

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/251/22	13.07.2021	9,500 Vials of Liposomal	01.06.2021	Rs. 35,000/=
	at 9.00 a.m.	Amphotericin B Injection		+ Taxes
		50mg for I.V. use		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/251/22

DATE OF ISSUE : 1ST JUNE 2021

CLOSING DATE & TIME : 13TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00024

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00107403	Liposomal form of Amphotoricin B 50 mg vial	9,500 Vials	5,000 Vials – May 2022
	Liposomal form of Amphotericin B 50 mg vial A sterile, pyrogen free, lyophilized powder for dispersion for infusion. Each vial should contain as active ingredient 50 mg (50,000 units) of Amphotericin B intercalated in liposomes. After reconstitution in sterile water for injection, the concentrated solution should contain 4mg/ml of Amphotericine B. Each vial should be packed individually in a carton with a product information leaflet including details on administration and a device for filtration with the mean pore diameter of the filter not less than 1.0 micron. Prequalification The manufacturer should have the following documents 1) Certificate of registration in a. the country of manufacturer b. Sri Lanka c. other countries where the product is registered 2) Evidence of current use in the country of manufacture 3) Evidence of current use in reference countries namely USA, UK and Ireland. Australia, Canada, Germany, Japan, Italy 4) Evidence of WHO pre- qualification is preferable	Viais	May 2022 4,500 Vials – August 2022
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 2,969,928.00 or USD 14,887.00.

Bid Bond should be submitted with valid up to 08.02.2022 together with the bid Bid should be valid till 09.01.2022.

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 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 1/6th (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)

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.)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description,

- 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 $^{\circ}$ C +/- 2 $^{\circ}$ 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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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
)./BID REFERENCE ER NO.)	:		
DATE (OF ISSUE	:		
CLOSI	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER I	LIST NO. :			
SR No.	Item		Quantity	Delivery Schedule
			- Qualitate,	
evalua	tion as tender samp	ive sar les.	mples for ti	ne item to be submitted for t
evalua Amoun Bid	Nos of Representati	ive sar les.	nples for th	ne item to be submitted for 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 NO./BID REFERENCE

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

Heading of 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE

Heading of 11th 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/285/22	15.07.2021	6,000 Vials of Desmopresin	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	acetate Nasal Spray 10mcg,		+ Taxes
		(60m spray)		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/285/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00012

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00703302	Desmopressin acetate Nasal spray 10mcg, (60 m spray)	6,000 Vials	2,000 Vials – February 2022
	Desmopressin acetate Nasal spray 10mcg/metered spray (60 metered sprays)		2,000 Vials – May 2022
	Each vial to contain 60 metered sprays (60 doses) and each metered spray to contain 10mcg of Desmopressin Acetate.		2,000 Vials – August 2022
	Note: 01. The shelf life of the product should be minimum of 24 months.		
	Packing: 10 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 95,728.00 or USD 480.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

BID NO	./BID REFERENCE	:		ANNEX
(TENDE	ER NO.)			
DATE (OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item		Quantity	Delivery Schedule
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	=	ive sar		e item to be submitted for t
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/284/22	15.07.2021 at 9.00 a.m.	45,000 L of Peracetic Acid	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/284/22
DATE OF ISSUE : 2ND JUNE 2021
CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00065

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01105603	Peracetic Acid Peracetic acid Peracetic acid as a high level	45,000 L	15,000 L – February 2022
	disinfectant and a sterilant for endoscopes, air ways, endotracheal tubes and other medical devices in 500g-1000g or 1L-5L, powder or liquid.		15,000 L – May 2022
	1. The working solution (in-use solution) used for high level disinfection should be equivalent to peracetic acid 2000ppm 3500ppm (0.2% - 0.35%.		15,000 L – September 2022
	The product should be virucidal, bactericidal (including mycobacteria), fungicidal and sporicidal.		
	3. The efficacy and suitability of the product as a high level disinfectant /sterilant for endoscope/ medical devices reprocessing should have been approved by FDA, European Union, WHO recognized laboratory or a comparable approving authority.		
	4. The product should be able to achieve high level disinfection within 10-15 minutes in order to minimize turnaround time.5. The product should be patient and user safe.		
	6. The product should produce negligible changes in either the appearance or function of processed items, even after repeated cycling.		
	7. The product should not corrode instrument or cause deterioration of rubber, plastics, metals or other construction materials.		
	8. The product should be able to monitor minimum effective concentration using a simple procedure such as using a test strips. Adequate test strips within the shelf life of the product, should be provided.		
	9. The product should have no requirements for special disposal (eg; Requirement for collection or neutralization prior to disposal)		
	Note: 1. The manufacturer should clearly indicate the content of peracetic acid of the product and concentration of the finished product.		

- 2. The shelf life of the product should be minimum of 24 months
- 3. Should have a valid registration from NMRA.
- 4. The supplier should provide a certificate endorsing good manufacturing practice at the production facility (GMP certification).
- 5. There should be a leaflet with each container giving relevant information such as chemical composition, instructions for use etc.
- 6. The strength of the solution should clearly be indicated in the label. Label should have letters of readable size.

Packing: One Litre

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 990,000.00 or USD 4,963.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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

set), shall be 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
- 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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

_)./BID REFERENCE ER NO.)	:		ANNE	<u>X – 1</u>
•	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specification	ons	Quantity	Delivery Schedule	
evalua Amoun Bid	tion as tender samples		. or USD	ne item to be submitted for to be submitted along with	
	idity period: Bid should	•	,	(date)	
	cument Fee:be paid in cash to SPC for			ocuments).	
MSD CO	NDITIONS OF SUPPLY				

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be</u> 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 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th 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/283/22	15.07.2021	980,000 Vials of Clindamycin	02.06.2021	Rs. 20,000/=
	at 9.00 a.m.	Phosphate Injection		+ Taxes
		300mg/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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/283/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00046

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00103203	Clindamycin Phosphate Injection 300mg/2ml	980,000	580,000 Vials –
		Vials	April 2022
	Clindamycin Injection BP		
	OR		400,000 Vials –
	Clindamycin Phosphate Injection USP		August 2022
	Each 2ml ampoule to contain Clindamycin		
	Phosphate BP/USP equivalant to 300mg of		
	Clindamycin in water for injection BP/USP for		
	intramuscular or intravenous injection.		
	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 Vials in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,028,608.00 or USD 5,156.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", $16^{\rm th}$ Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

