of	11.05.2021	Rs. 35,000/= +
	at 9.00 a.m.	Verapamil HCI Injection		Taxes
		5mg/2ml		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/63/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00018

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00203702	Verapamil HCl Injection 5mg/2ml  Verapamil Injection BP 5mg in 2ml	16,500 Ampoules	8,500 Ampoules – April 2022
	OR Verapamil Hydrochloride Injection USP 5mg in 2ml. Each 2ml ampoule to contain 5mg of Verapamil Hydrochloride BP/USP in Water for injection BP/USP for slow intravenous injection.		8,000 Ampoules – September 2022
	Note: 1. This injection should be stable for a minimum of 02 years when stored at a temperature range of 28'C-32'C		
	Each ampoule should be labelled accordingly.  Packing: 10 vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 2,203,206.00 or USD 11,039.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 35,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No.

26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace
  - period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available

for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows:

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specificati	ione	Quantity	Delivery Schedule	
	Description/Specificati	10115			
	Nos of Representative tion as tender samples		nples for th	ne item to be submitted	for the
Amour	t of Bid Bond : LKR		. or USD	to be submitted along	g with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid shoul	d be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC fo	or eacl	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/62/22	22.06.2021	140,000 Vials of Imipenem	11.05.2021	Rs. 20,000/= +
	at 9.00 a.m.	Injection 500mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/62/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00037

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00102001	Imipenem Injection 500mg	140,000	140,000 Vials
	Imipenem and Cilastatin for injection USP, 500mg. Each vial to contain mixture of Imipenam Monohydrate USP equivalent to 500mg of Imipenam and Cilastatin Sodium equivalent to 500mg of Cilastatin as sterile dry powder for reconstitution for intramuscular and intravenous injection or intravenous infusion.	Vials	– August 2022
	Note:  1. The product should be stable for 02 years when stored under controlled room temperature.  2. Each vial should be labelled accordingly.		
	Packing: 10 vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,272,656.00 or USD 6,377.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No.

26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace
  - period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available

for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows:

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/61/22	22.06.2021	4,000 Vials of Cefepime	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Injection 1g vial		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/61/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00037

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00101902	Cefepime Injection 1g vial	4,000	4,000 Vials –
	Cefepime for injection USP, 1g Each vial to contain sterile Cefepime for injection USP equivalent to 1g of Cefepime as sterile dry powder for reconstitution with water for injection BP/USP for Intravenous injection.	Vials	September 2022
	Note: 01. The product should be stable for a minimum of two years when stored at a temperature range of 25 C-30 C		
	02. Each vial should be labeled accordingly.  Packing: 10 vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 48,941.00 or USD 246.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No.

26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace
  - If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available

for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows:

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

## 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/60/22	22.06.2021	60,000 Vials of	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Sulbactam/Cefoperazone		
		Injection 1g vial		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/60/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00037

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00101101	Sulbactam/Cefoperazone Injection 1g vial  Sulbactam sodium and Cefoperazone sodium for injection 1g vial  Each vial to contain Sulbactam sodium equivalant to 0.5g of Sulbactam BP/USP and Cefoperazone sodium BP/USP equivalant to 0.5g of Cefoperazone as a sterile dry powder for reconstitution with suitable diluent for intramuscular or intravenous use.	60,000 Vials	60,000 Vials – June 2022
	Note:  01. The product should be stable for 02 years when stored at a temperature range of 28'C-32'C.  02. Each vial should be labeled accordingly.  Packing: 10 vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 73,932.00 or USD 371.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be :
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the

- Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eq. In delivery; time, product
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace
  - If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

## Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

### **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows:

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.			Quantity	Delivery Schedule	
	Description/Specific	ations			
	Nos of Representation as tender samp		nples for tr	ne item to be submitted	for the
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	y with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid va	lidity period: Bid sho	uld be v	valid till	(date)	
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for each	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/59/22	22.06.2021 at 9.00 a.m.	22,000 Vials of Vincristine Sulphate Injection 1mg vial	11.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE

75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA. TENDER NO. : DHS/P/WW/59/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO.: 2022/SPC/N/R/P/00032

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01202401	Vincristine Sulphate injection 1mg vial  Vincristine Sulphate for Injection BP/Vincristine Sulfate USP 1mg Each vial to contain Vincristine Sulphate BP/Vincristine Sulfate USP equivalent to 1mg of Vincristine and 10 parts by weight of Lactose BP/USP as sterile dry powder for reconstitution for intravenous use OR Vincristine injection BP 1mg/ml Each vial to contain Vincristine Sulphate BP equivalent to 1mg/ml of Vincristine in 0.9% w/v of Sodium Chloride intravenous infusion BP as ready to use injection for intravenous use.	22,000 Vials	11,000 Vials – March 2022 11,000 Vials – August 2022
	Note:  1. This injection should be stable for a minimum of 24 months when stored within a temperature range of 2'C - 8'C, do not freeze  2. Each dry powder form vial should be provided with a suitable diluent.  3. Each vial should be labelled accordingly  Packing: 10 vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 64,795.00 or USD 325.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

### (a) Part A

1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where

applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.

- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth)
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

of the original product shelf life.

8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.

9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of  $30\,^{\circ}\text{C}$  +/-  $2\,^{\circ}\text{C}$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

## **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/58/22	22.06.2021	70,000 Vials of Folinic Acid	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Injection 10mg/ml, 5ml vial		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/58/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/R/P/00032

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01202803	Folinic Acid Injection 10mg/ml, 5ml vial	70,000	25,000 Vials -
	Lecucovorin Calcium Injection USP 10mg/ml in	Vials	January 2022
	5ml vial.		25,000 Vials -
	Each 5ml vial to contain Leucovorin Calcium USP		May 2022
	equivalent to 10mg/ml of Leucovorin USP, for		
	intramuscular or intravenous injection.		20,000 Vials –
	Note:		October 2022
	1. This injection should be stable for a minimum of		
	24 months when stored within temperature of		
	2'C-8'C.		
	2.Each vial should be labelled accordingly.		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 689,808.00 or USD 3,457.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

## (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. <  $25\,^{\circ}$ C,  $2-25\,^{\circ}$ C,  $15-20\,^{\circ}$ C /30 °C,  $2-8\,^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No.

26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available

for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX – 1 to be amended to read as follows:

						ANNEX -
	D./BID REFERENCE ER NO.)	:				
DATE	OF ISSUE	:				
CLOSI	NG DATE & TIME	:				
(SRI L	ANKAN TIME)	:				
ORDER	LIST NO. :					
SR No.	Item Description/Specific	cations	Quantity	Deliv	ery Schedule	
	Description/Specific	cations				
evalua	Nos of Representat ntion as tender samp nt of Bid Bond : LKR	oles.	-			
Bid Bo	nd valid till	(	date)			
Bid va	lidity period : Bid sho	ould be	valid till	(d	ate)	
				`		
Bid Do	cument Fee :			,		
	cument Fee:					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/57/22	22.06.2021	480,000 Tablets of	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Metolazone Tablet 5mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/57/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22ND JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00017

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00208601	Metolazone Tablet 5mg	480,000	240,000 Tablets
	Metolazone tablets USP 5mg	Tablets	– January 2022
	Each tablet to contain 5mg of Metolazone USP		240,000 Tablets
	Note:		– May 2022
	01. The shelf life of the product should be minimum of 24 months.		
	02. The product should be kept in tight, light resistant containers, and store below 30 'C.		
	Packing: 100 Tablets in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 379,200.00 or USD 1,900.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a), embossed or printed in case of tablets
  - (b). printed in case of capsules

specified in the specification.)

- Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.
  - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain:

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms

(L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### <u>Sufficient quantity of Samples should be forwarded for evaluation</u>

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

## 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

<u> ANNEX – 1</u>

BID NO./BID REFERENCE

(TENDER NO.)

