

### **PROCUREMENT NOTICE**

### STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka, Colombo 01 invites sealed quotations from registered and previous sources for following items and bids will be closed at the respective times on the dates given below and will be opened immediately thereafter. **(E. mail /Fax offers as well as FOB offers are not acceptable)** 

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

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

| TENDER NO/BID<br>REFERENCE | CLOSING<br>DATE | CLOSING<br>TIME | ITEM   | QTY                           |
|----------------------------|-----------------|-----------------|--|-------------------------------|
| DHS/RL/74SSN/19            | 19.03.2020      | 02.30 P.M.      | Lab Items  | SPC web site<br>www.spc.lk    |
| DHS/RL/161SM/18            | 19.03.2020      | 02.30 P.M.      | 1/41301002 -Cresyl Fast Violet<br>2/41303701-Orcein stain  | 250g<br>30g                   |
| DHS/RL/77SM/19             | 23.03.2020      | 02.30 P.M.      | 04/50605402<br>Bottle for ceder wood oil clear glass<br>with rod and cap, capacity 50ml                | 60 Nos                        |
| DHS/RL/76NK/19             | 23.03.2020      | 02.30 P.M.      | Lab Items  | SPC web site<br>www.spc.lk    |
| DHS/RL/162MHR/18           | 23.03.2020      | 02.30 P.M.      | 2/45432201-Formaldehyde solution AR<br>4/45437601-N – Hexane AR<br>5/45462601-Trifluoro acetic acid AR | 1,250ml<br>1,500ml<br>2,250ml |
| DHS/RL/25CPW/20            | 23.03.2020      | 02.30 P.M.      | Lab Items  | SPC web site<br>www.spc.lk    |

#### LAB ITEMS

Bids should be prepared as per particulars given in the Bidding Documents available at the Head Office of State Pharmaceuticals Corporation of Sri Lanka, No.75, Sir Baron Jayatillake Mawatha, Colombo 1.

Wherever necessary potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bid Documents and also should get the contract registered after the award.

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

| FAX       | : 00 94-11- 2335008/2344082                         |
|-----------|---|
| TELEPHONE | : 00 94-11- 2335008/2326227/2335374                 |
| E-MAIL    | : <u>dgmsurgical@spc.lk / pharma.manager@spc.lk</u> |

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

### DHS/RL/74SSN/19 closing on 19.03.2020 @ 02.30 P.M.

#### 2019/SPC/N/C/D/00172

| SR No       | Item Specification   | Quantity |
|-------------|--|----------|
| 01/40101102 | Anti Xa assay<br>Packing : 1 kit                                       | 03 kits  |
| 02/40101302 | Collagen for platelet aggregation studies (100mcg/ml)<br>Packing : 1ml | 113ml    |
| 06/40102701 | Reagents for Protein S antigen assay<br>Packing : 1 kit                | 04 kits  |
| 08/40103001 | Reagents for Protein C activity assay<br>Packing : 1 vial              | 03 vials |

Delivery : Immediately

Samples/Literature/Catalogues must be submitted for evaluation on or before the time of tender closing.

#### (Also should be submitted certificate of Analysis along with the samples)

#### Bid Bond should be submitted together with the bid with validity up to (15.10.2020)

#### **General Conditions** :

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 <sup>3</sup>.

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. 37).

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 will not be entertained<sup>7</sup>.

#### Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or it's sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested(specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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<sup>1</sup>(as clause No. 37).

When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for surgical items and 24 months for pharma. / laboratory items.

#### Standards & Quality

- 9. <u>Standards</u>: In addition to Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards that are registered at National Medicines Regulatory Authority in Sri Lanka are also acceptable when no bidders have quoted for the standard specified in the item specification.
- 10. Any product deficient of 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<sup>4</sup>.
- **11.** 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<sup>8</sup> from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered<sup>8</sup> from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged<sup>8</sup> the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- **12.** 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.24)

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.

- 13. 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 <sup>11</sup>.(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.
- 14. 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 qualityfailed<sup>8</sup> (as clause No.11).

#### Pack size, Labeling & Packaging

- **15.** 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.
- 16. 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)

- 17. 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.
- 18. 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.
- **19.** 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.
- 20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels atall 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).
- 21. 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 <sup>5</sup> by SPC and refund to MSD.