BID NO)./BID REFERENCE			ANNEX
(TEND	ER NO.)			
DATE	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.			Quantity	Delivery Schedule
			, ,	Delivery Seriedate
	Description/Specific Nos of Representat tion as tender samp	ive sar		ne item to be submitted for t
evalua Amour Bid	Nos of Representat tion as tender samp	ive sar les.	nples for th	_
evalua Amour Bid Bid Bo	Nos of Representat tion as tender samp at of Bid Bond : LKR	ive sar les.	nples for the control of the control	ne item to be submitted for t
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evalua Amour Bid Bid Bo Bid val Bid Do	Nos of Representation as tender samp It of Bid Bond : LKR Ind valid till	ive san les. (nples for the control of the control	ne item to be submitted for t
evalua Amour Bid Bid Bo Bid val Bid Do (should	Nos of Representat tion as tender samp at of Bid Bond : LKR and valid tillidity period : Bid should cument Fee :	ive san les. (nples for the control of the control	ne item to be submitted for t

Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX - IIA Content of the cage to be amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/282/22	15.07.2021 at 9.00 a.m.	56,000 Vials of Amikacin Injection 250mg in 1ml	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/282/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00046

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00102601	Amikacin Injection 250mg in 1ml	56,000 Vials	36,000 Vials – March 2022
	Amikacin Sulphate Injection USP 250mg in 1ml Vial. Each 1ml vial to contain 250mg of Amikacin Sulphate USP in water for injection BP/USP for Intravenous or intramuscular Injection.		20,000 Vials – August 2022
	Note: 1.Should be stable for three years when stored at a temperature range of 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 191,028.00 or USD 958.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

RID NO)./BID REFERENCE			ANNEX
	ER NO.)	•		
DATE	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.			Quantity	Delivery Schedule
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	<u>=</u>	ive san		·
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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.
- 8.4 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/281/22	15.07.2021	900,000 Capsules of	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Fluconazole 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/281/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00046

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00107101	Fluconazole capsule 50mg	900,000 Capsules	900,000 Capsules
	Fluconazole capsule 50mg Each capsule to contain 50mg of Fluconazole. The Capsule should conforms to bio equivalence criterion Of the WHO	·	– July 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 81,900.00 or USD 411.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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 -
)./BID REFERENCE ER NO.)	:	
DATE	OF ISSUE	:	
	NG DATE & TIME ANKAN TIME)	:	
ORDER	LIST NO. :		
SR No.		Quantity	Delivery Schedule
	Description/Specifica		the item to be submitted for the
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evalua Amour Bid	Nos of Representati	ve samples for es.	the item to be submitted for the item to be submitted along with the item to be submitted for the item to be submitted for the item to be submitted for the item to be submitted along with the item to be submitted.
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/280/22	15.07.2021 at 9.00 a.m.	47,000 Vials of Fluconazole Injection 200mg in 100ml	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/280/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00046

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00107102	Fluconazole Injection 200mg in 100ml Vial	47,000 Vials	25,000 Vials – February 2022
	Fluconazole Injection for I.V. infusion 200mg in 100ml Vial Each 100ml vial to contain 200mg of Fluconazole for intravenous infusion		22,000 Vials – July 2022
	Note. 1.This injection should be stable for minimum of 24 months when stored at a temperature range of 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 63,460.00 or USD 319.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

BID NO)./BID REFERENCE			ANNEX
(TEND	ER NO.)			
DATE	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.			Quantity	Delivery Schedule
			, ,	Delivery Seriedate
	Description/Specific Nos of Representat tion as tender samp	ive sar		ne item to be submitted for t
evalua Amour Bid	Nos of Representat tion as tender samp	ive sar les.	nples for th	_
evalua Amour Bid Bid Bo	Nos of Representat tion as tender samp at of Bid Bond : LKR	ive sar les.	nples for the control of the control	ne item to be submitted for t
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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.
- 8.4 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/279/22	15.07.2021 at 9.00 a.m.	340,000 Capsules of Clindamycin Capsule 150mg	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/279/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00046

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00103201	Clindamycin Capsule 150mg	340,000	340,000
	Clindamycin Capsules BP,150mg OR Clindamycin Hydrochloride Capsules USP,150mg Each capsule to contain Clindamycin Hydrochloride BP/USP equivalent to 150mg of Clindamycin.	Capsules	Capsules – August 2022
	Note: 01.Product should conform to bio equivalence criteria Of the WHO		
	02. The shelf life of the product should be minimum of 24 months. Packing: 10 Capsules in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 66,436.00 or USD 333.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", $16^{\rm th}$ Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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 -
)./BID REFERENCE ER NO.)	:	
DATE	OF ISSUE	:	
	NG DATE & TIME ANKAN TIME)	:	
ORDER	LIST NO. :		
SR No.		Quantity	Delivery Schedule
	Description/Specifica		the item to be submitted for the
evalua	Nos of Representati	ve samples for es.	
evalua Amour Bid	Nos of Representati	ve samples for es.	the item to be submitted for the item to be submitted along with the item to be submitted for the item to be submitted for the item to be submitted for the item to be submitted along with the item to be submitted.
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/278/22	15.07.2021	840,000 Tablets of Aciclovir	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Tablet 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/278/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00045

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00107901	Aciclovir Tablet 200mg	840,000	840,000 Tablets
	Association for table to LICD 200ms or	Tablets	September
	Acyclovir tablet USP 200mg		2022
	Each tablet to contain 200mg of Acyclovir USP		
	OR		
	Aciclovir tablet BP 200mg		
	Each tablet to contain 200mg of Aciclovir BP.		
	Note:		
	01. The shelf life of the product should be minimum of 24 months.		
	Packing: 10 Tablets in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 66,684.00 or USD 336.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

RID NC)./BID REFERENCE			ANNEX
	ER NO.)	•		
DATE (OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item			
		ations	Quantity	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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/277/22	15.07.2021	200,000 Vials of	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	, .		+ Taxes
		200mg/100ml		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/277/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00045

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00105403	Ciprofloxacin Injection 200mg/100ml	200,000	200,000
	Ciprofloxacin intravenous infusion BP, 200mg in 100ml vial OR	Vials	Vials – November
	Ciprofloxacin intravenous infusion USP, 200mg in 100ml vial		2022
	Each 100ml bottle to contain Ciprofloxacin Lactate equivalent to 200mg of Ciprofloxacin BP/USP for intravenous infusion		
	Note: 1. The bottle should graduate 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 or piercing spike should be covered with a sterile rubber disk or bung and the plastic cover of the disc or bung should be fused to the neck of the bottle right round.		
	4.Each bottle should be packed individually in a protective polyethylene cover.		
	5. The product should be sterile and stable for a minimum of two years when stored under temperature not exceeding 30'C		
	6. The bottle should be labeled accordingly.		
	Packing : 10 Vials in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 115,800.00 or USD 581.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", $16^{\rm th}$ Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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>.</u>	ANNEX – 1
	D./BID REFERENCE ER NO.)	:			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specifi	cations	Quantity	Delivery Schedule	
	-		nples for th	ne item to be submitted	for the
	ntion as tender samp		ar HCD	to be submitted along	الا الدر الالالالالالالالالالالالالالالالالالال
Amour Bid	It of bid bond : LKK	•••••	. or บอบ	to be submitted along	with the
	and valid till	,	data\		
	ond valid till	,	,		
Bid va	lidity 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).	
MSD CC	ONDITIONS OF SUPPLY				

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be</u> 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 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th 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

1.

