

**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<br>Date<br>& Time | Item Description                             | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|--|--|-------------------------------|
| DHS/P/WW/224/22 | 13.07.2021                | 70,000 Ampoules of                           | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Fluphenazine Decanoate<br>Injection 25mg/1ml |  | + 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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"**, 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/224/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification   | <u>Quantity</u>    | <u>Delivery</u>      |
|---------------|---|--------------------|----------------------|
| 00301001      | Fluphenazine Deconoate Injection 25mg/ml  | 70,000<br>Ampoules | 70,000<br>Ampoules – |
|               | <ul> <li>Fluphenazine Deconate Injection BP/USP, 25mg/1ml</li> <li>Each 1ml amber coloured ampoule to contain 25mg of</li> <li>Fluphenazine Decanoate in sesame oil for Deep</li> <li>Intramuscular injection</li> <li>Note:</li> <li>1.The Injection should be stable for a minimum of 24 months when stored at a temperature range of 28'C-32'C</li> <li>2.Each ampoule should be labeled accordingly.</li> </ul> | Ampoules           | October 2022         |
|               | Packing : 10 Ampoules in a box  |                    |                      |

### **Representative Tender samples to be submitted for the evaluation.**

The amount of Bid Bond: LKR 66,640.00.00 or USD 334.00.

### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### Standards & Quality

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

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

### **Storage Conditions & Temperature**

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

### Special Conditions for Bidding :

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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

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

# 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.

- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  | )./BID REFERENCE                              |                  |                   | <u>ANNEX – 1</u>     |  |  |
|--|---|------------------|-------------------|----------------------|--|--|
|  | ER NO.)                                       | •                |                   |                      |  |  |
| DATE (   | OF ISSUE                                      | :                |                   |                      |  |  |
|  | NG DATE & TIME<br>ANKAN TIME)                 | :                |                   |                      |  |  |
| ORDER  | LIST NO. :                                    |                  |                   |                      |  |  |
| SR No.   | Item<br>Description/Specificat                | Quant tions      | ity Delivery S    | Schedule             |  |  |
|  |   |                  |                   |                      |  |  |
|  | Nos of Representativ<br>tion as tender sample | -                | or the item to be | submitted for the    |  |  |
| Amoun  | it of Bid Bond:LKR                            | or USD           | to be subm        | itted along with the |  |  |
| Bid  |   |                  |                   |                      |  |  |
| Bid Bo   | nd valid till                                 | (date)           |                   |                      |  |  |
| Bid val  | idity period: Bid shou                        | ld be valid till | (date)            |                      |  |  |
| Bid Do   | cument Fee :                                  |                  |                   |                      |  |  |
| (should be paid in cash to SPC 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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

#### FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time  | Item Description                             | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|----------------------------|--|--|-------------------------------|
| DHS/P/WW/250/22 | 13.07.2021<br>at 9.00 a.m. | 3,500 Bottles of Sevoflurane<br>250ml bottle | 01.06.2021                                       | Rs. 3,000/=<br>+ 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

## TENDER NO.: DHS/P/WW/250/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO.: 2022/SPC/N/R/P/00023

| <u>SR No.</u> | Item Description/ Specification  | <u>Quantity</u>  | <u>Delivery</u>                    |
|---------------|--|------------------|------------------------------------|
| 01500701      | Sevoflurane for anaesthetic inhalation 200ml -<br>300ml bottle   | 3,500<br>Bottles | 3,500 Bottles<br>- October<br>2022 |
|               | Sevoflurane for anaesthetic inhalation 200ml - 300ml bottle  |                  |                                    |
|               | Each 200ml - 300ml unbreakable bottle to contain<br>Sevoflurane for anaesthetic inhalation   |                  |                                    |
|               | Note:<br>1. The bottle should be light resistant.  |                  |                                    |
|               | <ol> <li>If the bottle is not an unbreakable one, action<br/>To be taken in case of breakage of the bottle,<br/>should be clearly mentioned on the label affixed.</li> </ol> |                  |                                    |
|               | <ol> <li>If the bottle has no inbuilt adapter, the<br/>successful bidder should provide one adapter<br/>per each ten bottle free of charge.</li> </ol>                       |                  |                                    |
|               | 4. The shelf life of the product should be minimum of 24 months  |                  |                                    |
|               | Packing : 10 Bottles in a box  |                  |                                    |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 51,764.00 or USD 260.00.

### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### Standards & Quality

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

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

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

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

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

### **Storage Conditions & Temperature**

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

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         |                               |                     | <u>A</u>                   | <u>NNEX – 1</u> |
|---------|-------------------------------|---------------------|----------------------------|-----------------|
|         | D./BID REFERENCE<br>ER NO.)   | :                   |                            |                 |
| DATE (  | OF ISSUE                      | :                   |                            |                 |
|         | NG DATE & TIME<br>ANKAN TIME) | :                   |                            |                 |
| ORDER   | LIST NO. :                    |                     |                            | -               |
| SR No.  | Item<br>Description/Specifica | Quantity ations     | Delivery Schedule          |                 |
|         |                               |                     |                            |                 |
| evalua  | tion as tender sample         | es.                 | the item to be submitted f |                 |
| Bid     |                               |                     |                            |                 |
| Bid Bo  | nd valid till                 | (date)              |                            |                 |
| Bid val | idity period: Bid shou        | 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            |                     |                            |                 |
|         |                               |                     |                            |                 |

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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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<br>Date<br>& Time | Item Description     | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|----------------------|--|-------------------------------|
| DHS/P/WW/249/22 | 13.07.2021                | 700,000 Ampoules of  | 01.06.2021                                       | Rs. 20,000/=                  |
|                 | at 9.00 a.m.              | Atracurium Besylate  |  | + Taxes                       |
|                 |                           | Injection 25mg/2.5ml |  |                               |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/249/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO.: 2022/SPC/N/R/P/00023

| <u>SR No.</u> | Item Description/ Specification   | <u>Quantity</u> | Delivery                      |
|---------------|---|-----------------|-------------------------------|
| 01501101      | Atracurium besylate Injection 25mg /2.5ml   | 700,000         | 250,000                       |
|               |   | Ampoules        | Ampoules                      |
|               | Atracurium besylate Injection 25mg /2.5ml<br>Each 2.5ml ampoule o contain 25mg of                 |                 | – June 2022                   |
|               | Atracurium Besylate for intravenous injection and intravenous infusion.                           |                 | 250,000                       |
|               |   |                 | Ampoules                      |
|               | Note:   |                 | <ul> <li>September</li> </ul> |
|               | 1. This Injection should be stable for a minimum of 24 months when stored with in the temperature |                 | 2022                          |
|               | range of 2'C - 8'C.Do not freeze.   |                 | 200,000                       |
|               | 2. This injection should comply with the  |                 | Ampoules                      |
|               | "No.15.4(d), labelling for anaesthetic products" of this tender documents.                        |                 | – November 2022               |
|               | 3.Each ampoule should be labelled accordingly   |                 |                               |
|               | Packing : 10 Ampules in a box   |                 |                               |

### **Representative Tender samples to be submitted for the evaluation.**

The amount of Bid Bond: LKR 1,648,360.00 or USD 8,263.00.

### 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. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

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

### **CONDITIONS OF SUPPLY**

### (a) Part A

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

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

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

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

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

### Shelf life & Warrantees.

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

### Standards & Quality

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

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

### **Storage Conditions & Temperature**

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

### Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         |   |                   | ANNEX                       | <u>(                                    </u> |
|---------|---|-------------------|-----------------------------|--|
|         | D./BID REFERENCE<br>ER NO.)                             | :                 |                             |  |
| DATE (  | OF ISSUE  | :                 |                             |  |
|         | NG DATE & TIME<br>ANKAN TIME)                           |                   |                             |  |
| ORDER   | LIST NO. :  |                   |                             |  |
| SR No.  | Item<br>Description/Specification                       | Quantity          | Delivery Schedule           |  |
|         |   |                   |                             |  |
|         | Nos of <b>Representative</b><br>tion as tender samples. | -                 | he item to be submitted for | the  |
| Amoun   | it of Bid Bond : LKR                                    | or USD            | to be submitted along with  | the  |
| Bid     |   |                   |                             |  |
| Bid Bo  | nd valid till   | (date)            |                             |  |
| Bid val | idity period: Bid should                                | be valid till     | (date)                      |  |
| Bid Do  | cument Fee :  |                   |                             |  |
| (should | be paid in cash to SPC for                              | each set of Bid D | 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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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<br>Date<br>& Time | Item Description                              | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|---|--|-------------------------------|
| DHS/P/WW/248/22 | 13.07.2021                | 90,000 Ampoules of                            | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Suxamethonium Chloride<br>Injection 100mg/2ml |  | + Taxes                       |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/248/22DATE OF ISSUE: 1<sup>ST</sup> JUNE 2021CLOSING DATE & TIME: 13<sup>TH</sup> JULY 2021 AT 09.00 HOURS SRI LANKA TIME

### ORDER LIST NO. : 2022/SPC/N/R/P/00023

| <u>SR No.</u> | Item Description/ Specification   | <u>Quantity</u> | Delivery  |
|---------------|---|-----------------|---|
| 01501401      | Suxamethonium chloride Injection 100mg /2ml.  | 90,000          | 45,000  |
|               | Suxamethonium chloride Injection BP 100mg /2ml.<br>Each 2ml ampoule to contain 100mg of sterile<br>solution of Suxamethonium chloride BP for<br>intravenous use.<br>OR<br>Succinylcholine Chloride injection USP (25)<br>100mg/2ml.<br>Each 2ml ampoule to contain 100mg of sterile<br>solution of Succinylcholine Chloride USP for   | Ampoules        | Ampoules<br>– July 2022<br>45,000<br>Ampoules<br>– October 2022 |
|               | <ul> <li>intravenous use.</li> <li>Note: <ol> <li>This injection should be stable for a minimum of 24 months when stored with in the temperature range of 2'C-8'C. Do not freeze.</li> <li>This injection should comply with "No.15.4(d), labelling for anaesthetic products" of this tender documents.</li> <li>Each ampoule should be labelled accordingly.</li> </ol> </li> <li>Packing : 10 Ampules in a box</li> </ul> |                 |   |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 312,516.00 or USD 1,567.00.

### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### Standards & Quality

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

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

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

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

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

### **Storage Conditions & Temperature**

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

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         |  |                   |                | <u>A</u>         | <u> NNEX – 1</u> |
|---------|--|-------------------|----------------|------------------|------------------|
|         | D./BID REFERENCE<br>ER NO.)                            | :                 |                |                  |                  |
| DATE (  | OF ISSUE   | :                 |                |                  |                  |
|         | NG DATE & TIME<br>ANKAN TIME)                          | :                 |                |                  |                  |
| ORDER   | LIST NO. :   |                   |                |                  | _                |
| SR No.  | Item<br>Description/Specificati                        | Quant             | ity Deliv      | ery Schedule     |                  |
|         |  |                   |                |                  |                  |
|         | Nos of <b>Representative</b><br>tion as tender samples | -                 | or the item to | be submitted f   | for the          |
| Amoun   | t of Bid Bond : LKR                                    | or USD            | to be s        | ubmitted along v | vith the         |
| Bid     |  |                   |                |                  |                  |
| Bid Bo  | nd valid till  | (date)            |                |                  |                  |
| Bid val | idity period:Bid shoul                                 | d be valid till . | (d             | ate)             |                  |
| Bid Do  | cument Fee :   |                   |                |                  |                  |
| (should | be paid in cash to SPC fo                              | or each set of E  | id 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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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<br>Date<br>& Time | Item Description       | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|------------------------|--|-------------------------------|
| DHS/P/WW/247/22 | 13.07.2021                | 15,000,000 Tablets of  | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Olanzapine Tablet 10mg |  | + Taxes                       |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

## TENDER NO.: DHS/P/WW/247/22DATE OF ISSUE: 1<sup>ST</sup> JUNE 2021CLOSING DATE & TIME: 13<sup>TH</sup> JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification   | <u>Quantity</u>       | Delivery                              |
|---------------|---|-----------------------|---------------------------------------|
| 00301902      | Olanzapine tablet 10mg  | 15,000,000<br>Tablets | 8,000,000<br>Tablets                  |
|               | Olanzapine tablet 10mg  |                       | – March 2022                          |
|               | Each coated tablet to contain 10mg of Olanzapine<br>Note:<br>01.The shelf life of the product should be minimum |                       | 7,000,000<br>Tablets<br>– August 2022 |
|               | of 24 months. Packing: 100 Tablets in a box   |                       |                                       |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 246,000.00 or USD 1,234.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### Standards & Quality

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

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

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack

(Applicability of the inhermost pack mentioned in this clause shall be adapted as per the pac specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

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

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

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

### **Storage Conditions & Temperature**

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

### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the

payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.
   Sufficient quantity of Samples chould be forwarded for evaluation
  - 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |   |         |                              | ANNE                        |
|--|---|---------|------------------------------|-----------------------------|
|  | )./BID REFERENCE<br>ER NO.)   | :       |                              |                             |
| DATE   | OF ISSUE  | :       |                              |                             |
|  | NG DATE & TIME<br>ANKAN TIME)   | :       |                              |                             |
| ORDER  | LIST NO. :  |         |                              |                             |
| SR No.   | Item<br>Description/Specific  | cations | Quantity                     | Delivery Schedule           |
|  |   |         |                              |                             |
|  | Nos of <b>Representa</b> t  | ive sam | nles for th                  | he item to be submitted for |
| evalua   | tion as tender samp   | oles.   | -                            | ne item to be submitted for |
| evalua   | tion as tender samp   | oles.   | -                            |                             |
| evalua<br>Amour<br>Bid   | tion as tender samp   | oles.   | or USD                       |                             |
| evalua<br>Amour<br>Bid<br>Bid Bo                                 | ntion as tender samp<br>nt of Bid Bond : LKR                                    | oles.   | or USD                       | to be submitted along with  |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val                      | nt of Bid Bond : LKR  | oles.   | or USD<br>late)<br>alid till | to be submitted along with  |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | nt of Bid Bond : LKR<br>nd valid till   | oles.   | or USD<br>late)<br>alid till | to be submitted along with  |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho<br>cument Fee : | oles.   | or USD<br>late)<br>alid till | to be submitted along with  |

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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time | Item Description           | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|----------------------------|--|-------------------------------|
| DHS/P/WW/246/22 | 13.07.2021                | 1,320,000 Capsules of      | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Duloxetine (Hydrochloride) |  | + Taxes                       |
|                 |                           | 20mg Capsules              |  |                               |

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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/246/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ 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> | Delivery    |
|----------|---|-----------------|-------------|
| 00305801 | Duloxetine (hydrochloride) 20 mg Capsules                         | 1,320,000       | 700,000     |
|          |   | Capsules        | Capsules –  |
|          | Duloxetine (as hydrochloride) 20 mg Capsules                      |                 | March 2022  |
|          | Each capsule to contain 20mg of Duloxetine                        |                 |             |
|          | hydrochloride BP  |                 | 620,000     |
|          |   |                 | Capsules –  |
|          | Note:   |                 | August 2022 |
|          | 01. The shelf life of the product should be minimum of 24 months. |                 |             |
|          | Packing : 100 Capsules in a box                                   |                 |             |

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 389,136.00 or USD 1,951.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### Standards & Quality

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 15<sup>th</sup> December to 10th January shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.
- 26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below ;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.
  - (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.
   Sufficient guantity of Samples should be forwarded for evaluation
  - 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         |   |                   | ANI                         | <u>NEX – 1</u> |
|---------|---|-------------------|-----------------------------|----------------|
|         | D./BID REFERENCE  | :                 |                             |                |
| DATE (  | OF ISSUE  | :                 |                             |                |
|         | NG DATE & TIME<br>ANKAN TIME)                           |                   |                             |                |
| ORDER   | LIST NO. :  |                   |                             |                |
| SR No.  | Item<br>Description/Specification                       | Quantity          | Delivery Schedule           |                |
|         |   |                   |                             |                |
|         | Nos of <b>Representative</b><br>tion as tender samples. |                   | the item to be submitted fo | r the          |
| Amoun   | t of Bid Bond : LKR                                     | or USD            | to be submitted along wi    | th the         |
| Bid     |   |                   |                             |                |
| Bid Bo  | nd valid till   | (date)            |                             |                |
| Bid val | idity period: Bid should                                | 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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/245/22 | 13.07.2021                | 1,200,000 Tablets of    | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Donepezil Hydrochloride |  | + Taxes                       |
|                 |                           | Tablet 5mg              |  |                               |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/245/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <u>Quantity</u>      | Delivery                     |
|---------------|--|----------------------|------------------------------|
| 00306301      | Donepezil Hydrochloride tablets 5mg  | 1,200,000<br>Tablets | 1,200,000<br>Tablets – April |
|               | Donepezil tablets 5mg<br>Each tablet to contain 5mg of Donepezil<br>Hydrochloride. |                      | 2022                         |
|               | Note:<br>01.The shelf life of the product should be minimum<br>of 24 months        |                      |                              |
|               | Packing : 100 Tablets in a box   |                      |                              |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 205,200.00 or USD 1,029.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

### **Storage Conditions & Temperature**

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the

condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|   |   |                      | ANNEX                      |
|---|---|----------------------|----------------------------|
| -   | )./BID REFERENCE<br>ER NO.)                           | :                    |                            |
| DATE  | OF ISSUE  | :                    |                            |
|   | NG DATE & TIME<br>ANKAN TIME)                         | :                    |                            |
| ORDER   | LIST NO. :  |                      |                            |
| SR No.  | Item<br>Description/Specific                          | Quanti<br>ations     | ity Delivery Schedule      |
|   | tion as tender samp                                   |                      | to be submitted along with |
| Amour   |   |                      |                            |
| Amour<br>Bid                                  |   |                      |                            |
| Bid   | nd valid till   | (date)               |                            |
| Bid<br>Bid Bo                                 | nd valid till   |                      | (date)                     |
| Bid<br>Bid Bo<br>Bid val                      | nd valid till   | ould be valid till . | (date)                     |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do            | nd valid till<br>idity period: Bid sho                | ould be valid till . |                            |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nd valid till<br>idity period: Bid sho<br>cument Fee: | ould be valid till . |                            |

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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

### 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/244/22 | 13.07.2021                | 400,000 Tablets of      | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Alprazolam Tablet 0.5mg |  | + 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

# TENDER NO.: DHS/P/WW/244/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <u>Quantity</u>    | Delivery           |
|---------------|--|--------------------|--------------------|
| 00306802      | Alprazolam tablets 0.5 mg  | 400,000<br>Tablets | 400,000<br>Tablets |
|               | Alprazolam tablets USP 0.5 mg  |                    | – April 2022       |
|               | Each tablet to contain 0.5mg of Alprazolam USP   |                    |                    |
|               | Note:  |                    |                    |
|               | 01. The shelf life of the product should be minimum of 24 months when stored at a temperature range of 28'C-32'C |                    |                    |
|               | 02. The Product should be protected from light and dispensed in tight, light-resistant container.                |                    |                    |
|               | 03.Each pack should be labeled accordingly.  |                    |                    |
|               | Packing : 100 Tablets in a box   |                    |                    |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 29,040.00 or USD 146.00.

### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### Standards & Quality

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

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

### **Storage Conditions & Temperature**

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

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

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

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

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

# 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.

- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

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

|         |  |          |                 |                       | ANNEX – 1  |  |
|---------|--|----------|-----------------|-----------------------|------------|--|
|         | D./BID REFERENCE<br>ER NO.)  | :        |                 |                       |            |  |
| DATE (  | DATE OF ISSUE :  |          |                 |                       |            |  |
|         | NG DATE & TIME<br>ANKAN TIME)  | :        |                 |                       |            |  |
| ORDER   | LIST NO. :   |          |                 |                       |            |  |
| SR No.  | Item<br>Description/Specifica  | tions    | Quantity        | Delivery Schedule     |            |  |
| evalua  | Nos of Representative samples for the item to be submitted for the evaluation as tender samples. |          |                 |                       |            |  |
| Bid     | IL OI DIU DOIIU . LKK .  |          | . 01 030        | to be submitted along | j with the |  |
| 2.4     | nd valid till  | (        | date)           |                       |            |  |
|         | idity period : Bid shou  | •        |                 | (date)                |            |  |
| Bid Do  | cument Fee :   |          |                 |                       |            |  |
| (should | be paid in cash to SPC f   | for each | n 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; |
|------------------|-------------------|--------|-----------------------------------|
| 0                |                   |        |                                   |

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

 Heading of 11<sup>th</sup> Column
 AND STORAGE TEMPERATURE

#### 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<br>Date<br>& Time  | Item Description                                 | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|----------------------------|--|--|-------------------------------|
| DHS/P/WW/243/22 | 13.07.2021<br>at 9.00 a.m. | 1,100,000 Tablets of<br>Alprazolam Tablet 0.25mg | 01.06.2021                                       | Rs. 3,000/=<br>+ 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

# TENDER NO.: DHS/P/WW/243/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <u>Quantity</u>      | Delivery                 |
|---------------|--|----------------------|--------------------------|
| 00306801      | Alprazolam tablets 0.25 mg   | 1,100,000<br>Tablets | 550,000<br>Tablets –     |
|               | Alprazolam tablets USP 0.25 mg<br>Each tablet to contain 0.25mg of Alprazolam USP                                      |                      | January 2022             |
|               | Note:  |                      | 550,000<br>Tablets – May |
|               | 01. The shelf life of the product should be minimum<br>of 24 months when stored at a temperature<br>range of 28'C-32'C |                      | 2022                     |
|               | 02.The Product should be protected from light and dispensed in tight, light-resistant container.                       |                      |                          |
|               | 03.Each pack should be labeled accordingly.  |                      |                          |
|               | Packing : 100 Tablets in a box   |                      |                          |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 41,800.00 or USD 210.00.

### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

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

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

### **Storage Conditions & Temperature**

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

### Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         |   |                   | <u> </u>                | <u> ANNEX – 1</u> |
|---------|---|-------------------|-------------------------|-------------------|
|         | D./BID REFERENCE<br>ER NO.)                             | :                 |                         |                   |
| DATE (  | OF ISSUE  | :                 |                         |                   |
|         | NG DATE & TIME<br>ANKAN TIME)                           |                   |                         |                   |
| ORDER   | LIST NO. :  |                   |                         |                   |
| SR No.  | Item<br>Description/Specification                       | Quantity          | Delivery Schedule       |                   |
|         |   |                   |                         |                   |
|         | Nos of <b>Representative</b><br>tion as tender samples. | -                 | he item to be submitted | for the           |
| Amoun   | it of Bid Bond : LKR                                    | or USD            | to be submitted along   | with the          |
| Bid     |   |                   |                         |                   |
| Bid Bo  | nd valid till   | (date)            |                         |                   |
| Bid val | idity period: Bid should                                | be valid till     | (date)                  |                   |
| Bid Do  | cument Fee :  |                   |                         |                   |
| (should | be paid in cash to SPC for                              | each set of Bid D | 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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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<br>Date<br>& Time  | Item Description                                | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|----------------------------|---|--|-------------------------------|
| DHS/P/WW/242/22 | 13.07.2021<br>at 9.00 a.m. | 1,600,000 Tablets of<br>Cinnarizine Tablet 25mg | 01.06.2021                                       | Rs. 3,000/=<br>+ 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

# TENDER NO.: DHS/P/WW/242/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification                                   | <b>Quantity</b>      | <u>Delivery</u>      |
|---------------|---|----------------------|----------------------|
| 00303001      | Cinnarizine tablets 25mg  | 1,600,000<br>Tablets | 1,600,000<br>Tablets |
|               | Cinnarizine tablets 25mg  |                      | – June 2022          |
|               | Each tablet to contain 25mg of Cinnarizine 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 24,320.00 or USD 122.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

### **Standards & Quality**

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets

(b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

### **Storage Conditions & Temperature**

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

### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the

condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

### **Common conditions**

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

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|   |   |                      | ANNEX                      |
|---|---|----------------------|----------------------------|
| -   | )./BID REFERENCE<br>ER NO.)                           | :                    |                            |
| DATE  | OF ISSUE  | :                    |                            |
|   | NG DATE & TIME<br>ANKAN TIME)                         | :                    |                            |
| ORDER   | LIST NO. :  |                      |                            |
| SR No.  | Item<br>Description/Specific                          | Quanti<br>ations     | ity Delivery Schedule      |
|   | tion as tender samp                                   |                      | to be submitted along with |
| Amour   |   |                      |                            |
| Amour<br>Bid                                  |   |                      |                            |
| Bid   | nd valid till   | (date)               |                            |
| Bid<br>Bid Bo                                 | nd valid till   |                      | (date)                     |
| Bid<br>Bid Bo<br>Bid val                      | nd valid till   | ould be valid till . | (date)                     |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do            | nd valid till<br>idity period: Bid sho                | ould be valid till . |                            |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nd valid till<br>idity period: Bid sho<br>cument Fee: | ould be valid till . |                            |

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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/241/22 | 13.07.2021                | 4,120,000 Capsules of   | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Venlafaxine HCI Capsule |  | + Taxes                       |
|                 |                           | E.R. 75mg               |  |                               |

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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/241/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <b>Quantity</b>              | Delivery   |
|---------------|--|------------------------------|--|
| 00302902      | Venlafaxine HCI capsules E.R. 75mg<br>Venlafaxine Hydrochloride extended release<br>capsules 75mg  | <b>4,120,000</b><br>Capsules | <b>4,120,000</b><br>Capsule <b>s</b> –<br><b>June 2022</b> |
|               | Each extended release capsule to contain 75mg of<br>Venlafaxine Hydrochloride<br>Note:<br>01.The shelf life of the product should be minimum |                              |  |
|               | of 24 months. Packing: 100 Capsules in a box   |                              |  |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 407,056.00 or USD 2,041.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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

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

# 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.

- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         | )./BID REFERENCE                            | _                |           |                       | <u>ANNEX – 1</u> |
|---------|---|------------------|-----------|-----------------------|------------------|
|         | ER NO.)                                     | :                |           |                       |                  |
| DATE (  | OF ISSUE                                    | :                |           |                       |                  |
|         | NG DATE & TIME<br>ANKAN TIME)               | :                |           |                       |                  |
| ORDER   | LIST NO. :                                  |                  |           |                       |                  |
| SR No.  | Item<br>Description/Specificat              | Quant            | tity      | Delivery Schedule     |                  |
|         |   |                  |           |                       |                  |
|         | Nos of Representative tion as tender sample | -                | or the i  | tem to be submitted   | for the          |
| Amoun   | t of Bid Bond:LKR                           | or USI           |           | to be submitted along | g with the       |
| Bid     |   |                  |           |                       |                  |
| Bid Bo  | nd valid till                               | (date)           |           |                       |                  |
| Bid val | idity period: Bid shou                      | ld be valid till |           | (date)                |                  |
| Bid Do  | cument Fee :                                |                  |           |                       |                  |
| (should | be paid in cash to SPC fe                   | or each set of I | Bid Docum | nents).               |                  |
| 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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

#### FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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



### 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/240/22 | 13.07.2021                | 22,000,000 Tablets of   | 01.06.2021                                       | Rs. 20,000/=                  |
|                 | at 9.00 a.m.              | Sodium Valproate 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/240/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification                     | <u>Quantity</u> | Delivery      |
|---------------|---|-----------------|---------------|
| 00304001      | Sodium Valproate tablets 100mg.                     | 22,000,000      | 8,000,000     |
|               |   | Tablets         | Tablets –     |
|               | Sodium Valproate tablets BP 100mg.                  |                 | January 2022  |
|               | Each tablet to contain 100mg of Sodium Valproate    |                 |               |
|               | BP.   |                 | 7,000,000     |
|               | OR  |                 | Tablets – May |
|               | Sodium Valproate enteric - coated tablets BP        |                 | 2022          |
|               | 100mg.  |                 |               |
|               | Each enteric coated tablet to contain 100mg of      |                 | 7,000,000     |
|               | Sodium Valproate BP.                                |                 | Tablets –     |
|               |   |                 | October 2022  |
|               | Note:   |                 |               |
|               | 1. This tablet should be stable for a minimum of 24 |                 |               |
|               | months when stored at a temperature range of        |                 |               |
|               | 28'C-32'C.  |                 |               |
|               | 2. Tablets should be packed in moisture proof strip |                 |               |
|               | pack.   |                 |               |
|               | 3. Tablets should be scored.                        |                 |               |
|               |   |                 |               |
|               | Packing : 100 Tablets in a box                      |                 |               |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 1,201,200.00 or USD 6,021.00.