DATE OF ISSUE :
CLOSING DATE & TIME :

(SRI LANKAN TIME) :

#### **ORDER LIST NO. :**

SR No.	Item Description/Specifications	Quantity	Delivery Schedule

...... Nos of Representative samples for the item to be submitted for the evaluation as tender samples.

Amount of Bid Bond : LKR ..... or USD ..... to be submitted along with the

Bid

Bid Bond valid till ...... (date)

Bid validity period: Bid should be valid till ...... (date)

Bid Document Fee : .....

(should be paid in cash to SPC for each set of Bid Documents).

#### MSD CONDITIONS OF SUPPLY

1.

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

**BID FOR THE SUPPLY OF** 

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX – II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

#### 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted

- in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/56/22	22.06.2021	1,400,000 Capsules of	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Fenofibrate Capsule 200mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/56/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00017

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00206601	Fenofibrate Capsule 200mg  Fenofibrate capsule 200mg	1,400,000 Capsules	700,000 Capsules – January 2022
	Each capsule to contain 200mg of Fenofibrate BP/USP.		700,000 Capsules – May
	Note: 01. The shelf life of the product should be minimum of 24 months.		2022
	Packing : One Capsule		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 219,240.00 or USD 1,099.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a), embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain:

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg.  $< 25\,^{\circ}$ C, 2-25  $^{\circ}$ C, 15-20  $^{\circ}$ C /30  $^{\circ}$ C, 2-8  $^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30  $^{\circ}$ C +/- 2  $^{\circ}$ C & 75% +/- 5% RH for AC stored items and at 25  $^{\circ}$ C +/- 2  $^{\circ}$ C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

## 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

## Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### Terms and Conditions of Bid/Instructions to Bidders

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows;

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

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BID NO./BID REFERENCE

(TENDER NO.)

DATE OF ISSUE : CLOSING DATE & TIME :

(SRI LANKAN TIME)

#### **ORDER LIST NO. :**

SR No.	Item Description/Specifications	Quantity	Delivery Schedule

...... Nos of Representative samples for the item to be submitted for the evaluation as tender samples.

Amount of Bid Bond : LKR ..... or USD ..... to be submitted along with the

Bid

Bid Bond valid till ..... (date)

Bid validity period: Bid should be valid till ...... (date)

Bid Document Fee : .....

(should be paid in cash to SPC for each set of Bid Documents).

#### MSD CONDITIONS OF SUPPLY

1.

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

**BID FOR THE SUPPLY OF** 

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### <u>Amendment to Bidding Document under 'Conditions of Contract'</u>

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

#### 08 TERMS OF DELIVERY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted

- in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows;
All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/55/22	22.06.2021 at 9.00 a.m.	2,200 Ampoules of Cadioplegia Infusion (ST. Thomas Solution)	11.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

## Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/55/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00017

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00207501	Cadioplegia Infusion (ST. Thomas Solution)	2,200	2,200 Ampoules
	Cadioplegia infusion bulb(St. Thomas Solution)	Ampoules	– August 2022
	1.Should be Packed individually and labelled Accordingly		
	2. The shelf life of the product should be minimum of 24 months		
	Packing: One Ampoule		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 145,105.00 or USD 728.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain:

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
Nos of Representative samples for the item to be submitted for the evaluation as tender samples.  Amount of Bid Bond: LKR					
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

#### 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/54/22	22.06.2021	400 Vials of Alteplase 20mg	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	vial		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/54/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22ND JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00017

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00205701	Alteplase 20mg vial  Alteplase (Recombinent Tissue type plasminogen	400 Vials	200 Vials – June 2022
	activator) 20mg vial Each vial to contain 20mg of Alteplase for intravenous injection		200 Vials – September 2022
	Note; 1. The product should be from freshly manufactured stock and should have a minimum shelf life of 24 months.		
	2.Each vial should be labelled accordingly.  Packing: One vial		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 676,811.00 or USD 3,392.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be :
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the

Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain:
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### **Sufficient quantity of Samples should be forwarded for evaluation**

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their **Authorized Agent in the Supplier's Country.**
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.			Quantity	Delivery Schedule	
	Description/Specific	ations			
	Nos of Representation as tender samp		nples for tr	ne item to be submitted	for the
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	y with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid va	lidity period: Bid sho	uld be v	valid till	(date)	
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for each	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

# **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/53/22	22.06.2021 at 9.00 a.m.	5,000 PF Syringes of Tinzaparin Sodium Injection 3,500 units	11.05.2021	Rs. 3,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/53/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

## ORDER LIST NO.: 2022/SPC/N/C/P/00017

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00204801	Tinzaparin Sodium Injection 3,500 units	5,000 PF	2,500 PF
	Tinzaparin sodium Injection 3,500 IU in 0.35ml prefilled syringe/vial	Syringes	Syringes – January 2022
	Each 0.35ml prefilled syringe or vial to contain 3,500 IU of Tinzaparin Sodium BP/Ph Eur, salt of a low molecular weight Heparin obtained by depolimerization of Heparin for subcutaneous and intravenous injection.		2,500 PF Syringes – May 2022
	Note; 1. The product to be stable for minimum of 24 months when stored under storage condition stipulated by the manufacturer.		
	2.Each prefilled syringe/vial to be labelled accordingly.		
	Packing: One PF Syringe		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 89,670.00 or USD 450.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

## Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

- 21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 22. Maintenance of Cold Chain;
  - a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
  - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
  - c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC

stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

# **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No.

26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

## **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows:

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
CLOSING DATE & TIME		:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.		ations	Quantity	Delivery	Schedule
	Description/Specific	ations			
evalua	ition as tender samp	les.	-		submitted for the mitted along with the
Bid Bo	nd valid till	(	(date)		
Bid va	lidity period: Bid sho	uld be	valid till	(date	))
Bid Do	cument Fee :				
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows;

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

# **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/52/22		370,000 Tablets of	11.05.2021	Rs. 35,000/= +
	at 9.00 a.m.	Everolimus Tablet 0.25mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/52/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22ND JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01204201	Everolimus tablet 0.25mg	370,000 Tablets	185,000 Tablets – May
	Everolimus tablet 0.25mg		2022
	Each tablet to contain 0.25mg of Everolimus.		185,000
	Note:		Tablets
	01. The shelf life of the product should be minimum of 24 months		<ul><li>September</li><li>2022</li></ul>
	Packing : 10 Tablets in a strip 10 strips in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 2,901,318.00 or USD 14,537.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 35,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a), embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain:

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg.  $< 25\,^{\circ}$ C, 2-25  $^{\circ}$ C, 15-20  $^{\circ}$ C /30  $^{\circ}$ C, 2-8  $^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30  $^{\circ}$ C +/- 2  $^{\circ}$ C & 75% +/- 5% RH for AC stored items and at 25  $^{\circ}$ C +/- 2  $^{\circ}$ C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

# FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specificati	ione	Quantity	Delivery Schedule	
	Description/Specificati	10115			
	Nos of Representative tion as tender samples		nples for th	ne item to be submitted	for the
Amour	t of Bid Bond : LKR		. or USD	to be submitted along	g with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid shoul	d be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC fo	or eacl	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/51/22	22.06.2021	80 Bottles of Mycophenolate	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Mofetil Oral Suspension		
		1g/5ml in 175ml bottle		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/51/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01205306	205306 Mycophenolate mofetil oral suspension 1g/5ml in 175ml bottle		40 Bottles – April 2022
	Mycophenolate mofetil oral suspension 1g/5ml in 175ml bottle Each mL to contain 200mg of Mycophenolate mofetil BP, in a suitable flavoured and sweetend syrup/suspension base		40 Bottles – September 2022
	Note: 01. The shelf life of the product should be minimum of 24 months 02. Each bottle should be labelled accordingly.		
	Packing: 10 Bottles in a Box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 232.00 or USD 2.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all

suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be :
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the

- Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

# **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace
  - If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

# Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

# Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per Annex III encashable on first written demand to the value stated against each item in the Annex 1 of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

## **FREE REPLACEMENT/ REIMBURSEMENT**

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows;

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows:

					ANI	<u>NEX – 1</u>
_	D./BID REFERENCE ER NO.)	:				
DATE (	OF ISSUE	:				
	NG DATE & TIME	:				
(SRI LA	ANKAN TIME)	:				
ORDER	LIST NO. :					_
SR No.	Item Description/Specifica	tions	Quantity	Delivery S	chedule	
	Description, Specifical	CIOIIS				1
	Nos of Representative tion as tender sample		nples for th	e item to be	submitted fo	r the
Amour	nt of Bid Bond : LKR .		. or USD	to be subm	itted along wi	th the
Bid						
Bid Bo	nd valid till	(	date)			
Bid val	idity period: Bid shou	ld be	valid till	(date)		
Bid Do	cument Fee :					
(should	be paid in cash to SPC f	or eac	h set of Bid Do	ocuments).		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/50/22	22.06.2021	100,000 Capsules of	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Cyclosporin capsule 100mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

TENDER NO. : DHS/P/WW/50/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01205403	Cyclosporin Capsules 100mg	100,000	50,000
		Capsules	Capsules – July
	Cyclosporin Capsules USP 100mg.		2022
	Each capsule to contain 100mg of Cyclosporin		50,000
	USP.		50,000
			Capsules – October 2022
	Note:		October 2022
	01. The shelf life of the product should be minimum of 24 months		
	Packing: 10 Capsules in a strip 10 strips in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 80,660.00 or USD 405.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a), embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain:

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg.  $< 25\,^{\circ}$ C, 2-25  $^{\circ}$ C, 15-20  $^{\circ}$ C /30  $^{\circ}$ C, 2-8  $^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30  $^{\circ}$ C +/- 2  $^{\circ}$ C & 75% +/- 5% RH for AC stored items and at 25  $^{\circ}$ C +/- 2  $^{\circ}$ C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					<u>ANNEX – 1</u>
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specificat	ions	Quantity	Delivery Scheo	dule
	Nos of Representative tion as tender samples		nples for th	ie item to be subi	nitted for the
Amour	t of Bid Bond : LKR		or USD	to be submitted	l along with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid shoul	d be '	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC fo	or eac	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/49/22	22.06.2021	830,000 Capsules of	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Cyclosporin Capsule 50mg		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/49/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

# ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01205402	Cyclosporin Capsules 50mg	830,000	430,000
		Capsules	Capsules –
	Cyclosporin Capsules USP 50mg.		August 2022
	Each capsule to contain 50mg of Cyclosporin USP.		
			400,000
	Note:		Capsules –
	01. The shelf life of the product should be minimum of 24 months		November 2022
	Packing : 10 Capsules in a strip 10 strips in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 306,934.00 or USD 1,538.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be

extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a), embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain:

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg.  $< 25\,^{\circ}$ C, 2-25  $^{\circ}$ C, 15-20  $^{\circ}$ C /30  $^{\circ}$ C, 2-8  $^{\circ}$ C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30  $^{\circ}$ C +/- 2  $^{\circ}$ C & 75% +/- 5% RH for AC stored items and at 25  $^{\circ}$ C +/- 2  $^{\circ}$ C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE (	OF ISSUE	:			
	NG DATE & TIME	:			
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specificati	ione	Quantity	Delivery Schedule	
	Description/Specificati	10115			
	Nos of Representative tion as tender samples		nples for th	ne item to be submitted	for the
Amour	t of Bid Bond : LKR		. or USD	to be submitted along	g with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid val	idity period:Bid shoul	d be v	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC fo	or eacl	h set of Bid Do	ocuments).	