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/276/22	15.07.2021	50,000 Tablets of Terbinafine	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Pivasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/276/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00045

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00110901	Terbinafine Tablet 250mg Terbinafine tablet 250mg	50,000 Tablets	25,000 Tablets – January 2022
	Each tablet to contain 250mg of Terbinafine as Terbinafine hydrochloride.		25,000 Tablets – June 2022
	Note: 01.The shelf life of the product should be minimum of 24 months.		
	Packing: 10 Tablets in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 67,000.00 or USD 336.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

BID NO)./BID REFERENCE			ANNEX
(TEND	ER NO.)			
DATE	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.			Quantity	Delivery Schedule
			, ,	Delivery Seriedate
	Description/Specific Nos of Representat tion as tender samp	ive sar		ne item to be submitted for t
evalua Amour Bid	Nos of Representat tion as tender samp	ive sar les.	nples for th	_
evalua Amour Bid Bid Bo	Nos of Representat tion as tender samp at of Bid Bond : LKR	ive sar les.	nples for the control of the control	ne item to be submitted for t
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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.
- 8.4 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/275/22	15.07.2021	15,000 Tubes of	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Metronidazole gel 0.75%-1% w/w, 30g tube		+ 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/275/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00009

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01107501	Metronidazole gel 0.75%-1% w/w, 30g tube	15,000	15,000 Tubes
	Metronidazole gel BP/USP 0.75% - 1% w/w, 30g tube	Tubes	- October 2022
	Each collapsible 30g tube to contain 0.75% - 1% w/w of Metronidazole BP/USP in a suitable water-soluble basis.		
	Note:		
	1. Self life of the product should be minimum of 24 months.		
	2. Each tube should be labeled accordingly		
	Packing: 10 Tubes in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 60,000.00 or USD 301.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

BID NO)./BID REFERENCE			ANNEX
(TEND	ER NO.)			
DATE	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.			Quantity	Delivery Schedule
			, ,	Delivery Seriedate
	Description/Specific Nos of Representat tion as tender samp	ive sar		ne item to be submitted for t
evalua Amour Bid	Nos of Representat tion as tender samp	ive sar les.	nples for th	_
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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.
- 8.4 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/274/22	15.07.2021 at 9.00 a.m.	17,000 Tubes of Cetrimide Cream 0.5%, 50g tube	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Pivasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/274/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00009

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01103602	Cetrimide Cream 0.5%, 50g tube	17,000	7,000 Tubes
	Cetrimide Cream BP 0.5%, W/W 50g tube	Tubes	– January 2022
	Each 50g collapsible tube to contain 0.5% W/W of		5,000 Tubes
	Cetrimide BP in suitable cream base.		– May 2022
	Note:		5,000 Tubes
	1. This product should be stable for a minimum of 24 months when stored at a temperature range of 28'C-32'C		– September 2022
	2.Each tube should be labelled accordingly.		
	Pack: 50g air-tight, sealed, printed collapsible tube in printed cartons		
	Packing: 10 Tubes in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 208,784.00 or USD 1,047.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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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						ANNEX – 1			
	BID NO./BID REFERENCE (TENDER NO.)		:						
	DATE	OF ISSUE	:						
	CLOSING DATE & TIME (SRI LANKAN TIME)		:						
	ORDER	LIST NO. :							
	SR No.	Item Description/Specific	ations	Quantity	Delivery Schedule				
		Nos of Representat tion as tender samp		nples for tl	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	valid till	(date)				
	Bid Do	cument Fee :							
	(should be paid in cash to SPC for each set of Bid Documents).								
	MSD CO	NDITIONS OF SUPPLY							
	1.								

Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX - IIA Content of the cage to be amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE
NMRA REGISTRATION

Heading of 11th 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/273/22	15.07.2021	15,000 Bottles of	02.06.2021	Rs. 12,500/=
	at 9.00 a.m.	Moxifloxacin Preservative		+ Taxes
		free Ophthalmic Solution 0.5%		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/273/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00009

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00904102	Moxifloxacin Preservative free Ophthalmic Solution 0.5%	15,000 Bottles	7,500 Bottles – June 2022
	Moxifloxacin hydrochloride ophthalmic solution 0.5% w/v , 5ml dropper bottle		7,500 Bottles – November 2022
	Each 5ml dropper bottle to contain 0.5% w/v of Moxifloxacin hydrochloride in purified water (Preservative free).		
	Note: 1. The tamper - evident container (dropper bottle) should assure the sterility of the product.		
	Each bottle should be packed in light-resistant boxes.		
	3. Product should be stable for minimum of 24 months when stored at a temperature range of 28'C-32'C		
	4.Each bottle should be labeled accordingly. Packing: 10 Bottles in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 240,000.00 or USD 1,203.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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, 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", $16^{\rm th}$ Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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 –
	./BID REFERENCE ER NO.)		
DATE (OF ISSUE		
	NG DATE & TIME ANKAN TIME)		
ORDER	LIST NO. :		
SR No.	Item Description/Specification	Quantity	Delivery Schedule
evalua	tion as tender samples.	•	
evalua Amoun Bid	tion as tender samples.	or USD	
evalua Amoun Bid Bid Bo	tion as tender samples. t of Bid Bond : LKR	or USD	e item to be submitted for th to be submitted along with th (date)
evalua Amoun Bid Bid Bod Bid val	tion as tender samples t of Bid Bond : LKR	or USD (date) be valid till	to be submitted along with th
evalua Amoun Bid Bid Bod Bid val	tion as tender samples t of Bid Bond : LKR nd valid till	or USD (date) be valid till	to be submitted along with th
evalua Amoun Bid Bid Bod Bid vali Bid Dod (should	tion as tender samples t of Bid Bond : LKR nd valid till idity period : Bid should cument Fee :	or USD (date) be valid till	to be submitted along with th

<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 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STOPA OF TEMPERATURE

AND STORAGE TEMPERATURE
Heading of 11th 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,

- 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/272/22	15.07.2021	11,000 Vials of Trypan Blue	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Ophthalmic Solution 0.06%-		+ Taxes
		0.08%, 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/272/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00009