#### Storage Conditions & Temperature

- 22. 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  $30^{0}c$  +/-  $2^{0}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 **WDNor 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 coldchain 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.

**24.** In respect of the products requiring controlled temperature storage (Eg.  $< 25^{\circ}$ c, 2- $25^{\circ}$ c, 15- $20^{\circ}$ c/ $30^{\circ}$ c, 2- $8^{\circ}$ c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at  $30^{\circ}$ c +/-  $2^{\circ}$ c & 75% +/- 5% RH for **AC stored** items and at  $25^{\circ}$ c +/-  $2^{\circ}$ c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

#### **Delivery Requirements**

**25.** 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. 27 on delayed deliveries, shall be applied.

- 26. 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.
- 27. 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 <sup>8</sup> 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 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.

**28.** (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.

**29.** 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. 27 (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.

- **30.** 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C  $^{12}$ .
- **31.** 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. 27, 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**

- **32.** 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.
- **33.** 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<sup>10</sup>.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.
- **34.** 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 <u>www.msd.gov.lk</u>), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.
- 35. 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<sup>6</sup> 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 27 will not be applicable.

#### Common conditions

- 36. 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.
- 37. 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. 08,05,13)
- 38. Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacture indicating that the Bidder has been duly authorized to supply the goods tendered for Failure to comply may result in the offer being rejected.

## DHS/RL/161SM/18 Closing on 19.03.2020 @ 02.30 P.M.

#### 2018/SPC/N/C/D/00078

| SR No      | Item Specification                 | Quantity |
|------------|------------------------------------|----------|
| 1/41301002 | Cresyl Fast Violet<br>Packing: 50g | 250g     |
| 2/41303701 | Orcein stain<br>Packing : 5g       | 30g      |

Delivery : 100 % Immediately

Samples/Literature/Catalogues must be submitted for evaluation on or before the time of tender closing.

#### (Also should be submitted certificate of Analysis along with the samples)

#### Bid bond should be submitted together with the bid with validity 210 days (15.10.2020)

#### **General Conditions** :

- 1. Offer should be submitted in the format as per annexed.
- 2. To be supplied from freshly manufactured stock & greater than 75% of total shelf life at the time of shipment arrival at Sri Lanka. (Details to be indicated in the offer)
- 3. Each item to bear Description of Item, Batch No, Date of Manufacture, Date of Expiry, SR No and "STATE LOGO" of Sri Lanka Government.
- 4. The product should have minimum of 24 months shelf life at the time of delivery at Medical Research Institute, Colombo 08
- 5. Description of Item, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer, MSD order list No, SR No, SPC Indent No and "STATE LOGO" of Sri Lanka Government should be clearly marked on the outer covering containing the item and on the outer cover of the carton/box.
- 6. The batch quantities shall be identical and number of batches shall be minimal. The proportionate size of the batch quantity should be not less than 15% of the quantity in the consignment and number of batches should be minimal & batch size should be an equal multiple of the consignment quantity.
- 7. Barcode (Code 128) for batch numbers shall be printed on the labels of innermost to outermost packing's as described below.
- a) Batch number should be separately bar-coded.
- b) Format should be according to CODE 128 standard.
- c) Maximum barcode size should be 2.5cm x 5.0cm
- d) Industry standard in barcode printing and pasting should be followed.

- 8. Storage condition of the items should be clearly indicated in the inner most and outer most carton labels. All outer most cartons to be stenciled with the MSD order list number and delivered at Medical Supplies Division Colombo 10
- 9. Offers for any other economically viable pack sizes different from the specified pack sizes are acceptable with the prior approval of Director, Medical Supplies Division.
- 10. If there is any deviation from the specified labeling requirement the product information leaflet, labels of primary pack and image of the primary pack showing the barcode label shall be brought to the approval of Director Medical Supplies Division prior to shipment.
- 11. MSD Order list No, SR No of item and SPC indent No description and storage condition of item should be indicated in all supplies Invoices and detailed packing lists.
- 12. In case the item is not delivered according to the given delivery schedule or non compliance of labeling requirement, specially the bar code labeling Director, Medical Supplies Division has the right to reject the whole consignment or part of it.
- 13. If any local purchase were to be made to ensure continuity of supply owing to delay in delivery, any excess expenditure incurred over indent cost on such purchases to Medical Supplies Division shall be recovered from the supplier.
- 14. Supplier should send SPC the specimen of the Label as per the Indent requirement when the goods are manufactured, and should obtain prior approval before the delivery of goods to MSD If the specified label is not received at SPC prior & delivery of goods to MSD, SPC will not be liable to clear the consignment and any consequences resulting this will be the supplier's responsibility.
- 15. C&F offers, not strictly adhering to labeling requirement stated in condition of supply are not acceptable
- 16. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.
- 17. Offers where samples are not received before the tender closing will be rejected.
- 18. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself authorized personnel having signatory powers (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.
- 19. In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned
- 20. Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. However, shipment on other vessels will be permitted, in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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 county.

21. Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacture indicating that the Bidder has been duly authorized to supply the goods tendered for Failure to comply may result in the offer being rejected.

### DHS/RL/77SM/19 closing on 23.03.2020 @ 02.30 P.M.

#### 2019/SPC/N/R/D/00018

| SR No       | Item Specification  | Quantity |
|-------------|---|----------|
| 04/50605402 | Bottle for ceder wood oil clear glass with rod and cap, capacity<br>50ml<br>Packing : 1 No x 1 pack | 60 Nos   |

Delivery : Immediately

Samples/Literature/Catalogues must be submitted for evaluation on or before the time of tender closing.

#### (Also should be submitted certificate of Analysis along with the samples)

# Bid Bond should be submitted together with the bid validity 210 days (19.10.2020) from closing of bid.

#### **General Conditions** :

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- 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 <sup>3</sup>.

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. 37).

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 will not be entertained<sup>7</sup>.

#### Shelf life & Warrantees

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  - 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested(specified in order/Indent/PO).

In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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<sup>1</sup> (as clause No. 37).

When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for surgical items and 24 months for pharma. / laboratory items.

#### **Standards & Quality**

- 9. <u>Standards</u>: In addition to Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards that are registered at National Medicines Regulatory Authority in Sri Lanka are also acceptable when no bidders have quoted for the standard specified in the item specification<del>.</del>
- 10. Any product deficient of 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<sup>4</sup>.
- 11. 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<sup>8</sup> from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered<sup>8</sup> from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged<sup>8</sup> the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.

12. 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.24)

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.

- 13. 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 <sup>11</sup>.(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.
- 14. 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 qualityfailed<sup>8</sup> (as clause No.11).

#### Pack size, Labeling & Packaging

- 15. 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.
- 16. 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) (not applicable)

17. 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

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

- 18. 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.
- 19. 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.

20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels atall 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).

21. 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 <sup>5</sup> by SPC and refund to MSD.

#### Storage Conditions & Temperature

- 22. 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  $30^{0}c$  +/-  $2^{0}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 **WDNor 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 coldchain 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.
- 24. In respect of the products requiring controlled temperature storage (Eg.  $< 25^{\circ}$ c, 2- $25^{\circ}$ c, 15- $20^{\circ}$ c/ $30^{\circ}$ c, 2- $8^{\circ}$ c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at  $30^{\circ}$ c +/-  $2^{\circ}$ c & 75% +/- 5% RH for **AC stored** items and at  $25^{\circ}$ c +/-  $2^{\circ}$ c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

#### **Delivery Requirements**

25. 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. 27 on delayed deliveries, shall be applied.

- 26. 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.
- 27. 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 <sup>8</sup> 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 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.

28. (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 supplierof the corresponding SPC main order.

29. 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. 27 (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.

- 30. 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C<sup>12</sup>.
- 31. 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. 27, 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**

- 32. 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.
- 33. 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<sup>10</sup>.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).
  The images of the specimen labels, minimum pack and outer most hox/shipper carton, that satisfies

The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.

- 34. 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.
- 35. 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<sup>6</sup> 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 27 will not be applicable.

- Common conditions
- 36. 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.
- 39. 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. 08,05,10,13)
  - 40. Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacture indicating that the Bidder has been duly authorized to supply the goods tendered for Failure to comply may result in the offer being rejected.