#### 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. 20,000.00 + Taxes** should be paid in cash to SPC for each set of Tender Documents.

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

#### CONDITIONS OF SUPPLY

#### (a) Part A

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

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

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

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

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

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

#### Shelf life & Warrantees.

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

#### Standards & Quality

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

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

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

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

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |   |  | ANNEX -  |
|--|---|--|--|
| -  | )./BID REFERENCE<br>ER NO.)   | :  |  |
| DATE   | OF ISSUE  | :  |  |
|  | NG DATE & TIME<br>ANKAN TIME)   | :  |  |
| ORDER  | LIST NO. :  |  |  |
| SR No.   | Item<br>Description/Specific  | Quantit<br>ations                              | y Delivery Schedule  |
|  | -   | -  | the item to be submitted for the                                     |
| evalua   | tion as tender samp   | les.   | the item to be submitted for the item to be submitted along with the |
| evalua   | tion as tender samp   | les.   |  |
| evalua<br>Amour<br>Bid   | tion as tender samp   | les.<br>or USD                                 |  |
| evalua<br>Amour<br>Bid<br>Bid Bo                                 | n <b>tion as tender samp</b><br>Int of Bid Bond : LKR                           | les.<br>or USD<br>(date)                       | to be submitted along with tl  |
| <b>evalua</b><br>Amour<br>Bid<br>Bid Bo<br>Bid val               | nt of Bid Bond : LKR<br>nd valid till   | les.<br>or USD<br>(date)<br>ould be valid till | to be submitted along with tl  |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho                 | les.<br>or USD<br>(date)<br>ould be valid till | to be submitted along with tl  |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho<br>cument Fee : | les.<br>or USD<br>(date)<br>ould be valid till | to be submitted along with th  |

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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

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<br>Date<br>& Time | Item Description       | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|------------------------|--|-------------------------------|
| DHS/P/WW/239/22 | 13.07.2021                | 11,000,000 Tablets of  | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Sertraline Tablet 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

\_\_\_\_\_

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

## TENDER NO.: DHS/P/WW/239/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification                                   | <b>Quantity</b>       | Delivery                    |
|---------------|---|-----------------------|-----------------------------|
| 00302801      | Sertraline tablet 50mg  | 11,000,000<br>Tablets | 6,000,000<br>Tablets –      |
|               | Sertraline tablet 50mg  |                       | February 2022               |
|               | Each tablet to contain 50mg of Sertraline<br>Note:                |                       | 5,000,000<br>Tablets – July |
|               | 01. The shelf life of the product should be minimum of 24 months. |                       | 2022                        |
|               | Packing : 30 Tablets in a box                                     |                       |                             |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 686,400.00 or USD 3,441.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### **Standards & Quality**

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

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

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

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

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.
   Sufficient guantity 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |   |          |                                 | ANNEX                         |
|--|---|----------|---------------------------------|-------------------------------|
|  | D./BID REFERENCE<br>ER NO.)   | :        |                                 |                               |
| DATE   | OF ISSUE  | :        |                                 |                               |
|  | NG DATE & TIME<br>ANKAN TIME)   | :        |                                 |                               |
| ORDER  | LIST NO. :  |          |                                 |                               |
| SR No.   | Item<br>Description/Specific  | ations   | Quantity                        | Delivery Schedule             |
| I  | nos of <b>Representat</b>   | ive san  | nples for tl                    | ne item to be submitted for t |
| evalua   | tion as tender samp   | les.     | -                               | ne item to be submitted for t |
| evalua   | tion as tender samp   | les.     | -                               |                               |
| evalua<br>Amour<br>Bid   | tion as tender samp   | les.     | . or USD                        |                               |
| <b>evalua</b><br>Amour<br>Bid<br>Bid Bo                          | n <b>tion as tender samp</b><br>nt of Bid Bond : LKR                                    | les.<br> | . or USD<br>date)               | to be submitted along with    |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val                      | ntion as tender samp<br>nt of Bid Bond : LKR<br>nd valid till                           | les.<br> | or USD<br>date)<br>/alid till   | to be submitted along with    |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | ntion as tender samp<br>nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho | les.<br> | . or USD<br>date)<br>/alid till | to be submitted along with a  |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho<br>cument Fee :         | les.<br> | . or USD<br>date)<br>/alid till | to be submitted along with a  |

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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time | Item Description         | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|--------------------------|--|-------------------------------|
| DHS/P/WW/238/22 | 13.07.2021                | 6,500,000 Capsules of    | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Fluoxetine Hydrochloride |  | + Taxes                       |
|                 |                           | Capsule 20mg             |  |                               |

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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/238/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <u>Quantity</u>              | <u>Delivery</u>                        |
|---------------|--|------------------------------|--|
| 00302701      | Fluoxetine Hydrochloride Capsule BP,20mg   | <b>6,500,000</b><br>Capsules | <b>6,500,000</b><br>Capsule <b>s –</b> |
|               | Fluoxetine Hydrochloride Capsule BP,20mg<br>Each capsule to contain 20mg of Fluoxetine<br>Hydrochloride BP |                              | July 2022                              |
|               | Note:<br>01.The shelf life of the product should be minimum<br>of 24 months.                               |                              |  |
|               | Packing : 1000 Capsules in a bottle  |                              |  |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 156,000.00 or USD 782.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## Standards & Quality

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

- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

- 16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack
  - (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)
- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

# **Storage Conditions & Temperature**

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

# **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

- 29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.
- 30. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its' amendments) under the

condition No. 26, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

# **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

# **Common conditions**

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

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

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

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

## **Special Conditions for Bidding :**

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|   |   |                      | ANNEX                      |
|---|---|----------------------|----------------------------|
| -   | )./BID REFERENCE<br>ER NO.)                           | :                    |                            |
| DATE  | OF ISSUE  | :                    |                            |
|   | NG DATE & TIME<br>ANKAN TIME)                         | :                    |                            |
| ORDER   | LIST NO. :  |                      |                            |
| SR No.  | Item<br>Description/Specific                          | Quanti<br>ations     | ity Delivery Schedule      |
|   | tion as tender samp                                   |                      | to be submitted along with |
| Amour   |   |                      |                            |
| Amour<br>Bid                                  |   |                      |                            |
| Bid   | nd valid till   | (date)               |                            |
| Bid<br>Bid Bo                                 | nd valid till   |                      | (date)                     |
| Bid<br>Bid Bo<br>Bid val                      | nd valid till   | ould be valid till . | (date)                     |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do            | nd valid till<br>idity period: Bid sho                | ould be valid till . |                            |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nd valid till<br>idity period: Bid sho<br>cument Fee: | ould be valid till . |                            |

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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

## 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/237/22 | 13.07.2021                | 2,000,000 Capsules of   | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Venlafaxine HCI Capsule |  | + Taxes                       |
|                 |                           | E.R. 37.5mg             |  |                               |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/237/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification   | <u>Quantity</u>              | <u>Delivery</u>                              |
|---------------|---|------------------------------|--|
| 00302901      | Venlafaxine HCl capsules E.R. 37.5mg<br>Venlafaxine Hydrochloride extended release capsules<br>37.5mg<br>Each extended release capsule to contain 37.5mg of                     | <b>2,000,000</b><br>Capsules | 2,000,000<br>Capsule <b>s</b><br>– June 2022 |
|               | <ul> <li>Venlafaxine Hydrochloride</li> <li>Note:</li> <li>01.The shelf life of the product should be minimum of 24 months.</li> <li>Packing: 1000 Capsules in a box</li> </ul> |                              |  |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 154,400.00 or USD 774.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

# Standards & Quality

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

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

# **Storage Conditions & Temperature**

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

## **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

# **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

# **Common conditions**

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

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

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

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

# Special Conditions for Bidding :

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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

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

# 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.

- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         | )./BID REFERENCE                            | _                |           |                       | <u>ANNEX – 1</u> |
|---------|---|------------------|-----------|-----------------------|------------------|
|         | ER NO.)                                     | :                |           |                       |                  |
| DATE (  | OF ISSUE                                    | :                |           |                       |                  |
|         | NG DATE & TIME<br>ANKAN TIME)               | :                |           |                       |                  |
| ORDER   | LIST NO. :                                  |                  |           |                       |                  |
| SR No.  | Item<br>Description/Specificat              | Quant            | tity      | Delivery Schedule     |                  |
|         |   |                  |           |                       |                  |
|         | Nos of Representative tion as tender sample | -                | or the i  | tem to be submitted   | for the          |
| Amoun   | t of Bid Bond:LKR                           | or USI           |           | to be submitted along | g with the       |
| Bid     |   |                  |           |                       |                  |
| Bid Bo  | nd valid till                               | (date)           |           |                       |                  |
| Bid val | idity period: Bid shou                      | ld be valid till |           | (date)                |                  |
| Bid Do  | cument Fee :                                |                  |           |                       |                  |
| (should | be paid in cash to SPC fe                   | or each set of I | Bid Docum | nents).               |                  |
| 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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

#### FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time  | Item Description                                  | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|----------------------------|---|--|-------------------------------|
| DHS/P/WW/236/22 | 13.07.2021<br>at 9.00 a.m. | 2,000,000 Tablets of<br>Amitriptyline Tablet 10mg | 01.06.2021                                       | Rs. 3,000/=<br>+ 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

\_\_\_\_\_

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

# TENDER NO.: DHS/P/WW/236/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification                     | <u>Quantity</u> | <u>Delivery</u> |
|---------------|---|-----------------|-----------------|
| 00302201      | Amitriptyline Tablets BP 10mg                       | 2,000,000       | 2,000,000       |
|               |   | Tablets         | Tablets         |
|               | Amitriptyline Tablets BP 10mg                       |                 | – July 2022     |
|               | Each coated tablet to contain 10mg of Amitriptyline |                 |                 |
|               | Hydrochloride BP                                    |                 |                 |
|               | Tablet should also conform to dissolution test for  |                 |                 |
|               | Amitriptyline Hydrochloride Tablets as per USP      |                 |                 |
|               | OR  |                 |                 |
|               | Amitriptyline Hydrochloride Tablets USP, 10mg       |                 |                 |
|               | Each coated tablet to contain 10mg of Amitriptyline |                 |                 |
|               | Hydrochloride 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.** 

## 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

# Standards & Quality

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

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

# **Storage Conditions & Temperature**

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

# **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

# **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

# **Common conditions**

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

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

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

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

# Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|                        | 9./BID REFERENCE<br>ER NO.)                    | :                  | <u> </u>               | <u> ANNEX – 1</u> |
|------------------------|--|--------------------|------------------------|-------------------|
| DATE (                 | OF ISSUE                                       | :                  |                        |                   |
|                        | NG DATE & TIME<br>ANKAN TIME)                  | :                  |                        |                   |
| ORDER                  | LIST NO. :                                     |                    |                        |                   |
| SR No.                 | Item<br>Description/Specification              | Quantity<br>ons    | Delivery Schedule      |                   |
| evalua<br>Amoun<br>Bid | tion as tender samples<br>at of Bid Bond : LKR | or USD             | e item to be submitted |                   |
| Bid Bo                 | nd valid till                                  | (date)             |                        |                   |
| Bid val                | idity period : Bid should                      | l be valid till    | (date)                 |                   |
| Bid Do                 | cument Fee :                                   |                    |                        |                   |
| (should                | be paid in cash to SPC for                     | each 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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/235/22 | 13.07.2021                | 5,500,000 Tablets of    | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Phenytoin Sodium 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/235/22DATE OF ISSUE: 1<sup>ST</sup> JUNE 2021CLOSING DATE & TIME: 13<sup>TH</sup> JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification   | <u>Quantity</u>      | <u>Delivery</u>      |
|---------------|---|----------------------|----------------------|
| 00303703      | Phenytoin sodium tablets 100mg  | 5,500,000<br>Tablets | 5,500,000<br>Tablets |
|               | Phenytoin sodium tablets BP/USP 100mg<br>Each coated tablets to contain 100mg of Phenytoin<br>sodium BP/USP |                      | – August 2022        |
|               | Note:<br>01.The shelf life of the product should be minimum<br>of 24 months.                                |                      |                      |
|               | Packing : 100 Tablets in a bottle   |                      |                      |

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 250,800.00 or USD 1,258.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

## Standards & Quality

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

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

# Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding

defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

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

|                                       |  |         |                 | ANNEX –           |  |  |  |
|---------------------------------------|--|---------|-----------------|-------------------|--|--|--|
| BID NO./BID REFERENCE<br>(TENDER NO.) |  | :       |                 |                   |  |  |  |
| DATE (                                | OF ISSUE   | :       |                 |                   |  |  |  |
|                                       | NG DATE & TIME<br>ANKAN TIME)  | :       |                 |                   |  |  |  |
| ORDER                                 | LIST NO. :   |         |                 |                   |  |  |  |
| SR No.                                | Item<br>Description/Specificat   | tions   | Quantity        | Delivery Schedule |  |  |  |
| evalua                                | Nos of Representative samples for the item to be submitted for the evaluation as tender samples.         Amount of Bid Bond : LKR or USD |         |                 |                   |  |  |  |
| Bid                                   |  |         |                 | C C               |  |  |  |
| Bid Bo                                | nd valid till  | (c      | date)           |                   |  |  |  |
| Bid val                               | idity period: Bid shou   | ld be v | alid till       | (date)            |  |  |  |
| Bid Do                                | cument Fee :   |         |                 |                   |  |  |  |
| (should                               | be paid in cash to SPC f   | or each | n 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 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD Heading of 11th ColumnAND STORAGE TEMPERATURENMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

#### 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<br>Date<br>& Time | Item Description          | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|---------------------------|--|-------------------------------|
| DHS/P/WW/234/22 | 13.07.2021                | 6,000,000 Tablets of      | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Flunarizine Hydrochloride |  | + Taxes                       |
|                 |                           | Tablet 5mg                |  |                               |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/234/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <u>Quantity</u>      | <u>Delivery</u>      |
|---------------|--|----------------------|----------------------|
| 00304702      | Flunarizine hydrochloride Tablet 5mg   | 6,000,000<br>Tablets | 6,000,000<br>Tablets |
|               | Flunarizine hydrochloride Tablet 5mg<br>Each tablet to contain Flunarizine Hydrochloride<br>equivalent to 5mg of Flunarizine |                      | – July 2022          |
|               | Note:<br>01.The shelf life of the product should be minimum<br>of 24 months.   |                      |                      |
|               | Packing : 100 Tablets in a box   |                      |                      |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 98,400.00 or USD 494.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the

conditions of supply.

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

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace

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

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> on the closing date of tender and acknowledgement receipt to be obtained from Administration Department of SPC.
   Sufficient quantity of Samples chould be forwarded for evaluation
  - 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |  |  | ANNEX   |
|--|--|--|---|
|  | D./BID REFERENCE<br>ER NO.)                                      | :  |   |
| DATE   | OF ISSUE   | :  |   |
|  | NG DATE & TIME<br>ANKAN TIME)                                    | :  |   |
| ORDER  | LIST NO. :   |  |   |
| SR No.   | Item   | Quantity                                     | Delivery Schedule   |
|  | Description/Specifica  |  |   |
|  | NOS OF REDFESENTALT  | ve sallibles lui                             | the item to be submitted for t                              |
| evalua   | tion as tender sampl   | es.  |   |
| evalua<br>Amour<br>Bid   | tion as tender sampl   | es.<br>or USD                                |   |
| <b>evalua</b><br>Amour<br>Bid<br>Bid Bo                          | tion as tender samplet<br>tof Bid Bond : LKR                     | es.<br>or USD<br>(date)                      | the item to be submitted for t to be submitted along with t |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val                      | ition as tender sample<br>it of Bid Bond : LKR<br>nd valid till  | es.<br>or USD<br>(date)<br>uld be valid till | to be submitted along with t                                |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid show | es.<br>or USD<br>(date)<br>uld be valid till | to be submitted along with t                                |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid show | es.<br>or USD<br>(date)<br>uld be valid till | to be submitted along with 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 2<sup>nd</sup> Column FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD 

 AND STORAGE TEMPERATURE

 Heading of 11<sup>th</sup> Column

 NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Amendment to Bidding Document under 'Conditions of Contract'

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

08 TERMS OF DELIVERY

- 8.1 All shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation Ltd or those chartered by CSCL. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation Ltd do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.
- 8.2 SPC may nominate Independent Competent Authorities for issue of shipment Inspection Certificate (Certificate of Quality, Quantity and Loading) cost of such certificate should be borne by the supplier.
- 8.3 All items should be shipped to the destination and strictly conform to the delivery dates as per schedule I hereto marked .....
- 8.4 Delivery of all goods should be within the period of validity of the Letter of Credit, Except in exceptional circumstances no extensions will be granted. Cost of such extension in any would be borne by the supplier.
- 8.5 If the supplier fails to make deliveries within the time specified by the SPC (without prejudice to the other rights of SPC resulting from breach of the contract conditions) May be written notice to the supplier terminate the right of the supplier to proceed with any or all of the remaining part of the contract as provided for in clause 9.1 hereof in addition the SPC reserves the right to purchase from other sources any or all undelivered items and to recover excess costs from the supplier.
- 8.6 Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after the grace period shall be considered for acceptance subject to a surcharge to the supplier as stated below ;
  - (a). A surcharge of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.
- 8.7 In case of local suppliers, requests may be made for supply of goods in more installments than indicated in Annex 1.