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00904401	Trypan Blue Ophthalmic Solution 0.06%-0.08%, 1ml	11,000 Vials	6,000 Vials – September
	Trypan Blue ophthalmic solution 0.06%-0.08%, 1ml vial /PFS	Viais	2022
	Each 1 ml vial / Pre-filled syringe to contain 0.06%-0.08% w/v sterile solution of Trypan Blue		5,000 Vials – November
	Note: 1. The tamper evident dropper bottle / Pre-filled syringe should assure the sterility of the product.		2022
	2. The product should be stable for a minimum of 02 years when stored at temperature 32'C.		
	3. Each bottle should be labelled accordingly.		
	Packing: 10 Vials in a pack		

Representative Tender samples to be submitted for the evaluation.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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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						ANNEX – 1
		D./BID REFERENCE ER NO.)	:			
	DATE	OF ISSUE	:			
		NG DATE & TIME ANKAN TIME)	:			
	ORDER	LIST NO. :				
	SR No.	Item Description/Specific	ations	Quantity	Delivery Schedule	
		Nos of Representat tion as tender samp		nples for tl	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	valid till	(date)	
	Bid Do	cument Fee :				
	(should	be paid in cash to SPC	for eac	h set of Bid Do	ocuments).	
	MSD CO	NDITIONS OF SUPPLY				
	1.					

Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX - IIA Content of the cage to be amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE
NMRA REGISTRATURE

Heading of 11th 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/271/22	15.07.2021	100,000 Vials of Bimatoprost	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Ophthalmic Suspension		+ Taxes
		300mcg/ml, 3ml		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/271/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00009

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00902901	Bimatoprost Ophthalmic Suspension 300mcg/ml, 3ml Bimatoprost ophthalmic suspension 300mcg/ml, 3ml dropper bottle Each 3ml dropper bottle to contain 300mcg/ml of Bimatoprost for ophthalmic use Note: 01.The tamper - evident container (dropper bottle) should assure the sterility of the product. 02.The shelf life of the product should be minimum of 24 months 03.Each dropper bottle should be labelled accordingly Packing: 10 Vials in a pack	100,000 Vials	50,000 Vials - June 2022 50,000 Vials - September 2022

Representative Tender samples to be submitted for the evaluation.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

	D./BID REFERENCE :		ANNEX -
•	ER NO.)		
	OF ISSUE :		
	NG DATE & TIME : ANKAN TIME) :		
ORDER	LIST NO. :		
SR No.	Item	Quantity	Delivery Schedule
	<u>-</u>		e item to be submitted for the
evalua Amoun Bid	Nos of Representative tion as tender samples.	samples for th	e item to be submitted for the submitted along with the submitted along
evalua Amoun Bid Bid Bo	Nos of Representative tion as tender samples.	samples for th or USD	to be submitted along with tl
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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 NO./BID REFERENCE

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

Heading of 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STOPAGE TEMPERATURE

AND STORAGE TEMPERATURE

Heading of 11th 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,

- 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/270/22	15.07.2021 at 9.00 a.m.	10,000 Vials of Lignocain Injection 2% 5ml vial for	02.06.2021	Rs. 3,000/= + Taxes
	at 7.00 a	ophthalmic use (preservative free)		, and

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/270/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00009

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00942201	Lignocain Injection 2% 5ml vial for ophthalmic use (preservative free)	10,000 Vials	5,000 Vials – August 2022
	Lignocaine Injection BP/Lignocaine Injection BP 2% w/v, 5ml. Each 5ml amber coloured vial to contain 2% w/v sterile solution of Lidocaine Hydrochloride BP for local anaesthesia OR Lidocaine Hydrochloride Injection USP 2% w/v,5ml Each 5ml amber coloured vial to contain 2% w/v sterile solution of Lidocaine Hydrochloride USP for local anaesthesia.		5,000 Vials – November 2022
	Note: 1. The product should be preservative free		
	2. This injection should be stable for a minimum of 02 years when stored at a temperature range of 28'C-32'C		
	3. This injection should comply with the "No. 15.4(d) labelling for anaesthetic products"		
	4.Each vial should be labelled accordingly		
	Packing: 10 Vials in a pack		

Representative Tender samples to be submitted for the evaluation.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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)

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.)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description,

- 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 $^{\circ}$ C +/- 2 $^{\circ}$ 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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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;

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.

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

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 ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item Description/Specific	cations	Quantity	Delivery Schedule
				I
	 Nos of Representat ation as tender samp		 mples for tl	ne item to be submitted for the
evalua	ation as tender samp	oles.		ne item to be submitted for the
evalua	ation as tender samp	oles.		
evalua Amoui Bid	ation as tender samp	oles.	or USD	
Amour Bid Bid Bo	ation as tender samp	oles.	or USD (date)	to be submitted along with the
Amount Bid Bid Bid Va	ation as tender samp nt of Bid Bond : LKR ond valid till	oles.	or USD (date)	to be submitted along with the
Amount Bid Bid Bid value Bid Do	ation as tender samp nt of Bid Bond: LKR and valid till	oles.	or USD (date) valid till	to be submitted along with the
Amount Bid Bid Bid Value Bid Did Value (should	ation as tender samp nt of Bid Bond : LKR ond valid till lidity period : Bid sho	oles.	or USD (date) valid till	to be submitted along with the

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

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/269/22	15.07.2021	7,000 Bottles of Balanced	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Salt, Solution 500ml glass		+ Taxes
		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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/269/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00009

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00902002	Balanced Salt, Solution 500ml glass bottle	7,000	7,000 Bottles -
	Balanced salt solution for ophthalmic use Each 500ml glass bottle to contain sterile solution of 0.64% of Sodium Chloride 0.39% of Sodium Acetate 0.17% of Sodium Citrate, 0.048% of Calcium Chloride 0.03% of Magnesium Chloride and 0.075% of Potassium Chloride in a suitable base to use with "Constellation" vitrectomy	Bottles	August 2022
	machine.Note:01. Each bottle to be labelled accordingly.02. The shelf life of the product should be minimum of 24 monthsPacking: 10 Bottles in a pack		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 187,096.00 or USD 938.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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

set), shall be 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
- 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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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 LA	ANKAN TIME)	:				
ORDER	LIST NO. :					
SR No.	Item		Quantity	Delivery Schedule		
	Description/Specific	cations			—	
1	Nos of Renresentat	ive sar	nnles for ti	 ne item to be submitted		
	tion as tender samp		iipies ioi ti	ic item to be submitted	ioi the	
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	with the	
Bid	Amount of Bid Bond : LKR or USD to be submitted along with the Bid					
Bid Bo	nd valid till	(date)			
Bid val	lidity period: Bid sho	ould be v	valid till	(date)		
Bid Do	cument Fee :					
	be paid in cash to SPC			ncumants)		
•	•	TOI Eaci	ii set oi bid bi	ocuments).		
MSD CO	NDITIONS OF SUPPLY					
1.						
	005011451150014050	15 (0) 15	21.150\ ANINE\/			
<u>e No. 24 :</u>	<u>Specimen form Of B</u>	ID (SUPI	<u> PLIES) ANNEX</u>	 IIA Content of the cage to 	<u>be</u>	