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

## DHS/RL/76NK/19 closing on 23.03.2020 @ 02.30 P.M.

#### 2019/SPC/N/C/D/00093

| SR No       | Item Specification                            | Quantity     | Delivery   |
|-------------|---|--------------|--|
| 6/40660101  | Cefotaxime MIC strips<br>Packing : 25 strips  | 4,500 strips | 2250 strips — Immediately<br>2250 strips — 06 months after 1 <sup>st</sup> lot |
| 7/40660201  | Ceftriaxone MIC strips<br>Packing : 25 strips | 2,300 strips | 1300 strips – Immediately<br>1000 strips – 06 months after 1 <sup>st</sup> lot |
| 8/40660401  | Penicillin MIC strips<br>Packing : 50 strips  | 4,800 strips | 2400 strips – Immediately<br>2400 strips – 05 months after 1 <sup>st</sup> lot |
| 9/40660501  | Imipenem MIC strips<br>Packing : 25 strips    | 1,300 strips | 800 strips – Immediately<br>500 strips – 05 months after 1 <sup>st</sup> lot   |
| 10/40660701 | Vancomycin MIC strips<br>Packing : 25 strips  | 4,800 strips | 2400 strips – Immediately<br>2400 strips – 05 months after 1 <sup>st</sup> lot |
| 11/40660301 | Meropenem MIC strips<br>Packing : 700 strips  | 1,400 strips | 700 strips – Immediately<br>700 strips – 05 months after 1 <sup>st</sup> lot   |

Delivery : Immediately

Samples/Literature/Catalogues must be submitted for evaluation on or before the time of tender closing.

Bid Bond should be submitted together with the bid validity 210 days (19.10.2020) from closing of bid

#### (Also should be submitted certificate of Analysis along with the samples)

#### **General Conditions** :

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<sup>3</sup>.

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. 37).

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 will not be entertained<sup>7</sup>.

#### Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or it's sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested(specified in order/Indent/PO).

In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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<sup>1</sup> (as clause No. 37).

When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for surgical items and 24 months for pharma. / laboratory items.

- 9. <u>Standards</u>: In addition to Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards that are registered at National Medicines Regulatory Authority in Sri Lanka are also acceptable when no bidders have quoted for the standard specified in the item specification.
- 10. Any product deficient of 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<sup>4</sup>.
- 11. 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<sup>8</sup> from the supplier.
- (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered<sup>8</sup> from the supplier.
- (c). In the event of either a) or b) above, supplier shall be surcharged<sup>8</sup> the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
  - 12. 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.24)

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.

- 13. 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 <sup>11</sup>.(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.
- 14. 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 qualityfailed<sup>8</sup>(as clause No.11).

#### Pack size, Labeling & Packaging

- 15. 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.
- 16. 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) (Not applicable)

17. 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.

- 18. 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.
- 19. 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.
- 20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels atall 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).

21. 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 <sup>5</sup> by SPC and refund to MSD.

#### Storage Conditions & Temperature

22. 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  $30^{0}$ c +/-  $2^{0}$ c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

#### 23. 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 **WDNor 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 coldchain 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.

f) In respect of the products requiring controlled temperature storage (Eg.  $< 25^{\circ}$ c,  $2-25^{\circ}$ c,  $15-20^{\circ}$ c/ $30^{\circ}$ c,  $2-8^{\circ}$ c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at  $30^{\circ}$ c +/-  $2^{\circ}$ c & 75% +/- 5% RH for **AC stored** items and at  $25^{\circ}$ c +/-  $2^{\circ}$ c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

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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. 27 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 <sup>8</sup> 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 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.

**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 supplierof 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. 27 (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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C <sup>12</sup>.
- **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. 27, 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<sup>10</sup>.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).

The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.

- **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<sup>6</sup> 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 27 will not be applicable.

#### Common conditions

- 36. 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.
- 41. 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. 08,05,10,13)
- 42. Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacture indicating that the Bidder has been duly authorized to supply the goods tendered for Failure to comply may result in the offer being rejected.
- 43. Items to be delivered at Medical Supplies Division, Colombo 10.

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

### DHS/RL/162MHR/18 Closing on 23.03.2020 @ 02.30 P.M.

#### 2018/SPC/N/C/D/00170

| SR No      | Item Specification                          | Quantity |
|------------|---|----------|
| 2/45432201 | Formaldehyde solution AR<br>Packing : 250ml | 1,250ml  |
| 4/45437601 | N – Hexane AR<br>Packing : 500ml            | 1,500ml  |
| 5/45462601 | Trifluoro acetic acid AR<br>Packing : 250ml | 2,250ml  |

#### Delivery : 100% Immediately

Samples/Literature/Catalogues must be submitted for evaluation on or before the time of tender closing.