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/48/22	22.06.2021	580,000 Capsules of	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Cyclosporin capsule 25mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : pharma.manager@spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/48/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01205401	Cyclosporin Capsules 25mg	580,000	300,000
	Cyclosporin Capsules USP 25mg.	Capsules	Capsules – August 2022
	Each capsule to contain 25mg of Cyclosporin USP.		280,000
	Note: 01. The shelf life of the product should be minimum of 24 months		Capsules – November 2022
	Packing: 10 Capsules in a strip 10 strips in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 147,436.00 or USD 739.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.
  - When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

  Format shall be according to Code 128 or 2D standards.

  Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

## **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain:

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

## **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those

offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their **Authorized Agent in the Supplier's Country.**
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

## FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

Page No. 23 SPECIMEN OF ANNEX - 1 to be amended to read as follows;

						ANNEX	<u>( – 1</u>
	D./BID REFERENCE ER NO.)	:					
DATE	OF ISSUE	:					
CLOSI	NG DATE & TIME	:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item Description/Specific	rations	Quantity	Delive	ry Schedule		
	Description/Specific	ations					
	Nos of Representat Ition as tender samp		nples for th	ne item to b	e submitted	for t	the
Amour	nt of Bid Bond : LKR		. or USD	to be รเ	ıbmitted alonç	y with 1	the
Bid							
Bid Bo	nd valid till	(	date)				
Bid val	lidity period : Bid sho	ould be	valid till	(da	ite)		
Bid Do	cument Fee :						
(should	I be paid in cash to SPC	for eac	h set of Bid Do	ocuments).			

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/47/22	22.06.2021	330 Bottles of Cyclosporin	11.05.2021	Rs. 12,500/= +
	at 9.00 a.m.	Syrup 100mg in 1ml, 50ml bottle		Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

# Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

E-MAIL : <a href="mailto:pharma.manager@spc.lk">pharma.manager@spc.lk</a>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
75, SIR BARON JAYATILLAKE MAWATHA
COLOMBO 1
SRI LANKA.

TENDER NO. : DHS/P/WW/47/22 DATE OF ISSUE : 11<sup>TH</sup> MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01205404	Cyclosporin Syrup, 100mg in 1ml, 50ml bottle	330 Bottles	130 Bottles – January 2022
	Cyclosporin Syrup USP, 100mg in 1ml, 50ml bottle Each 1 ml of concentrate for oral solution to contain 100 mg of Cyclosporin USP		100 Bottles – May 2022
	Note: 01. The shelf life of the product should be		100 Bottles - September 2022
	minimum of 24 months 02. Each bottle should be labelled accordingly.  Packing: 10 Bottles in a Box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 221,057.00 or USD 1,107.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 12,500.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.

- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

- 24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.
  - Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.
- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

  In the event of failure to meet this deadline due to supplier/s fault (eq. In delivery; time, product
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.

- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.
- 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### **Terms and Conditions of Bid/Instructions to Bidders**

Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.

Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows;

### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows:

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

					ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE	DATE OF ISSUE :				
	CLOSING DATE & TIME :				
(SRI L	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.			Quantity	Delivery Schedule	
	Description/Specific	ations			
	l Daniel	•			
Nos of Representative samples for the item to be submitted for the evaluation as tender samples.					
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	y with the
Bid					
Bid Bo	nd valid till	(	date)		
Bid va	lidity period: Bid sho	uld be v	valid till	(date)	
Bid Do	cument Fee :				
(should be paid in cash to SPC for each set of Bid Documents).					

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended to read as follows;</u>

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF ANNEX - II(B) to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



# **PROCUREMENT NOTICE - GLOBAL**

# STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2022.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non- refundable Bid Fee
DHS/P/WW/46/22	22.06.2021	1,000,000 Capsules of	11.05.2021	Rs. 3,000/= + Taxes
	at 9.00 a.m.	Tacrolimus capsule 0.5mg		

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Internal Audit Department in the mezzanine floor of the State Pharmaceuticals Corporation at No. 75, Sir Baron Jayatillake Mawatha, Colombo 1, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

Bidders or their authorised representatives will be permitted to be present at the time of opening of Bids.