Pag amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

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/268/22	15.07.2021 at 9.00 a.m.	380,000 Tablets of Propylthiouracil Tablet 50mg	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/268/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00039

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00701301	Propylthiouracil tablets 50mg	380,000	190,000 Tablets -
		Tablets	April 2022
	Propylthiouracil tablets BP 50mg		
	Each tablet to contain 50mg of Propylthiouracil BP		190,000 Tablets
	Tablet should also conform to dissolution test for		- September 2022
	Propylthiouracil tablets as per USP		
	OR		
	Propylthiouracil Tablets USP 50mg		
	Each tablet to contain 50mg of Propylthiouracil		
	USP.		
	Note:		
	01. The shelf life of the product should be		
	Minimum of 24 months.		
	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 66,120.00 or USD 332.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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 LA	ANKAN TIME)	:				
ORDER	LIST NO. :					
SR No.	Item		Quantity	Delivery Schedule		
	Description/Specific	cations			—	
1	Nos of Renresentat	ive sar	nnles for ti	 ne item to be submitted		
	tion as tender samp		iipies ioi ti	ic item to be submitted	ioi the	
Amour	nt of Bid Bond : LKR		. or USD	to be submitted along	with the	
Bid	Amount of Bid Bond : LKR or USD to be submitted along with the Bid					
Bid Bo	nd valid till	(date)			
Bid val	lidity period: Bid sho	ould be v	valid till	(date)		
Bid Do	cument Fee :					
	be paid in cash to SPC			ncumants)		
•	•	TOI Eaci	ii set oi bid bi	ocuments).		
MSD CO	NDITIONS OF SUPPLY					
1.						
	005011451150014050	15 (0) 15	21.150\ ANINE\/			
<u>e No. 24 :</u>	<u>Specimen form Of B</u>	ID (SUPI	<u> PLIES) ANNEX</u>	 IIA Content of the cage to 	<u>be</u>	

Pag amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

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/267/22	15.07.2021	4,000,000 Tablets of	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Carbimazole 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/267/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00039

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00701201	Carbimazole tablets BP 5mg	4,000,000 Tablets	4,000,000 Tablets - September 2022
	Carbimazole tablets BP 5mg Each tablet to contain 5mg of Carbimazole BP.		
	Note: 01. The shelf life of the product should be Minimum of 24 months.		
	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 88,000.00 or USD 442.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 $^{\circ}$ C +/- 2 $^{\circ}$ 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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", $16^{\rm th}$ Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

				ANNEY
	./BID REFERENCE	:		ANNEX
(TENDE	ER NO.)			
DATE (OF ISSUE	:		
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(SRI LA	ANKAN TIME)	:		
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SR No.	Item	_	Quantity	Delivery Schedule
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	Description/Specific	ations		
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/266/22	15.07.2021	78,000 Tablets of	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Dexamethasone Tablet 4mg		+ 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/266/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00039

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00701603	Dexamethazone Tablets 4mg	78,000	78,000 Tablets –
		Tablets	October 2022
	Dexamethazone Tablets BP 4mg		
	Each tablet to contain 4mg of Dexamethazone BP		
	Tablet should also conformed to dissolution test		
	for Dexamethazone Tablets as per USP		
	OR		
	Dexamethazone Tablets USP 4mg		
	Each tablet to contain 4mg of Dexamethazone		
	USP		
	Note:		
	01.Tablets should be scored		
	02. The shelf life of the product should be		
	minimum of 24 months		
	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 82,041.00 or USD 412.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

BID NO)./BID REFERENCE			ANNEX
(TEND	ER NO.)			
DATE	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.			Quantity	Delivery Schedule
			, ,	Delivery Seriedate
	Description/Specific Nos of Representat tion as tender samp	ive sar		ne item to be submitted for t
evalua Amour Bid	Nos of Representat tion as tender samp	ive sar les.	nples for th	_
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evalua Amour Bid Bid Bo Bid val Bid Do	Nos of Representation as tender samp It of Bid Bond : LKR Ind valid till	ive san les. (nples for the control of the control	ne item to be submitted for t
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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.
- 8.4 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/265/22	15.07.2021 at 9.00 a.m.	850,000 Tablets of Hydrocortisone Tablet 10mg	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/265/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00039

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00701502	Hydrocortisone Tablets 10mg	850,000 Tablets	850,000 Tablets - August 2022
	Hydrocortisone Tablets USP 10mg Each tablet to contain 10mg of Hydrocortisone USP.		
	Note: 01. The shelf life of the product should be Minimum of 24 months.		
	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 135,830.00 or USD 681.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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 REFERENCE ER NO.)	:					
	DATE (OF ISSUE	:					
	CLOSII	NG DATE & TIME	:					
	(SRI LA	ANKAN TIME)	:					
_	ORDER	LIST NO. :					_	
	SR No.	Item Description/Specifi	cations	Quantity	Delivery	Schedule		
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L		Nos of Representa tion as tender samp		nples for th	ne item to be	submitted f	or	the
	Amoun	nt of Bid Bond : LKF	R	. or USD	to be sub	mitted along v	vith	the
	Bid							
	Bid Bo	nd valid till	(date)				
	Bid val	idity period: Bid sh	ould be v	valid till	(date)		
	Bid Do	cument Fee :						
	(should	be paid in cash to SPG	C 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 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th 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/264/22	15.07.2021	280,000 Tablets of	02.06.2021	Rs. 12,500/=
	at 9.00 a.m.	Fludrocortisone Tablet		+ Taxes
		0.1mg		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/264/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00039

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00701401	Fludrocortisone tablets 0.1mg	280,000	140,000 Tablets
	Fludrocortisone tablets BP 100mcg	Tablets	– January 2022
	Each tablet to contain 100mcg of Fludrocortisone Acetate BP		140,000 Tablets – May 2022
	Tablet should also conform to dissolution test for Fludrocortisone Acetate tablets as per USP OR		- May 2022
	Fludrocortisone Acetate Tablets USP 100mcg. Each tablet to contain 100mcg of Fludrocortisone Acetate USP.		
	Note:		
	01. The shelf life of the product should be minimum of 24 months.		
	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 596,344.00 or USD 2,990.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