#### (Also should be submitted certificate of Analysis along with the samples)

#### Bid Bond should be submitted together with the bid with validity 210 days (19.01.2020)

#### General Conditions :

- 1 Offers should be submitted in the format as per annexure.
- 2 To be supplied from freshly manufactured stock & greater than 75% of total shelf life at the time of shipment arrival at Sri Lanka. (Details to be indicated in the offer)
- **3** Each individual item to bear Description of Item, Batch No, Order List No, Indent No, Name and Address of Manufacturer, Date of Manufacture, Date of Expiry, SR No and "STATE LOGO" of Sri Lanka Government.
- 4 The product should have minimum of 24 months shelf life at the time of delivery at Medical Supplies Division.
- 5 The item shall be suitably packed and precaution must be taken to maintain the cold chain while transportation, until they reach the Medical Research Institute.
- 6 Description of Item, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer, MSD order list No, SR No, SPC Indent No and "STATE LOGO" of Sri Lanka Government should be clearly marked on the outer covering containing the item and on the outer cover of the carton/box.

- 7 The batch quantities shall be identical and number of lot Numbers shall be minimal. Each batch quantity should be individually shrunk wrapped and palletized. The shrunk wrapped pallet shall be labeled as described under conditions No 04 and bar code also to be labeled.
- **8** Barcode (code 128) for Batch Numbers shall be printed on the labels of innermost to outermost packing's as described below;
  - Batch number should be separately bar-coded.
  - Format should be according to CODE 128 standard.
  - Maximum barcode size should be 2.5cm x 5.0cm
  - Industry standard in barcode printing and pasting should be followed.
- 9 Offers for any other economically viable pack sizes different from the specified pack sizes are acceptable with the prior approval of Director, Medical Supplies Division.
- **10** MSD order list No, SPC Indent No, SR No, Description and storage condition of item shall be indicated in all supply invoices and detailed packing lists.
- 11 Storage condition of the items should be clearly indicated in the inner most and outer most carton labels. All outer most cartons to be stenciled with the MSD order list number and delivered at Medical Supplies Division.
- 12 If there is any deviation from the specified labeling requirement the product information leaflet, labels of primary pack and image of the primary pack showing the barcode label shall be brought to the approval of Director Medical Supplies Division prior to shipment.
- 13 In case the item is not delivered according to the given delivery schedule or non compliance of labeling requirement, specially the bar code labeling Director, Medical Supplies Division has the right to reject the whole consignment or part of it delivered thereafter.
- 14 If any local purchase were to be made to ensure continuity of supply owing to delay in delivery, any excess expenditure incurred over indent cost on such purchases to Medical Supplies Division shall be debited to SPC, to be recovered from the supplier.
- 15 In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- 16 Shipment should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. However, shipment on other vessels will be permitted, in instances where vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely 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 county.
- 17 Supplier should send SPC the specimen of the Label as per the Indent requirement when the goods are manufactured, and should obtain prior approval before the delivery of goods to MSD If the specified label is not received at SPC prior & delivery of goods to MSD, SPC will not be liable to clear the consignment and any consequences resulting this will be the supplier's responsibility.
- **18** C&F offers, not strictly adhering to labeling requirement stated in condition of supply are not acceptable
- **19** Offers where samples are not received before the tender closing will be rejected.

- 20 The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself authorized personnel having signatory powers (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.
- 21 Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacture indicating that the Bidder has been duly authorized to supply the goods tendered for Failure to comply may result in the offer being rejected.