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

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC



**PROCUREMENT NOTICE - GLOBAL** 

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

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

| Bid Number      | Closing<br>Date<br>& Time  | Item Description                            | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|----------------------------|---|--|-------------------------------|
| DHS/P/WW/233/22 | 13.07.2021<br>at 9.00 a.m. | 1,000,000 Tablets of<br>Clobazam Tablet 5mg | 01.06.2021                                       | Rs. 12,500/=<br>+ 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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",** 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

## TENDER NO.: DHS/P/WW/233/22DATE OF ISSUE: 1<sup>ST</sup> JUNE 2021CLOSING DATE & TIME: 13<sup>TH</sup> JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| SR No.   | Item Description/ Specification                                   | <b>Quantity</b>      | <u>Delivery</u>      |
|----------|---|----------------------|----------------------|
| 00304201 | Clobazam tablet 5mg   | 1,000,000<br>Tablets | 1,000,000<br>Tablets |
|          | Clobazam tablet 5mg   |                      | – July 2022          |
|          | Each tablet to contain 5mg of Clobazam BP.                        |                      |                      |
|          | Note:   |                      |                      |
|          | 01. The shelf life of the product should be minimum of 24 months. |                      |                      |
|          | Packing : 30 Tablets in a box                                     |                      |                      |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 257,000.00 or USD 1,289.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

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

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

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

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |  |                         |                               | ANNEX                         |
|--|--|-------------------------|-------------------------------|-------------------------------|
|  | )./BID REFERENCE<br>ER NO.)  | :                       |                               |                               |
| DATE   | OF ISSUE   | :                       |                               |                               |
|  | NG DATE & TIME<br>ANKAN TIME)  | :                       |                               |                               |
| ORDER  | LIST NO. :   |                         |                               |                               |
| SR No.   | Item<br>Description/Specific   | ations                  | Quantity                      | Delivery Schedule             |
|  |  |                         |                               |                               |
| evalua   | tion as tender samp  | les.                    | -                             | ne item to be submitted for t |
| evalua   | tion as tender samp  | les.                    | -                             |                               |
| evalua<br>Amoun<br>Bid   | tion as tender samp  | les.                    | or USD                        |                               |
| <b>evalua</b><br>Amoun<br>Bid<br>Bid Bo                          | tion as tender samp<br>It of Bid Bond : LKR  | les.<br>                | or USD                        | to be submitted along with t  |
| evalua<br>Amoun<br>Bid<br>Bid Bo<br>Bid val                      | tion as tender samp<br>at of Bid Bond : LKR<br>nd valid till   | les.<br>(c<br>ould be v | or USD<br>date)<br>valid till | to be submitted along with t  |
| evalua<br>Amoun<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | tion as tender samp<br>at of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho                 | les.<br>(c<br>ould be v | or USD<br>date)<br>valid till | to be submitted along with t  |
| evalua<br>Amoun<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | tion as tender samp<br>at of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho<br>cument Fee : | les.<br>(c<br>ould be v | or USD<br>date)<br>valid till | to be submitted along with 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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time  | Item Description                                       | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|----------------------------|--|--|-------------------------------|
| DHS/P/WW/232/22 | 13.07.2021<br>at 9.00 a.m. | 3,500,000 Tablets of Lithium<br>Carbonate Tablet 250mg | 01.06.2021                                       | Rs. 12,500/=<br>+ 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

## TENDER NO.: DHS/P/WW/232/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| SR No.   | Item Description/ Specification   | <b>Quantity</b>      | <u>Delivery</u>             |
|----------|---|----------------------|-----------------------------|
| 00302101 | Lithium Carbonate Tablet 250mg  | 3,500,000<br>Tablets | 3,500,000<br>Tablets – July |
|          | Lithium Carbonate Tablet BP 250mg<br>Each tablet to contain 250mg Lithium Carbonate BP.<br>Tablet should also conform to dissolution test for<br>Lithium Carbonate Tablets as per USP<br>OR<br>Lithium Carbonate Tablets USP, 250mg<br>Each tablet to contain 250mg of Lithium Carbonate<br>USP<br>Note:<br>01.The shelf life of the product should be minimum<br>of 24 months.<br>Packing : 100 Tablets in a box |                      | 2022                        |

#### **Representative Tender samples to be submitted for the evaluation.**

#### The amount of Bid Bond: LKR 210,700.00 or USD 1,057.00.

#### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         |   |                   | <u>AN</u>                 | <u>INEX – 1</u> |
|---------|---|-------------------|---------------------------|-----------------|
|         | D./BID REFERENCE<br>ER NO.)                             | :                 |                           |                 |
| DATE (  | OF ISSUE  | :                 |                           |                 |
|         | NG DATE & TIME<br>ANKAN TIME)                           |                   |                           |                 |
| ORDER   | LIST NO. :  |                   |                           | -               |
| SR No.  | Item<br>Description/Specification                       | Quantity          | Delivery Schedule         |                 |
|         |   |                   |                           |                 |
|         | Nos of <b>Representative</b><br>tion as tender samples. | -                 | he item to be submitted f | or the          |
| Amoun   | it of Bid Bond : LKR                                    | or USD            | to be submitted along w   | vith the        |
| Bid     |   |                   |                           |                 |
| Bid Bo  | nd valid till   | (date)            |                           |                 |
| Bid val | idity period: Bid should                                | be valid till     | (date)                    |                 |
| Bid Do  | cument Fee :  |                   |                           |                 |
| (should | be paid in cash to SPC for                              | each set of Bid D | 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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

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<br>Date<br>& Time | Item Description       | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|------------------------|--|-------------------------------|
| DHS/P/WW/231/22 | 13.07.2021                | 4,250,000 Tablets of   | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Risperidone Tablet 1mg |  | + Taxes                       |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

 FAX
 : 00 94-11- 2582496

 TELEPHONE
 : 00 94-11- 2582509

 E-MAIL
 : pharma.manager@spc.lk

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

# TENDER NO.: DHS/P/WW/231/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <b>Quantity</b>      | Delivery                    |
|---------------|--|----------------------|-----------------------------|
| 00302003      | Risperidone tablet 1mg   | 4,250,000<br>Tablets | 2,250,000<br>Tablets –      |
|               | Risperidone tablet 1mg   |                      | February 2022               |
|               | Each coated tablet to contain 1mg of Risperidone<br>BP/USP                   |                      | 2,000,000<br>Tablets – July |
|               | Note:<br>01.The shelf life of the product should be minimum of<br>24 months. |                      | 2022                        |
|               | Packing : 500 Tablets in a box   |                      |                             |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 296,650.00 or USD 1,487.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances.(refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |   |  | <u>ANNEX -</u>                   |
|--|---|--|----------------------------------|
|  | D./BID REFERENCE<br>ER NO.)                                       | :  |                                  |
| DATE   | OF ISSUE  | :  |                                  |
|  | NG DATE & TIME<br>ANKAN TIME)                                     | :  |                                  |
| ORDER  | LIST NO. :  |  |                                  |
| SR No.   | Item<br>Description/Specifica                                     | Quantit<br>ations                              | y Delivery Schedule              |
|  | -   | -  | the item to be submitted for the |
| evalua   | ition as tender sampl   | es.  | to be submitted along with th    |
| evalua   | ition as tender sampl   | es.  |                                  |
| evalua<br>Amour<br>Bid   | ition as tender sampl   | es.<br>or USD                                  |                                  |
| <b>evalua</b><br>Amour<br>Bid<br>Bid Bo                          | ntion as tender sampl<br>nt of Bid Bond : LKR                     | es.<br>or USD                                  | to be submitted along with the   |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val                      | nt of Bid Bond : LKR  | es.<br>or USD<br>(date)<br>uld be valid till   | to be submitted along with t     |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | nt of Bid Bond : LKR<br>and valid till<br>lidity period : Bid sho | es.<br>or USD .<br>(date)<br>uld be valid till | to be submitted along with tl    |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nt of Bid Bond : LKR<br>and valid till<br>lidity period : Bid sho | es.<br>or USD .<br>(date)<br>uld be valid till | to be submitted along with th    |

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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/230/22 | 13.07.2021                | 1,200,000 Tablets of    | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Phenytoin Sodium Tablet |  | + Taxes                       |
|                 |                           | 50mg                    |  |                               |

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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

# TENDER NO.: DHS/P/WW/230/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification                                   | <u>Quantity</u>      | <u>Delivery</u>      |
|---------------|---|----------------------|----------------------|
| 00303702      | Phenytoin sodium tablets 50mg                                     | 1,200,000<br>Tablets | 600,000<br>Tablets – |
|               | Phenytoin sodium tablets BP/USP 50mg                              |                      | February 2022        |
|               | Each coated tablets to contain 50mg of Phenytoin sodium BP/USP    |                      | 600,000<br>Tablets – |
|               | Note:   |                      | August 2022          |
|               | 01. The shelf life of the product should be minimum of 24 months. |                      |                      |
|               | Packing : 100 Tablets in a bottle                                 |                      |                      |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 29,280.00 or USD 147.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