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE STATE PHARMACEUTICALS CORPORATION OF SRI LANKA 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1 SRI LANKA.

FAX : 00 94-11- 2344082

TELEPHONE : 00 94-11- 2326227/94-11-2335374

: pharma.manager@spc.lk E-MAIL

GENERAL MANAGER STATE PHARMACEUTICALS CORPORATION OF SRI LANKA FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE 75, SIR BARON JAYATILLAKE MAWATHA COLOMBO 1

SRI LANKA.

TENDER NO. : DHS/P/WW/46/22 DATE OF ISSUE :  $11^{TH}$  MAY 2021

CLOSING DATE & TIME : 22<sup>ND</sup> JUNE 2021 AT 09.00 HOURS SRI LANKA TIME

#### ORDER LIST NO.: 2022/SPC/N/C/P/00051

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01205601	Tacrolimus capsule 0.5mg	1,000,000	500,000
		Capsules	Capsules –
	Tacrolimus capsule 0.5mg		June 2022
	Each capsule to contain 0.5mg of Tacrolimus		
			500,000
	Note:		Capsules –
	01. The shelf life of the product should be		October 2022
	minimum of 24 months		
	Packing: 10 Capsules in a strip 10 strips in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 159,200.00 or USD 798.00.

Bid Bond should be submitted with valid up to 18.01.2022 together with the bid Bid should be valid till 19.12.2021.

**Non refundable Bid Fee Rs. 3,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

Bid Evaluation Summary sheets should be submitted with the Bid (Please refer SPC website for more details)

#### **CONDITIONS OF SUPPLY**

#### (a) Part A

- 1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.
- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- 3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a prerequisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

When the validity of the product/manufacturing licenses and registrations of NMRA (eg; manufacturing license, product registration and GMP certificates), of local manufacturers / local suppliers, lapses during the year or during the period of supply (delivery schedule), it shall be extended / renewed by the supplier. A certified copies of afore mentioned valid certificates shall be submitted to MSD by the supplier when deliveries are made.

- **4.** The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.
- 5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

All possible tender deviations such as Packing, labeling, delivery schedule, storage status, payment mode & conditions, etc., shall be communicated and agreed upon before accepting the tender award by the supplier. Noncompliance of same shall be considered as tender violations, to apply penalty (as clause No. 36).

6. The specifications of the product offered in the bid, by the supplier shall match with the tender specifications for the item and any form of alternate offers for the same will not be entertained, when there are product/s offered in compliance with the tender specification.

#### **Shelf life & Warrantees.**

- 7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.
  - (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.

    The difference of the residual and requested product shelf life shall not exceed 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

- 8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.
- 9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards—or all its components not unitized appropriately in packaging (as a set), shall be rejected.

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b). In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.

- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)
  - If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.
- 12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
  - If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.
  - 13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules
  - Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)
- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.
  - It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.

  Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

In respect of SPC imported supplies, if the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier by SPC and refund to MSD.

#### **Storage Conditions & Temperature**

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 °C +/- 2 °C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 22. Maintenance of Cold Chain;

- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
- b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.
- c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 23. In respect of the products requiring controlled temperature storage (Eg. < 25 °C, 2-25 °C, 15-20 °C /30 °C, 2-8 °C etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30 °C +/- 2 °C & 75% +/- 5% RH for AC stored items and at 25 °C +/- 2 °C & 60% +/- 5% RH for Cold stored items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.11)

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part

thereof, that is delivered after the due delivery date, Condition No. 26 on delayed deliveries, shall be applied.

- 25. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments to reach Sri Lanka from 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.
  - (ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.
- 28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.
  - In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.
  - As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all adl. expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the

conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).