### DHS/RL/25CPW/20 Closing on 23.03.2020 @ 02.30 P.M.

#### 2020/SPC/N/C/D/00088

| SR No      | Item Specification  | Quantity     | Delivery  |
|------------|---|--------------|---|
| 1/40600901 | Cefixime 5 mic.g<br>Packing : 50 Disc                         | 2,000 Discs  | 100% Immediately  |
| 2/40602401 | Colistin 10 mic.g<br>Packing : 50 Disc                        | 10,000 Discs | 5,000 – Immediately<br>5,000 – 5 months after 1 <sup>st</sup> lot |
| 3/40660001 | Beta – Lactamase identification strips<br>Packing : 25 strips | 1,000 Strips | 100% Immediately  |
| 4/40660101 | Cefotaxime MIC strips<br>Packing : 25 strips                  | 2,000 strips | 1,000 – Immediately<br>1,000 – 5 months after 1 <sup>st</sup> lot |
| 5/40660201 | Ceftrizxone MIC strips<br>Packing : 25 strips                 | 1,000 strips | 500 – Immediately<br>500 – 5 months after 1 <sup>st</sup> lot     |
| 6/40660401 | Penicillin MIC strips<br>Packing : 25 strips                  | 3,000 strips | 1,500 – Immediately<br>1,500 – 5 months after 1 <sup>st</sup> lot |
| 7/40660701 | Vancomycin MIC strips<br>Packing : 25 strips                  | 4,000 strips | 2,000 – Immediately<br>2,000 – 5 months after 1 <sup>st</sup> lot |
| 8/40660301 | Meropenem MIC strips<br>Packing : 50 strips                   | 1,000 strips | 1,000 – Immediately<br>1,000 – 5 months after 1 <sup>st</sup> lot |

Samples/Literature/Catalogues must be submitted for evaluation on or before the time of tender closing.

#### (Also should be submitted certificate of Analysis along with the samples)

#### Bid Bond should be submitted together with the bid with validity 210 days (19.10.2020)

#### **General Conditions** :

- 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 <sup>3</sup>.

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. 37).

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 will not be entertained<sup>7</sup>.

#### Shelf life & Warrantees

- 7. In the supply of all Non consumables; Manufacturer or supplier or local agent shall provide a minimum of 02 year warranty period or as specified in the specification, for each such item or it's sub components supplied (through the local agent), unless otherwise agreed upon with MSD, prior to awarding the tender. Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary.
- 8. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods in Sri Lanka/MSD stores in case of local supplies) of the product, shall be 85% of the shelf life requested(specified in order/Indent/PO). In respect of the items with requested shelf life equal or more than 24 months, any deficit between the residual shelf life and requested shelf, shall not be more than 04 months.

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<sup>1</sup>(as clause No. 37).

When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for surgical items and 24 months for pharma. / laboratory items.

#### **Standards & Quality**

- 9. <u>Standards</u>: In addition to Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards that are registered at National Medicines Regulatory Authority in Sri Lanka are also acceptable when no bidders have quoted for the standard specified in the item specification.
- 10. Any product deficient of 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<sup>4</sup>.

- 11. 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<sup>8</sup> from the supplier.
  - (b).In case of product withdrawal, value of entire product quantity supplied shall be recovered<sup>8</sup> from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged<sup>8</sup> the total **cost involved for MSD**, of the quality failed supplies with 25% administrative surcharge of the same.
- 12. 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.24)

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.

- 13. 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 <sup>11</sup>.(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.
- 14. 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 qualityfailed<sup>8</sup> (as clause No.11).

#### Pack size, Labeling & Packaging

15. 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.

16. 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)

- 17. 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.
- 18. 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.

- 19. 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.
- 20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels atall 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).

21. 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<sup>5</sup> by SPC and refund to MSD.

#### Storage Conditions & Temperature

- 22. 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  $30^{0}c$  +/-  $2^{0}c$  temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
- 23. 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 **WDNor 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 coldchain 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.
    - 24. In respect of the products requiring controlled temperature storage (Eg.  $< 25^{\circ}$ c, 2- $25^{\circ}$ c, 15- $20^{\circ}$ c/ $30^{\circ}$ c, 2- $8^{\circ}$ c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at  $30^{\circ}$ c +/-  $2^{\circ}$ c & 75% +/- 5% RH for **AC stored** items and at  $25^{\circ}$ c +/-  $2^{\circ}$ c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.12)

#### **Delivery Requirements**

25. 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. 27 on delayed deliveries, shall be applied.

- 26. 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.
- 27. 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 <sup>8</sup> 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 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.

28. (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 supplierof the corresponding SPC main order.

29. 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. 27 (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.

30. 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. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C<sup>12</sup>.

31. 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. 27, 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. (Not applicable)

#### **Documents & Information**

- 32. 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.
- 33. 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<sup>10</sup>.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists). The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies

The images of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided within 14 days of releasing the indent by SPC.

- 34. 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.
- 35. 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<sup>6</sup> 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 27 will not be applicable. **Common conditions**
- 36. 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. 08,05,10,13)
- 37. Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacture indicating that the Bidder has been duly authorized to supply the goods tendered for Failure to comply may result in the offer being rejected.

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