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

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

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

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |  |                         |                               | ANNEX                         |
|--|--|-------------------------|-------------------------------|-------------------------------|
|  | )./BID REFERENCE<br>ER NO.)  | :                       |                               |                               |
| DATE   | OF ISSUE   | :                       |                               |                               |
|  | NG DATE & TIME<br>ANKAN TIME)  | :                       |                               |                               |
| ORDER  | LIST NO. :   |                         |                               |                               |
| SR No.   | Item<br>Description/Specific   | ations                  | Quantity                      | Delivery Schedule             |
|  |  |                         |                               |                               |
| evalua   | tion as tender samp  | les.                    | -                             | ne item to be submitted for t |
| evalua   | tion as tender samp  | les.                    | -                             |                               |
| evalua<br>Amoun<br>Bid   | tion as tender samp  | les.                    | or USD                        |                               |
| <b>evalua</b><br>Amoun<br>Bid<br>Bid Bo                          | tion as tender samp<br>It of Bid Bond : LKR  | les.<br>                | or USD                        | to be submitted along with t  |
| evalua<br>Amoun<br>Bid<br>Bid Bo<br>Bid val                      | tion as tender samp<br>at of Bid Bond : LKR<br>nd valid till   | les.<br>(c<br>ould be v | or USD<br>date)<br>valid till | to be submitted along with t  |
| evalua<br>Amoun<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | tion as tender samp<br>at of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho                 | les.<br>(c<br>ould be v | or USD<br>date)<br>valid till | to be submitted along with t  |
| evalua<br>Amoun<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | tion as tender samp<br>at of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho<br>cument Fee : | les.<br>(c<br>ould be v | or USD<br>date)<br>valid till | to be submitted along with 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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time | Item Description           | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|----------------------------|--|-------------------------------|
| DHS/P/WW/229/22 | 13.07.2021                | 70,000 Bottles of Sodium   | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Valproate Syrup 200mg/5ml, |  | + Taxes                       |
|                 |                           | 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/229/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification   | <u>Quantity</u>   | <u>Delivery</u>                  |
|---------------|---|-------------------|----------------------------------|
| 00304004      | Sodium Valproate Syrup 200mg/5ml, 100ml   | 70,000<br>Bottles | 35,000 Bottles<br>- January 2022 |
|               | Sodium Valproate Oral Solution BP, 200mg/5ml,<br>100ml bottle Each bottle to contain 200mg / 5ml of<br>Sodium Valproate BP in a suitable flavoured vehicle. |                   | 35,000 Bottles<br>- May 2022     |
|               | Note:<br>01.The shelf life of the product should be minimum<br>of 24 months.  |                   |                                  |
|               | Packing : 50 Bottles in a box   |                   |                                  |

**Representative Tender samples to be submitted for the evaluation.** 

The amount of Bid Bond: LKR 395,220.00 or USD 1,978.00.

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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

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

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.
- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards.

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

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

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

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

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

#### **Delivery Requirements**

24. All items shall be supplied as per the latest/final delivery schedule, communicated to the supplier, as an amended Indent/PO delivery schedule (if not amended, original schedule in the Indent/PO will apply) mutually agreed between MSD& SPC, at the time of establishing the

payment terms (L/C, DP, TT, etc). Any deviation from this agreed delivery schedule shall be treated as a defaulted delivery.

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |   |          |                                 | ANNEX  |
|--|---|----------|---------------------------------|--|
|  | D./BID REFERENCE<br>ER NO.)   | :        |                                 |  |
| DATE   | OF ISSUE  | :        |                                 |  |
|  | NG DATE & TIME<br>ANKAN TIME)   | :        |                                 |  |
| ORDER  | LIST NO. :  |          |                                 |  |
| SR No.   | Item<br>Description/Specific  | ations   | Quantity                        | Delivery Schedule  |
| I  | nos of <b>Representat</b>   | ive san  | nples for tl                    | ne item to be submitted for t  |
| evalua   | tion as tender samp   | les.     | -                               | ne item to be submitted for to the submitted for the submitted along with the submitted along wi |
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| evalua<br>Amour<br>Bid   | tion as tender samp   | les.     | . or USD                        |  |
| <b>evalua</b><br>Amour<br>Bid<br>Bid Bo                          | n <b>tion as tender samp</b><br>nt of Bid Bond : LKR                                    | les.<br> | . or USD<br>date)               | to be submitted along with   |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val                      | ntion as tender samp<br>nt of Bid Bond : LKR<br>nd valid till                           | les.<br> | or USD<br>date)<br>/alid till   | to be submitted along with   |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | ntion as tender samp<br>nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho | les.<br> | . or USD<br>date)<br>/alid till | to be submitted along with a   |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho<br>cument Fee :         | les.<br> | . or USD<br>date)<br>/alid till | to be submitted along with a   |

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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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



### 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/228/22 | 13.07.2021                | 20,000,000 Tablets of   | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Sodium Valproate Tablet |  | + Taxes                       |
|                 |                           | 200mg                   |  |                               |

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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/228/22DATE OF ISSUE: $1^{ST}$ JUNE 2021CLOSING DATE & TIME: $13^{TH}$ JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| Se dium Meluweete teklete 200mm   |   |   |
|---|---|---|
| Sodium Valproate tablets 200mg.<br>Sodium Valproate Tablet BP, 200mg.<br>Each tablet to contain 200mg of Sodium Valproate<br>BP.    | 20,000,000<br>Tablets   | 20,000,000<br>Tablets<br>– October<br>2022  |
| OR<br>Sodium Valproate enteric - coated tablets BP 200mg.<br>Each enteric coated tablet to contain 200mg of<br>Sodium Valproate BP. |   |   |
| lote:<br>.This tablet should be stable for a minimum of 24<br>months when stored at a temperature range of<br>28'C-32'C             |   |   |
| 2. Tablets should be packed in moisture proof strip<br>pack   |   |   |
|   | This tablet should be stable for a minimum of 24<br>months when stored at a temperature range of<br>28'C-32'C<br>Tablets should be packed in moisture proof strip | This tablet should be stable for a minimum of 24<br>months when stored at a temperature range of<br>28'C-32'C<br>Tablets should be packed in moisture proof strip<br>pack |

#### **Representative Tender samples to be submitted for the evaluation.**

The amount of Bid Bond: LKR 868,000.00 or USD 4,343.00.

#### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

- 10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:
  - (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

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

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

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

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding

defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|   |   |                    | ANNEX -                       |
|---|---|--------------------|-------------------------------|
| -   | )./BID REFERENCE<br>ER NO.)                   | :                  |                               |
| DATE  | OF ISSUE                                      | :                  |                               |
|   | NG DATE & TIME<br>ANKAN TIME)                 | :                  |                               |
| ORDER   | LIST NO. :                                    |                    |                               |
| SR No.  | Item<br>Description/Specific                  | Quantit<br>cations | y Delivery Schedule           |
|   | ntion as tender samp<br>Int of Bid Bond : LKR |                    | to be submitted along with th |
|   |   |                    | C C                           |
| Bid   |   |                    |                               |
| Bid   | nd valid till                                 | (date)             |                               |
| Bid<br>Bid Bo                                 | nd valid till<br>lidity period: Bid sho       |                    | (date)                        |
| Bid<br>Bid Bo<br>Bid val                      |   | ould be valid till | (date)                        |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do            | lidity period: Bid sho                        | ould be valid till |                               |
| Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | lidity period: Bid sho<br>cument Fee:         | ould be valid till |                               |

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 2<sup>nd</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY

Heading of 11<sup>th</sup> Column

#### 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



### 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/227/22 | 13.07.2021                | 600,000 Tablets of      | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Chlordiazepoxide Tablet |  | + Taxes                       |
|                 |                           | 10mg                    |  |                               |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26**<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/227/22DATE OF ISSUE: 1<sup>ST</sup> JUNE 2021CLOSING DATE & TIME: 13<sup>TH</sup> JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification                     | <u>Quantity</u> | <u>Delivery</u> |
|---------------|---|-----------------|-----------------|
| 00300201      | Chlordiazepoxide Tablets 10mg                       | 600,000         | 600,000         |
|               |   | Tablets         | Tablets –       |
|               | Chlordiazepoxide Hydrochloride Tablets BP, 10mg     |                 | June 2022       |
|               | Each tablet to contain 10mg of Chlordiazepoxide     |                 |                 |
|               | Hydrochloride BP.                                   |                 |                 |
|               | Tablet should also conform to dissolution test for  |                 |                 |
|               | Chlordiazepoxide Tablets as per USP                 |                 |                 |
|               | OR  |                 |                 |
|               | Chlordiazepoxide Tablet USP 10mg                    |                 |                 |
|               | Each tablet to contain 10mg of Chlordiazepoxide USP |                 |                 |
|               | Note:   |                 |                 |
|               | 01. The shelf life of the product should be minimum |                 |                 |
|               | of 24 months.                                       |                 |                 |
|               | Packing : 500 Tablets in a box                      |                 |                 |

#### **Representative Tender samples to be submitted for the evaluation.**

#### The amount of Bid Bond: LKR 183,720.00 or USD 920.00.

#### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

- (a). In case of batch withdrawal, value of entire batch quantity supplied shall be recovered from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice. (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

29. The extension of L/C's overstepping delivery schedules in the Indent/PO/its' amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 26 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

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

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

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

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

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

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

- 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.
- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|  |   |                  |                                | ANNE                          |
|--|---|------------------|--------------------------------|-------------------------------|
|  | )./BID REFERENCE<br>ER NO.)   | :                |                                |                               |
| •  | OF ISSUE  | :                |                                |                               |
|  | NG DATE & TIME<br>ANKAN TIME)   | :                |                                |                               |
| ORDER  | LIST NO. :  |                  |                                |                               |
| SR No.   | Item<br>Description/Specific  | ations           | Quantity                       | Delivery Schedule             |
|  | Nos of Representat  | ive sai          | mples for t                    | he item to be submitted for t |
| evalua   | tion as tender samp   | les.             |                                | he item to be submitted for   |
| evalua   | tion as tender samp   | les.             |                                |                               |
| evalua<br>Amour<br>Bid   | tion as tender samp   | les.             | or USD                         |                               |
| <b>evalua</b><br>Amour<br>Bid<br>Bid Bo                          | n <b>tion as tender samp</b><br>Int of Bid Bond : LKR                                   | les.<br>         | or USD                         | to be submitted along with    |
| <b>evalua</b><br>Amour<br>Bid<br>Bid Bo<br>Bid val               | nt of Bid Bond : LKR  | l <b>es.</b><br> | or USD<br>(date)<br>valid till | to be submitted along with    |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do            | ntion as tender samp<br>nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho | les.<br>         | or USD<br>(date)<br>valid till | to be submitted along with    |
| evalua<br>Amour<br>Bid<br>Bid Bo<br>Bid val<br>Bid Do<br>(should | nt of Bid Bond : LKR<br>nd valid till<br>idity period : Bid sho<br>cument Fee :         | les.<br>         | or USD<br>(date)<br>valid till | to be submitted along with    |

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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time | Item Description        | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|-------------------------|--|-------------------------------|
| DHS/P/WW/226/22 | 13.07.2021                | 1,000,000 Tablets of    | 01.06.2021                                       | Rs. 3,000/=                   |
|                 | at 9.00 a.m.              | Clomipramine HCI Tablet |  | + Taxes                       |
|                 |                           | 25mg                    |  |                               |

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/226/22DATE OF ISSUE: 1<sup>ST</sup> JUNE 2021CLOSING DATE & TIME: 13<sup>TH</sup> JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification  | <u>Quantity</u>      | <u>Delivery</u>        |
|---------------|--|----------------------|------------------------|
| 00302402      | Clomipramine HCI Tablets 25mg  | 1,000,000<br>Tablets | 1,000,000<br>Tablets – |
|               | Clomipramine Hydrochloride Tablets 25mg<br>Each tablet to contain 25mg of Clomipramine<br>Hydrochloride BP   |                      | July 2022              |
|               | <ul> <li>Note:</li> <li>01.Analitical methods applicable to this tablet form may be the one given for clomipramine capsules BP</li> <li>02.The shelf life of the product should be minimum of 24 months.</li> <li>Packing: 100 Tablets in a box</li> </ul> |                      |                        |

#### **Representative Tender samples to be submitted for the evaluation.**

#### The amount of Bid Bond: LKR 75,200.00 or USD 377.00.

#### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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

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

# 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.

- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         | )./BID REFERENCE                                     |          |               |                         | <u>ANNEX – 1</u> |
|---------|--|----------|---------------|-------------------------|------------------|
|         | ER NO.)  | •        |               |                         |                  |
| DATE (  | OF ISSUE   | :        |               |                         |                  |
|         | NG DATE & TIME<br>ANKAN TIME)                        | :        |               |                         |                  |
| ORDER   | LIST NO. :   |          |               |                         |                  |
| SR No.  | Item<br>Description/Specifica                        | tions    | Quantity      | Delivery Schedule       |                  |
|         |  |          |               |                         |                  |
|         | Nos of <b>Representativ</b><br>tion as tender sample |          | ples for th   | ne item to be submitted | for the          |
| Amoun   | it of Bid Bond:LKR.                                  |          | or USD        | to be submitted along   | g with the       |
| Bid     |  |          |               |                         |                  |
| Bid Bo  | nd valid till  | (d       | ate)          |                         |                  |
| Bid val | idity period: Bid shou                               | ld be va | alid till     | (date)                  |                  |
| Bid Do  | cument Fee :   |          |               |                         |                  |
| (should | be paid in cash to SPC f                             | or each  | 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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

#### FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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<br>Date<br>& Time | Item Description          | Date of issue<br>of Bidding<br>Documents<br>from | Non-<br>refundable<br>Bid Fee |
|-----------------|---------------------------|---------------------------|--|-------------------------------|
| DHS/P/WW/225/22 | 13.07.2021                | 1,200,000 Ampoules of     | 01.06.2021                                       | Rs. 12,500/=                  |
|                 | at 9.00 a.m.              | Ondensetron Injection 8mg |  | + Taxes                       |
|                 |                           | in 4ml 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", 16<sup>th</sup> 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", 16**<sup>th</sup> 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", 26<sup>TH</sup> FLOOR NO. 41, KIRULA ROAD COLOMBO 5. SRI LANKA.

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

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

## TENDER NO.: DHS/P/WW/225/22DATE OF ISSUE: 1<sup>ST</sup> JUNE 2021CLOSING DATE & TIME: 13<sup>TH</sup> JULY 2021 AT 09.00 HOURS SRI LANKA TIME

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

| <u>SR No.</u> | Item Description/ Specification                          | <u>Quantity</u> | <u>Delivery</u> |
|---------------|--|-----------------|-----------------|
| 00303103      | Ondansetron Injection 8mg in 4ml ampoule                 | 1,200,000       | 600,000         |
|               |  | Ampoules        | Ampoules –      |
|               | Ondansetron Injection 8mg in 4ml ampoule                 |                 | January 2022    |
|               | Each 4ml ampoule to contain Ondansetron                  |                 |                 |
|               | Hydrochloride equivalent to 8mg of Ondansetron for       |                 | 600,000         |
|               | slow intravenous infusion and intravenous injection.     |                 | Ampoules –      |
|               |  |                 | June 2022       |
|               | Note:  |                 |                 |
|               | 1. This injection should be stable for a minimum 24      |                 |                 |
|               | months when stored 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 268,080.00 or USD 1,342.00.

#### 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 1/6<sup>th</sup> (one sixth) of the original product shelf life.
  - (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

#### Standards & Quality

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

- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged the total cost involved for MSD, of the quality failed supplies with 25% administrative surcharge of the same.
- 11. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration or shall conform to the information submitted for waiver of registration granted by NMRA in exceptional circumstances. (refer clause No.23)

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).

If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

13. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.10).

#### Pack size, Labeling & Packaging

- 14. Offers for pack sizes at a lower level(smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.
- 15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
  - (a). embossed or printed in case of tablets
  - (b). printed in case of capsules

Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

16. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Reference/Catalogue no.(not for pharmaceuticals), Date of Manufacture, Date of Expiry and 'STATE LOGO' of Government of Sri Lanka. It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.

(Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

- 17. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and 'STATE LOGO' of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box. Any deviations of the Date of Manufacture (DOM)/ Date of Expiry (DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.
- 18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting. Format shall be according to Code 128 or 2D standards. Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 20. In case of receiving goods under inappropriate packaging conditions (not in good order), was to be sorted out by MSD to select the items in good order by 100% checking/handling of the consignment, all expenses incurred to MSD in such an event (including demurrage charges, cold stores charges, labor charges etc. or any other charges incurred until goods are ready for acceptance), have to be paid to MSD by the local supplier, before attending to checking the consignment 100%, by MSD.

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

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

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

#### **Delivery Requirements**

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

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

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

(ii). If a delivery defaulted (violating delivery schedule in the indent/PO) SPC supplier/his local agent, who participate in an urgent local purchase tender of SPC or MSD for the same item, quoting the same product or any similar product, is bound to supply the local purchase order at the landed cost of the defaulted SPC main order. In violations of the same, the cost difference will be set off from the payments to the supplier of the corresponding SPC main order.

28. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier/s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 26 (regarding defaulted consignment) of the conditions of supply.

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

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

storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

#### **Documents & Information**

- 31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
- 32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.
- 33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail(follow instructions in website www.msd.gov.lk ), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.( follow instructions in the website www.msd.gov.lk) If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

#### **Common conditions**

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

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

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

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

#### Special Conditions for Bidding :

- 1. Offers should be accompanied with the valid registration certificate (Notary Certified) issued by the National Medicines Regulatory Authority in Sri Lanka formerly Cosmetic Devices and Drugs Authority.
- 2. Offered item should bear our SR number.
- 3. If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC/Ministry would result in the supplier being surcharge 0.5% of total bid amount per day from the due delivery date.

4. Foreign offers should be on C & F (CPT/CFR) Colombo basis. FOB offers are not acceptable. If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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

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

# 5. Fax/E-mail offers directly sent to State Pharmaceuticals Corporation are not acceptable. Tenderers are requested to draw their attention to the clause "Submission of Tenders" of the tender document in this regard.

- 6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m<sup>3</sup>).
- Representative samples in respect of items offered should be submitted to reach SPC on or before the <u>closing time</u> 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", 16<sup>th</sup> 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) 2<sup>nd</sup> line delete the words 'replaced or'

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

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

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

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

|         | D./BID REFERENCE<br>ER NO.)   | :         |               |                         | <u>ANNEX – 1</u> |
|---------|-------------------------------|-----------|---------------|-------------------------|------------------|
| DATE (  | OF ISSUE                      | :         |               |                         |                  |
|         | NG DATE & TIME<br>ANKAN TIME) | :         |               |                         |                  |
| ORDER   | LIST NO. :                    |           |               |                         |                  |
| SR No.  | Item<br>Description/Specifica | tions     | Quantity      | Delivery Schedule       |                  |
| evalua  | tion as tender sample         | es.       | -             | ne item to be submitted |                  |
| Bid Bo  | nd valid till                 | (d        | ate)          |                         |                  |
| Bid val | idity period: Bid shou        | uld be va | alid till     | (date)                  |                  |
| Bid Do  | cument Fee :                  |           |               |                         |                  |
| (should | be paid in cash to SPC        | for each  | 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 2<sup>nd</sup> Column

Heading of 11<sup>th</sup> Column

#### FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND STORAGE TEMPERATURE 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