)./BID REFERENCE	:		ANNEX
(TEND	ER NO.)			
DATE (OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item		Quantity	Delivery Schedule
	Description/Specific Nos of Representati tion as tender samp	ive sar	nples for th	e item to be submitted for t
evalua Amour Bid	Nos of Representation as tender samp	ive sar les.	. or USD	e item to be submitted for t
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evalua Amour Bid Bid Bo Bid val Bid Do	Nos of Representation as tender samplet of Bid Bond : LKR and valid till	ive sar les. (ould be v	or USD date) valid till	to be submitted along with to the submitted along with the submi
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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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/263/22	15.07.2021	34,000 Ampoules of	02.06.2021	Rs. 35,000/=
	at 9.00 a.m.	Phenytoin Sodium Injection 250mg in 5ml		+ 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/263/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00303704	Phenytoin sodium Injection 250mg in 5ml	34,000 Ampoules	17,000 Ampoules - April 2022
	Phenytoin Injection BP/USP, 250mg Each 5ml ampoule to contain 250mg of Phenytoin Sodium BP/USP in a mixture of 40%v/v of Propylene Glycol and 10% of Ehanol in water for injection BP/USP, for slow intravenous injection or intravenous infusion	·	17,000 Ampoules – August 2022
	Note: 1. This injection should be stable for a minimum 02 years when stored under at a temperature range of 28'C-32'C. 2. Each ampoule should be labeled accordingly.		
	Packing: 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 2,138,961.00 or USD 10,722.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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 –
)./BID REFERENCE : ER NO.)		
DATE (OF ISSUE :		
	NG DATE & TIME : ANKAN TIME) :		
ORDER	LIST NO. :		
SR No.	Item Description/Specification	Quantity ns	Delivery Schedule
	los of Panrasantativa	samples for th	a itam to be submitted for th
evalua	tion as tender samples.	-	e item to be submitted for th to be submitted along with th
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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 NO./BID REFERENCE

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

Heading of 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND GROUP A CHARGE TEMPERATURE

AND STORAGE TEMPERATURE
Heading of 11th 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,

- 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/262/22	15.07.2021 at 9.00 a.m.	8,000,000 Tablets of Olanzapine Tablet 5mg	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/262/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00301901	Olanzapine tablet 5mg	8,000,000 Tablets	4,000,000 Tablets –
	Olanzapine tablet 5mg		February 2022
	Each coated tablet to contain 5mg of Olanzapine		4,000,000
	Note:		Tablets – June
	01. The shelf life of the product should be minimum of 24 months.		2022
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 132,800.00 or USD 666.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

BID NO)./BID REFERENCE			ANNEX
(TEND	ER NO.)			
DATE	OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.			Quantity	Delivery Schedule
			, ,	Delivery Seriedate
	Description/Specific Nos of Representat tion as tender samp	ive sar		ne item to be submitted for t
evalua Amour Bid	Nos of Representat tion as tender samp	ive sar les.	nples for th	_
evalua Amour Bid Bid Bo	Nos of Representat tion as tender samp at of Bid Bond : LKR	ive sar les.	nples for the control of the control	ne item to be submitted for t
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evalua Amour Bid Bid Bo Bid val Bid Do	Nos of Representation as tender samp It of Bid Bond : LKR Ind valid till	ive san les. (nples for the control of the control	ne item to be submitted for t
evalua Amour Bid Bid Bo Bid val Bid Do (should	Nos of Representat tion as tender samp at of Bid Bond : LKR and valid tillidity period : Bid should cument Fee :	ive san les. (nples for the control of the control	ne item to be submitted for t

Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX - IIA Content of the cage to be amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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.
- 8.4 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/261/22	15.07.2021 at 9.00 a.m.	4,250,000 Tablets Clozapine Tablet 100mg	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/261/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00301801	Clozapine tablet 100mg	4,250,000 Tablets	4,250,000 Tablets
	Clozapine tablet 100mg		– May 2022
	Each tablet to contain 100mg of Clozapine BP/USP		
	Note:		
	01. The shelf life of the product should be minimum of 24 months.		
	Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 282,200.00 or USD 1,415.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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, decument, etc.) goods shall be assented on the following working day, such date shall
 - 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

DID NO	VIDE DEFENSE			ANNEX -	1
_	D./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	DIIS			
	Nos of Representative tion as tender samples.		nples for th	ne item to be submitted for the	9
Amoun	t of Bid Bond : LKR		. or USD	to be submitted along with the	е
Bid					
Bid Bo	nd valid till	(date)		
Bid val	idity period:Bid should	l 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				

<u>Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX – IIA Content of the cage to be</u> 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 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th 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/260/22	15.07.2021	62,000 Ampoules of	02.06.2021	Rs. 12,500/=
	at 9.00 a.m.	Flupenthixol Decanoate		+ Taxes
		Injection 40mg/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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/260/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00301101	Flupenthixol decanoate Injection 40mg/2ml.	62,000 Ampoules	32,000 Ampoules –
	Flupenthixol Injection BP 40mg/2ml.	Ampoules	January 2022
	Each 2ml ampoule to contain 40mg Flupenthixol decanoate in this vegetable oil for intramuscular Injection.		30,000 Ampoules – May 2022
	Note: 1. This injection should be stable for a minimum of 02 years 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 686,898.00 or USD 3,444.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", $16^{\rm th}$ Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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	:				
0_0	NG DATE & TIME	:				
(SRI L	ANKAN TIME)	:				
ORDER	LIST NO. :	. ,				
SR No.	Item Description/Specific	ations	Quantity	Deliv	ery Schedule	
	Description/Specific	acions				
	Nos of Representat ation as tender samp		nples for th	e item to	be submitted	for the
Amou	nt of Bid Bond : LKR		. or USD	to be	submitted along	g with the
Bid						
Bid Bo	ond valid till	(date)			
Bid va	lidity period : Bid sho	ould be v	valid till	(0	date)	
Bid Do	cument Fee :		•••			
(should	d be paid in cash to SPC	for eacl	h set of Bid Do	cuments).		

<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 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th 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/259/22	15.07.2021	153,000 Tablets of	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Disulfiram 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/259/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00305402	Disulfiram Tablet 250mg	153,000 Tablets	153,000 Tablets
	Disulfiram 250mg Tablet		– May 2022
	Each tablet to contain Disufiram BP/USP 250mg		
	Note; 01. Tablets should be protected from light.		
	02. The shelf life of the product should be minimum of 24 months.		
	Packing : 50 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 34,364.00 or USD 173.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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 REFERENCE ER NO.)	:					
	DATE (OF ISSUE	:					
	CLOSII	NG DATE & TIME	:					
	(SRI LA	ANKAN TIME)	:					
_	ORDER	LIST NO. :					_	
	SR No.	Item Description/Specifi	cations	Quantity	Delivery	Schedule		
I		Description/Specific	Cations				\dashv	
L		Nos of Representa tion as tender samp		nples for th	ne item to be	submitted f	or	the
	Amoun	nt of Bid Bond : LKF	R	. or USD	to be sub	mitted along v	vith	the
	Bid							
	Bid Bo	nd valid till	(date)				
	Bid val	idity period: Bid sh	ould be v	valid till	(date)		
	Bid Do	cument Fee :						
	(should	be paid in cash to SPG	C 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 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th 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/258/22	15.07.2021 at 9.00 a.m.	4,000,000 Tablets of Co- careldopa Tablet 25/250mg	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/258/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00305002	Co-careldopa tablets 25/250mg	4,000,000	4,000,000
		Tablets	Tablets – April
	Co-careldopa tablets BP 25/250mg		2022
	Each tablet to contain 250mg of Levodopa BP, and		
	carbidopa BP equivalent to 25mg of Anhydrous		
	Carbidopa		
	OR		
	Carbidopa and Levodopa tablets USP 25/250mg		
	Each tablet to contain 250mg of Levodopa USP and		
	Carbidopa USP equivalent to 25mg of Anhydrous		
	Carbidopa.		
	Nicko		
	Note:		
	01. The shelf life of the product should be minimum		
	of 24 months.		
	Packing : 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 940,000.00 or USD 4,712.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

RID NC)./BID REFERENCE			ANNEX
	ER NO.)	•		
DATE (OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item			
		ations	Quantity	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 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/257/22	15.07.2021	1,500,000 Tablets of	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Carbamazepine Tablet		+ Taxes
		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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/257/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00303801	Carbamazepine Tablets 100mg	1,500,000	1,500,000
		Tablets	Tablets
	Carbamazepine Tablets BP 100mg.		– May 2022
	Each tablet to contain 100mg of Carbamazepine BP.		
	Tablet should also conformed to dissolution test for		
	Carbamazepine Tablet as per USP		
	OR		
	Carbamazepine Tablets USP 100mg.		
	Each tablet to contain 100mg of Carbamazepine		
	USP.		
	Note:		
	01. The tender should provide a detailed bio- equivalent data		
	02. The shelf life of the product should be minimum		
	of 24 months.		
	Packing : 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 90,900.00 or USD 456.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

RID NC)./BID REFERENCE			ANNEX
	ER NO.)	•		
DATE (OF ISSUE	:		
	NG DATE & TIME	:		
(SRI LA	ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item			
		ations	Quantity	Delivery Schedule
	Description/Specific	ive san		Delivery Schedule ne item to be submitted for t
evalua	Description/Specific Nos of Representat tion as tender samp	ive san les.	mples for ti	·
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evalua Amoun Bid Bid Bo Bid val Bid Do (should	Description/Specific Nos of Representat Ition as tender samp It of Bid Bond : LKR Ind valid till	ive san les. (nples for the control of the control	ne item to be submitted for t to be submitted along with t (date)

Page No. 24 SPECIMEN FORM OF BID (SUPPLIES) ANNEX - IIA Content of the cage to be amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th Column

NMRA RECISTRATION

NMRA R

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,

- 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/256/22	15.07.2021	700 Tubes of Diazepam	02.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Rectal Solution 10mg in		+ Taxes
		2.5ml Tube		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/256/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00300105	Diazepam rectal solution 10mg in 2.5ml Tube	700 Tubes	700 Tubes – May 2022
	Diazepam rectal solution 10mg in 2.5ml Tube Each 2.5ml tube to contain 10mg of Diazepam BP/USP as solution for rectal use.		
	Note: 01. The tube should be suitably formulated for rectal use. 02. The shelf life of the product should be minimum of 24 months.		
	Packing: 10 Tubes in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 20,967.00 or USD 106.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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	:			
	CLOSING DATE & TIME				
(SRI LA	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item		Quantity	Delivery Schedule	
	Description/Specific	cations			—
1	Nos of Renresentat	ive sar	nnles for ti	 ne item to be submitted	
	tion as tender samp		iipies ioi ti	ic item to be submitted	ioi 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 sho	ould be v	valid till	(date)	
Bid Do	cument Fee :				
	be paid in cash to SPC			ncumants)	
•	•	TOI Eaci	ii set oi bid bi	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					
	005011451150014050	15 (0) 15	21.150\ ANINE\/		
<u>e No. 24 :</u>	<u>Specimen form Of B</u>	ID (SUPI	<u> PLIES) ANNEX</u>	 IIA Content of the cage to 	<u>be</u>

Pag amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

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/255/22	15.07.2021 at 9.00 a.m.	13,000,000 Tablets of Risperidone Tablet 2mg	02.06.2021	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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/255/22

DATE OF ISSUE : 2ND JUNE 2021

CLOSING DATE & TIME : 15TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00003

SR No.	Item Description/ Specification	<u>Quantity</u>	<u>Delivery</u>
00302001	Risperidone tablet 2mg Risperidone tablet 2mg Each coated tablet to contain 2mg of Risperidone BP/USP	13,000,000 Tablets	13,000,000 Tablets – July 2022
	Note: 01.The shelf life of the product should be minimum of 24 months. Packing: 100 Tablets in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 215,800.00 or USD 1,082.00.

Bid Bond should be submitted with valid up to 10.02.2022 together with the bid Bid should be valid till 11.01.2022.

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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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	:			
	CLOSING DATE & TIME				
(SRI LA	ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item		Quantity	Delivery Schedule	
	Description/Specific	cations			—
1	Nos of Renresentat	ive sar	nnles for ti	 ne item to be submitted	
	tion as tender samp		iipies ioi ti	ic item to be submitted	ioi 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 sho	ould be v	valid till	(date)	
Bid Do	cument Fee :				
	be paid in cash to SPC			ncumants)	
•	•	TOI Eaci	ii set oi bid bi	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					
	005011451150014050	15 (0) 15	21.150\ ANINE\/		
<u>e No. 24 :</u>	<u>Specimen form Of B</u>	ID (SUPI	<u> PLIES) ANNEX</u>	 IIA Content of the cage to 	<u>be</u>

Pag amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE

Heading of 11th Column NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

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/254/22	13.07.2021	10,000 Vials of Tuberculin	01.06.2021	Rs. 12,500/=
	at 9.00 a.m.	for Mantoux test 5TU/0.1ml,		+ Taxes
		1ml 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/254/22

DATE OF ISSUE : 1ST JUNE 2021

CLOSING DATE & TIME : 13TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/C/P/00005

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00603603	Tuberculin for Mantoux test 5TU/0.1ml, 1ml vial Tuberculin for Mantoux test 1ml vial Tuberculin PPD/RT-23(ready for use dilution)5TU per	10,000 Vials	5,000 Vials – January 2022 5,000 Vials –
	0.1ml,in 1 ml vial (10 doses vial) for intradermal use. Packing: 10 vials in a box		May 2022

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 630,932.00 or USD 3,163.00.

Bid Bond should be submitted with valid up to 08.02.2022 together with the bid Bid should be valid till 09.01.2022.

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 1/6th (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 15th 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 decument atc.) goods shall be assented on the following working days such data shall be
 - 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses 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) 2nd 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.

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

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 REFERENCE ER NO.)	:		
DATE (OF ISSUE	:		
	NG DATE & TIME ANKAN TIME)	:		
ORDER	LIST NO. :			
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule
	<u>=</u>		ples for th	e item to be submitted for the
evalua Amoun Bid	tion as tender sampl t of Bid Bond : LKR	es.	or USD	e item to be submitted for the to be submitted along with the
evalua Amoun Bid Bid Bo	tion as tender samplet of Bid Bond: LKR	es. (d	or USD	to be submitted along with the
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amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE Heading of 11th 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



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/253/22	13.07.2021 at 9.00 a.m.	390,000 IU of Somatropin for Injection 2IU-30IU	01.06.2021	Rs. 35,000/= + 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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/253/22

DATE OF ISSUE : 1ST JUNE 2021

CLOSING DATE & TIME : 13TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00011

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
00703202	Somatropin for injection 2 IU - 30 IU Somatropin for injection BP/USP, 2 IU - 30 IU	390,000 IU	130,000 IU – January 2022
	Each container to contain 2 IU - 30 IU of Somatropin for injection BP/USP as freeze-dried sterile powder, produced by recombinat DNA technology for reconstitution in a suitable diluent for		130,000 IU – May 2022
	subcutaneous or intramuscular injection.		130,000 IU – October 2022
	Note: 1. This Injection should be stable for a minimum of 24 months when stored below 25' C and shelf life of the reconstituted solution should be minimum of 28 days when stored at 2'C -8'C.		
	2. Each container should be labelled accordingly.		
	Packing: 2 IU in a vial		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 3,694,080.00 or USD 18,517.00.

Bid Bond should be submitted with valid up to 08.02.2022 together with the bid Bid should be valid till 09.01.2022.

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 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 1/6th (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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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) 2nd 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.

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

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.

)./BID REFERENCE			ANI	<u>NEX – 1</u>
_	ER NO.)	•			
DATE	OF ISSUE	:			
	NG DATE & TIME ANKAN TIME)	:			
ORDER	LIST NO. :				
SR No.	Item Description/Specification	ations	Quantity	Delivery Schedule	
evalua	tion as tender sampl	es.	-	ne item to be submitted fo	
Amoun Bid	nt of Bid Bond : LKR		or USD	to be submitted along wi	th the
	nd valid till		(date)		
Bid val	idity period : Bid sho	uld be	valid till	(date)	
Bid Do	cument Fee :				
(should	be paid in cash to SPC	for eac	ch set of Bid Do	ocuments).	
MSD CO	NDITIONS OF SUPPLY				
1.					
^	SPECIMEN FORM OF BI	D (SUP	PLIFS) ANNEX	- IIA Content of the cage to be	

amended 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 2nd Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD

AND STORAGE TEMPERATURE

Heading of 11th 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



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/252/22	13.07.2021	350,000 Ampoules of	01.06.2021	Rs. 3,000/=
	at 9.00 a.m.	Midazolam Injection		+ Taxes
		5mg/1ml ampoule		

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, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. 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 Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, 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 "MEHEWARA PIYASA", 26TH FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

FAX : 00 94-11- 2582496 TELEPHONE : 00 94-11- 2582509 E-MAIL : <u>pharma.manager@spc.lk</u>

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
FOR CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
"MEHEWARA PIYASA", 26TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.

TENDER NO. : DHS/P/WW/252/22

DATE OF ISSUE : 1ST JUNE 2021

CLOSING DATE & TIME : 13TH JULY 2021 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO.: 2022/SPC/N/R/P/00049

SR No.	Item Description/ Specification	Quantity	<u>Delivery</u>
01500902	Midazolam inj. 5mg/1ml amp Midazolam Injection BP, 5mg in 1ml Each 1ml ampoule to contain 5mg of Midazolam BP in water for injection BP/USP containing Hydrochloric Acid for intravenous or intramuscular injection. OR Midazolam Maleate Injection 5mg in 1ml. Each 1ml ampoule to contain Midazolam Maleate equivalent to 5mg of Midazolam BP in water for injection BP/USP containing Hydrochloric Acid for intravenous or intramuscular injection.	350,000 Ampoules	350,000 Ampoules – October 2022
	Note; 1.This injection should be stable for minimum of 24 months when stored at a temperature range of 28'C-32'C 2.This injection should comply with the "No 15.4(d) labelling for Anaesthetic products" of tender documents.		
	3.Injection should be protected from light. 4.Each ampoule should belabelled accordingly. Packing: 10 Ampoules in a box		

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 147,700.00 or USD 741.00.

Bid Bond should be submitted with valid up to 08.02.2022 together with the bid Bid should be valid till 09.01.2022.

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 1/6th (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 guantity/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 15th 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)

Address to be read as "State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", $16^{\rm th}$ Floor, No. 41, Kirula Road, Colombo 5" mentioned in all specified clauses

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.

FREE REPLACEMENT/ REIMBURSEMENT

Page No. 8 Condition No. 12.2 under the Para b) 2nd 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;

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						ANNEX – 1		
	BID NO./BID REFERENCE (TENDER NO.)		:					
	DATE (OF ISSUE	:					
	CLOSING DATE & TIME (SRI LANKAN TIME)		:					
	ORDER	LIST NO. :						
	SR No.	Item Description/Specific	cations	Quantity	Delivery Schedule			
,		Nos of Representate tion as tender samp		mples for tl	ne item to be submitted	for the		
	Amoun	nt of Bid Bond : LKR	·	. or USD	to be submitted along	with the		
	Bid							
	Bid Bo	nd 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 CO	NDITIONS OF SUPPLY						
	1.							

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

	BID	FOR	THE	SUPP	LY	OF
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BID NO./BID REFERENCE

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

Heading of 2nd Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE

Heading of 11th 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