The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.

- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)

  If it is not complied or the information so provided are found to be incomplete/false, the grace

period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

- 35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.
- 36. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

Abbreviations: NMRA; National Medicines Regulatory Authority/Sri Lanka, SPC; State Pharmaceuticals Corporation, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka.

#### (b) Part B - Special Order Conditions (SOC) of supply

Note: SOCs are used, when it is really necessary to enable, item/order list specific deviations from the GOC clauses that are applicable to all or selected items in the order list concerned and in which case the relevant order list No. & S.R. No.s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

#### **Special Conditions for Bidding:**

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.
- 4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

Comparison of foreign offer and local offer made on Imports & Supply basis will be compared as follows.

Local offers which are for Import & Supply basis will be divided by a hypothetical value for comparison of offers against C & F value based on the HS Code of the item as determined by SPC.

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m³).
- 7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time** on **the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.

#### Sufficient quantity of Samples should be forwarded for evaluation

- 8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.
- 9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.
- 10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies Sri Lanka (where applicable).
- 11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.
- 14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

# 15. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.

- 16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.
- 17. SPC reserves the right to reject offers which do not comply with above conditions.

Amendments to the Bidding Documents for procurement of pharmaceuticals for the Department of Health Services of Government of Sri Lanka (Blue Book). (DPC)

#### Page No. 6 Condition No. 8 (BONDS/GUARANTEES) to be amended to read as follows:

- 08.1 Bidders should furnish an unconditional Bid Bond as per **Annex III** encashable on first written demand to the value stated against each item in the **Annex 1** of the Bidding Document.
  - Bid Bond should be submitted together with the Bid or to reach SPC on or before the closing date and time of Bid. Bids submitted without Bid Bonds, will not be considered.
- 08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid. The amount of bid bond and the date until which the bid should be valid is indicated in the Annex I.
- Page No. 8 Condition No. 12 FREE REPLACEMENT to be amended to read as follows:

#### FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2<sup>nd</sup> line delete the words 'replaced or'

Page No. 14 Condition No. 20 (REGISTRATION) 20.1 (b) to be amended to read as follows;

(b) A Certified copy of the NMRA registration Certificate certified by Attorney-at-Law, Commissioner of Oaths or Justice of Peace should be submitted along with the bid.

Page No. 16 Condition No. 22 (TESTING OF BATCH SAMPLES) 22.1 to be amended to read as follows:

22.1 In the case of distribution to Hospitals/ State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL / Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports /committee decisions will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an Administrative cost. within 30 days from the date of intimation.

						ANNEX -	<u>· 1</u>
	D./BID REFERENCE ER NO.)	:					
DATE OF ISSUE : CLOSING DATE & TIME :		:					
		:					
(SRI L	ANKAN TIME)	:					
ORDER	LIST NO. :						
SR No.	Item	cations	Quantity	Deliv	ery Schedule		
	Description/Specific	Cations					
evalua	Nos of Represental stion as tender samp at of Bid Bond : LKR	oles.	-				
Bid Bo	nd valid till	(	date)				
Bid va	lidity period : Bid she	ould be v	valid till	(d	ate)		
		oulu bo			•		
Bid Do	cument Fee :			(4	•		
	cument Fee:				·		

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be amended</u> to read as follows:

BID NO./BID REFERENCE

Page No. 26 & 27 SPECIMEN OF **ANNEX - II(B)** to be amended to read as follows:

Heading of 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11<sup>th</sup> Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### **Amendment to Bidding Document under 'Conditions of Contract'**

Page No. 39, Condition No. 8 TERMS OF DELIVERY to be amended to read as,

# 08 TERMS OF DELIVERY

MSD CONDITIONS OF SUPPLY

8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of

- shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .......
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions)

  May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

Page No. 39 Condition No. 9.2 (Payment) - To be amended to read as follows; All payments will be on confirmed irrevocable letter of credit payable at sight/credit.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC