

# 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.

#### **LAB ITEMS**

TENDER NO/BID REFERENCE	CLOSING DATE	CLOSING TIME	ITEM	QTY
DHS/RL/26WKL/20	27.05.2020	02.30 P.M.	1/40601504-Ceftriaxone 0.5mic.g 150 Dis	
			2/40604002-Penicillin 0.5 Units	150 Discs
			3/40608902-Spectinomycin 100 mic.g	150 Discs
DHS/RL/80SM/19	27.05.2020	02.30 P.M.	3/50400108 Citrated blood collecting tube for adults: (for ESR) plastic vacutainer tube with black colour cap, disposable, citrate 3.8%	690,000 Nos
DHS/RL/81SM/19	27.05.2020	02.30 P.M.	1/42811001 EBV IgM antibody – ELISA (96 tests – kit)	02 kits
			2/42811002 EBV IgG antibody – ELISA (96 tests/kit)	02 kits
			3/42815001 CMV IgG antibody – ELISA (96 tests / kit)	05 kits
			4/42815002 CMV IgM antibody – ELISA (96 tests/kit)	04 kits

#### **PHARMA ITEMS**

Tender No.	Closing date	Time	Item	Quantity
DHS/RP/89/2020	19.05.2020	3.00 PM	Capecitabine Tablet 500mg	400,000 Tabs.
DHS/RP/M/85/2020	19.05.2020	11.00 AM	Desferrioxamine Injection	250,000 vials
DHS/RP/94/2020	21.05.2020	3.00 PM	Aspirin Tablet 75mg	115,000,000 Tabs.
DHS/RP/677/2018	19.05.2020	3.00 PM	Acetylcholine Chloride Intraocular solution 10mg/ml, 2ml vial	75 vials

#### **SURGICAL SPECIAL ITEMS**

Tender No.	Closing Date	Closing Time	Item	Quantity
DHS/RSS/RQ/14/20	04.06.2020	2.00 pm	Drug Eluting Coronary Stent, 3.0 mm diameter,40mm length,sterile.	120 Nos
DHS/RSS/RQ/15/20	04.06.2020	2.00 pm	Surgical Suture, Coated, Braided, Absorbable Synthetic Surgical Suture BP/USPStandard or Equivalent standards, Gauge size 6/0,75cm length attached to a 13mm(approx.) curved cutting eyeless needle.Each sterile suture packed individuallyin peel open foil and peel/tear open over wrap and labeled accordingly.	1,900 Nos
DHS/RSS/RQ/16/20	04.06.2020	2.00 pm	Surgical Non-Consumables	SPC web site www.spc.lk
DHS/RSS/RQ/17/20	04.06.2020	2.00 pm	Urine Drainage Leg Bag with Non Return Valve, bottom outlet for emptying, 20cmto 30cm tubing with connector, with strap for tying on thigh, 500ml to 800mlcapacity, graduated, sterile.	
DHS/RSS/RQ/19/20	27.05.2020	2.00 pm	Auto - Disable syringes for DMPA injection, 1ml.	300,000 Nos
DHS/RSS/RQ/20/20	27.05.2020	2.00 pm	Surgical Sutures	SPC web site www.spc.lk
DHS/RSS/RQ/307/18	27.05.2020	2.00 pm	Snare, Amplatzer type or similar, size 10mm, 120cm (approx.) length, with size 5F introducer, sterile.	54 Nos
DHS/RSS/RQ/181/19	04.06.2020	2.00 pm	Surgical Consumables	SPC web site www.spc.lk
DHS/RSS/RQ/183/19	04.06.2020	2.00 pm	Surgical Non-Consumables	SPC web site www.spc.lk
DHS/RSS/RQ/184/19	04.06.2020	2.00 pm	Retractor, Valves	SPC web site www.spc.lk
DHS/RSS/RQ/186/19	27.05.2020	2.00 pm	Coronary Guiding Catheters	SPC web site www.spc.lk
DHS/RSS/RQ/187/19	27.05.2020	2.00 pm	Arterial Cannulas for ECMO. SPC wwww	

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

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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/RSS/RQ/16/20**

2020/SPC/N/C/S/00213 CLOSING ON: 04<sup>TH</sup> JUNE, 2020 AT 2.00 pm

ITEM/ SR NO	ITEM	QTY	DELIVERY
13/20502517	Kocher- Langenbeck retractor, semi-sharp,4prongs, stainless steel.	10 Nos	05 Nos – Immediately 05 Nos – 4 months after a 1 <sup>st</sup> lot
14/20502518	Kocher- Langenbeck retractor 40x13mm blade, stainless steel.	20 Nos	20 Nos – Immediately
20/20502802	Retractor Self Retaining, Adson type or similar, 4 / 4 teeth, semi - sharp,200mm (approx.) length, stainless steel.	20 Nos	20 Nos – April/2020
24/20503002	Sauerbruch Retractor Longslender blade with sligthly tips hollow handle,Blade 7/8"(2.3cm)x2"1/2(6.3cm), packed individually and labeled accordingly	06 Nos	06 Nos – April/2020
25/20503003	Sauerbruch Retractor Longslender blade with slightly tips hollow handle ,blade 3/4"(2.0cm)X 2"7/8(7.3cm.	06 Nos	06 Nos – April/2020

Packing: 1 Nos

#### NB:

If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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.

#### Samples Catalogue/Literature should be submitted for evaluation

#### **General Conditions:**

Offers should be submitted in the format as per annexure.

#### General (Product & Consignments)

1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.

- 2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.
- **3.** Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining waiver of registration &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by MSD/SPC.

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

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

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

#### **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. (Not applicable for Surgical Non Consumables)

In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty(as clause No. 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. (Not applicable for Surgical Non Consumables)

#### **Standards & Quality**

- **9.** Standards: 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.
- 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 from the supplier.
  - (b).In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of **the quality failed supplies** with 25% administrative surcharge of the same.
- 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.(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 quality failed (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 for surgical Non-Consumables

- **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 at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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 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°c +/- 2°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 **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- **24.** In respect of the products requiring controlled temperature storage (Eg. < 25°c, 2-25°c, 15-20°c/30°c, 2-8°c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30°c +/- 2°c & 75% +/- 5% RH for **AC stored** items and at 25°c +/- 2°c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.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 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.
- **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.(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 <a href="www.msd.gov.lk">www.msd.gov.lk</a>), 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. 08,05,10,13)
- 38. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 39. To be supplied as per the delivery schedule indicated in the order list.
- 40. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.

- 41. Where a purchase for a particular item is being made for the first time from a supplier or where there are previous quality failures on goods supplied by a particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- 42. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement
- 43. This tender is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Tender or shall register himself and such public contract act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of Registration with the tender.
- 44. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 45. Offer validity should be 01/12/2020.
- 46. When the time of arrival of goods to Sri Lanka, the residual shelf life should be remained 85% or more out of total product shelf life as per the regulation of Import & Export Controller of Sri Lanka.
- 47. If you are not interested in participating, please acknowledge the receipt of this invitation with the reason for not quoting.

#### 48. BIDS FROM THOSE OTHER THAN MANUFACTURERS

Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacturer 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.

#### Special conditions for Surgical Non Consumable Item

- a. No. -17, under general condition for Non Consumable item shelf-life is not applicable.
- b. No. -17, under general condition for Non Consumable- Freshly manufactured product should be supplied.
  - Warranty document should be address to SPC with a copy to D/MSD and Warranty period is consider from the date of acceptance the consignment by MSD. Each individual items should be included a Warranty card with contact details of authorized local agent. Warranty details/period should be included in label and invoice.
- c. General condition 8 and 16 are not applicable for Surgical Non-Consumables.
- d. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided, if requested by MSD.
- e. Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)
- f. Provide copy of quotation with catalogue numbers for all article/components including special instrument sets at the stage of offered item acceptance.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the total Tendered Price exceeds LKR 1 million. Bid Bond should be submitted with valid up to 31/12/2020 together with the tender.

Sufficient quantity of samples should be forwarded for evaluation.

### CONTRACT AND ARBITRATION (A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement is applicable normally for awards which are over LKR 500,000.00 (Five Hundred Thousand).

## (NEW PROCEDURES TO BE ADOPTED TO FACILITATE THE IMPLEMENTATION OF MSMIS PROJECT)

(a) In respect of multi-component items that are ordered as kit items under single SR number, representing all components as one assembled unit, all deliveries of such items to MSD should be in the form of kits (all its components assembled together) with a commercial invoice indicating the number of kits and its S.R. number, describing & quantifying the individual components that forms the kit.

MSD will not accept parts of the full complement of components making the kit, that are delivered by different suppliers at different times and such deliveries will be rejected, even when the different components are sourced from different suppliers.

### DHS/RSS/RQ/19/20

#### 2020/SPC/A/C/S/00372 CLOSING ON: 27<sup>TH</sup> MAY, 2020 AT 2.00 pm

ITEM/ SR NO	ITEM	QTY
01/14003700	Auto - Disable syringes for DMPA injection, 1ml. General characteristics: Single - use, Sterile, non toxic and non pyrogenic including a mechanism to prevent reuse. Material: Polypropylene Syringe size with pre-set volume and single marking: 1ml Needle: Diameter; 22G (0.7mm), Length 25mm- 32mm Each Syringe with needle should be in one blister pack. Needle cap and cap over thumb plate (if applicable) make syringe into a sterile unit. Shelf life: Remaining minimum of 3/4 of the life time at the time of delivery. Requirements: Should conform to WHO performance specification E8/DS.1 and ISO quality system standard 7886-4. Offers should be only from WHO pre-qualified AD syringe suppliers recommended by World Health Organization (WHO) for bulk purchase for U.N. Agencies.	300,000 Nos

Packing: 1 Nos

Delivery: JUNE/2020

#### NB:

If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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.

### Samples Catalogue/Literature should be submitted for evaluation

#### **General Conditions:**

Offers should be submitted in the format as per annexure.

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

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

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

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

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

#### **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. (only applicable for Non Consumable Items)
- 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

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 life, 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 (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 quality failed (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) (only applicable for Pharmaceutical Products)

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 at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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°c +/- 2°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 **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses bone by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

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

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.(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 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. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 38. To be supplied as per the delivery schedule indicated in the order list.
- 39. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.
- 41. Where a purchase for a particular item is being made for the first time from a supplier or where there are previous quality failures on goods supplied by a particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.

- 42. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement
- 43. This tender is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Tender or shall register himself and such public contract act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of Registration with the tender.
- 44. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 45. Offer validity should be 23/11/2020.
- 46. When the time of arrival of goods to Sri Lanka, the residual shelf life should be remained 85% or more out of total product shelf life as per the regulation of Import & Export Controller of Sri Lanka.
- 47. If you are not interested in participating, please acknowledge the receipt of this invitation with the reason for not quoting.

#### 48. BIDS FROM THOSE OTHER THAN MANUFACTURERS

Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacturer 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.

#### Special Conditions for Surgical Consumables item

- a. The product should have minimum of 36 months shelf life at the time of delivery to Medical Supplies Division. Requested shelf life for Surgical Consumable is 36 months unless specified in the special order conditions/specifications/order list remarks.
- b. General condition 7 and 16 are not applicable or Surgical Consumable Items.
- c. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided.
- d. Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)
- e. Further to the condition 33, Tender Sample of the selected bid shall be forwarded to MSD to use as reference sample to check the consignment supplied on the indent/PO.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the total Tendered Price exceeds LKR 1 million. Bid Bond should be submitted with valid up to 23/12/2020 together with the tender.

Sufficient quantity of samples should be forwarded for evaluation.

### CONTRACT AND ARBITRATION (A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement is applicable normally for awards which are over LKR 500,000.00 (Five Hundred Thousand).

## (NEW PROCEDURES TO BE ADOPTED TO FACILITATE THE IMPLEMENTATION OF MSMIS PROJECT)

(a) In respect of multi-component items that are ordered as kit items under single SR number, representing all components as one assembled unit, all deliveries of such items to MSD should be in the form of kits (all its components assembled together) with a commercial invoice indicating the number of kits and its S.R. number, describing & quantifying the individual components that forms the kit.

MSD will not accept parts of the full complement of components making the kit, that are delivered by different suppliers at different times and such deliveries will be rejected, even when the different components are sourced from different suppliers.

### DHS/RSS/RQ/181/19

### 2019/SPC/A/C/S/00252 CLOSING ON: 04<sup>TH</sup> JUNE, 2020 AT 2.00 pm

ITEM SR No	Item Specification	Quantity
17/13408001	8Fr 18-20cm: Percutaneous Femoral Venous Cannula for ECMO, for weight 2-5 Kg, kink resistant, wire wounded, bevel tipped catheter, Seldinger needle, scalpel blade, 0.025¿x 60 cm Seldinger guide wire, Introducer with depth marker, stepped vessel dilators, non vented 6.3mm connector, peel open, sterile.	01 Nos
18/13408002	10Fr 18-20cm: Percutaneous Femoral Venous Cannula for ECMO, for weight 2-5 Kg, kink resistant, wire wounded, bevel tipped catheter, Seldinger needle, scalpel blade, 0.038¿x 100 cm Seldinger guide wire, Introducer with depth marker, stepped vessel dilators 8/10Fr, non vented 6.3mm connector, peel open, sterile.	01 Nos
19/13408003	12Fr 18-20cm: Percutaneous Femoral Venous Cannula for ECMO, for weight 2-5 Kg, kink resistant, wire wounded, bevel tipped catheter, Seldinger needle, scalpel blade, 0.038¿x 100 cm Seldinger guide wire, Introducer with depth marker, stepped vessel dilators 8/10Fr and 11/12Fr, non vented 6.3mm connector, peel open, sterile.	01 Nos
20/13408004	14/15Fr 18-20cm: Percutaneous Femoral Venous Cannula for ECMO, for weight 2-5 Kg, kink resistant, wire wounded, bevel tipped catheter, Seldinger needle, scalpel blade, 0.038?x 100 cm Seldinger guide wire, Introducer with depth marker, stepped vessel dilators 8/10Fr and 12/14Fr, non vented 6.3mm connector, peel open, sterile.	01 Nos
25/13408009	23 Fr 40-50cm long, Percutaneous Femoral Venous Cannula for ECMO, for 15 -30 Kg weight, Kink resistant, wire wounded, multiport tipped catheter, Seldinger needle, scalpel blade, Haemostasis cap, 0.038¿x 180 seldinger guide wire, Introducer with depth marker, Stepped vessel dilators 8/10Fr and 12/14Fr, Non vented 12.5mm connector, sterile, peel ope	01 Nos
26/13408010	25 Fr 40-50cm long, Percutaneous Femoral Venous Cannula for ECMO, for 30 -50 Kg weight, Kink resistant, wire wounded,multiport tipped catheter, Seldinger needle, scalpel blade, Haemostasis cap, 0.038?x 180 seldinger guide wire, Introducer with depth marker, Stepped vessel dilators 8/10Fr, 12/14Fr and 16/18Fr Non vented 6.3mm connector, sterile, peel open.	01 Nos
27/13408011	27 Fr 40-50cm long, Percutaneous Femoral Venous Cannula for ECMO, for 30 -50 Kg weight, Kink resistant, wire wounded,multiport tipped catheter, Seldinger needle, scalpel blade, Haemostasis cap, 0.038?x 180 seldinger guide wire, Introducer with depth marker, Stepped vessel dilators 8/10Fr, 12/14Fr and 16/18Fr Non vented 6.3mm connector, sterile, peel open.	01 Nos

28/13408012	29 Fr 40-50cm long, Percutaneous Femoral Venous Cannula for ECMO, for over 50 Kg weight, Kink resistant, wire wounded, multiport tipped catheter, Seldinger needle, scalpel blade, Haemostasis cap, 0.038&x 180 seldinger guide wire, Introducer with depth marker, Stepped vessel dilators 8/10Fr, 12/14Fr and 16/18Fr Non vented 6.3mm connector, sterile, peel open.	02 Nos
29/13408101	8Fr 18-20cm: Percutaneous Femoral Arterial Cannula for ECMO, for weight 2-5 Kg, kink resistant, wire wounded, bevel tipped catheter, Seldinger needle, scalpel blade, 0.025¿x 60 cm Seldinger guide wire, Introducer with depth marker, stepped vessel dilators, non vented 6.3mm connector, peel open, sterile.	02 Nos
30/13408102	10Fr 18-20cm: Percutaneous Femoral Arterial Cannula for ECMO, for weight 2-5 Kg, kink resistant, wire wounded, bevel tipped catheter, Seldinger needle, scalpel blade, 0.038?x 100 cm Seldinger guide wire, Introducer with depth marker, stepped vessel dilators 8/10Fr, non vented 6.3mm connector, peel open, sterile	02 Nos
31/13408103	12Fr 18-20cm: Percutaneous Femoral Arterial Cannula for ECMO, for weight 2-5 Kg, kink resistant, wire wounded, bevel tipped catheter, Seldinger needle, scalpel blade, 0.038¿x 100 cm Seldinger guide wire, Introducer with depth marker, stepped vessel dilators 8/10Fr and 11/12Fr, non vented 6.3mm connector, peel open, sterile.	02 Nos
37/13408201	13Fr Percutaneous VenoVeno Cannula for ECMO for 2-5 Kg weight, maximum insertion length of 6-8 .5 cm, drain flow @ -50mmHg 600ml, Maximum return flow range@ +250mmHg 500ml/min, connector size 6.3mm, wire wounded, Kink resistant, multiple side holes, with introducer kit: 22G needle, 18 G IV catheter, 24G IV catheter, 0.018?guide wire in coil sheath, 0.035¿-0.038?guide wire in coil sheath, dilators & introducer sheath, sterile.	03 Nos
38/13408202	16Fr Percutaneous VenoVeno Cannula for ECMO for 5- 8 Kg weight, maximum insertion length of 8 - 10 cm, drain flow @ -50mmHg 850ml, Maximum return flow range@ +250mmHg 775ml/min, connector size 6.3mm, wire wounded, Kink resistant, multiple side holes, with introducer kit: 22G needle, 18 G IV catheter, 24G IV catheter, 0.018¿guide wire in coilsheath, 0.035¿guide wire in coil sheath, dilators & introducer sheath, sterile.	03 Nos
40/13408204	23Fr Percutaneous VenoVeno Cannula for ECMO for 15- 30 Kg weight, maximum insertion length of 16 - 18 cm, drain flow @ -50mmHg 3000ml, Maximum return flow range@ +250mmHg 2500ml/min, connector size 9.4mm, wire wounded, Kink resistant, multiple side holes, with introducer kit: 22G needle, 18 G IV catheter, 24G IV catheter, 0.018¿guide wire in coil sheath, 0.035¿guide wire in coil sheath, dilators & introducer sheath, sterile.	03 Nos
41/13408205	28Fr Percutaneous VenoVeno Cannula for ECMO for 15- 30 Kg weight, maximum insertion length of 20 - 24 cm, drain flow @ -50mmHg 4300ml, Maximum return flow range@ +250mmHg 3500ml/min, connector size 9.4mm, wire wounded, Kink resistant, multiple side holes, with introducer kit: 22G needle, 18 G IV catheter, 24G IV catheter, 0.018¿x 180 cmguide wire in coil sheath, 0.035¿x 180 cm guide wire in coil sheath, dilators & introducer sheath, sterile.	03 Nos

42/13408206	32Fr Percutaneous VenoVeno Cannula for ECMO for over 50 Kg weight,	03 Nos
	maximum insertion length of 25 cm, drain flow @ -50mmHg 5300ml,	
	Maximum return flow range@ +250mmHg 4700ml/min, connector size	
	9.4mm, wire wounded, Kink resistant, multiple side holes, with	
	introducer kit: 22G needle, 18 G IV catheter, 24G IV catheter, 0.018¿x	
	180 cm guide wire in coil sheath, 0.035¿x 180 cm guide wire in coil	
	sheath, dilators & introducer sheath, sterile.	

Packing: 1 Nos

**Delivery: Immediately** 

#### NB:

If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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#### Samples Catalogue/Literature should be submitted for evaluation

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

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

4. The number of batches per consignment shall be minimal. Batch quantity shall be an equal multiple of the quantity of the consignment and the proportionate size of the batch quantity shall be not less than 15% of the quantity in the consignment.

5. If MSD decides to accept a part or full consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging etc.) due to an urgency, that shall be done subject to, either rectifying the defect within 05 working days by the supplier, or recovering the total cost [a] of rectifying the defect by MSD (via a duly contracted third party providing such services), from the supplier with a 25% surcharge on the labeling cost. (total charge = [a]+[a]x0.25) or 2% of the invoiced value, whichever is the highest.

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

#### **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. (only applicable for Non Consumable Items)
- 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 life, 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 (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 quality failed (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) (only applicable for Pharmaceutical Products)
- 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
  - 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 at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
  - Format shall be according to Code 128 or 2D standards.
  - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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°c +/- 2°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;

- 24. 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.
- 25. 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.
- 26. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses bone by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- 27. 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.
- 28. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 29. 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**

30. 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.

- 31. 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.
- 32. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below;
  - (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its' latest amended delivery schedules.
  - (b). When the delay exceeds 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.
- 33. (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.
- 34. 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 other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.
- 35. 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.
- 36. 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**

37. 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.

- 38. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).
  - The 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.
- 39. 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.
- 40. 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. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 43. To be supplied as per the delivery schedule indicated in the order list.
- 44. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.
- 41. Where a purchase for a particular item is being made for the first time from a supplier or where there are previous quality failures on goods supplied by a particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- 42. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement
- 43. This tender is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Tender or shall register himself and such public contract act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of Registration with the tender.

- 44. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 45. Offer validity should be 01/12/2020.
- 46. When the time of arrival of goods to Sri Lanka, the residual shelf life should be remained 85% or more out of total product shelf life as per the regulation of Import & Export Controller of Sri Lanka.
- 47. If you are not interested in participating, please acknowledge the receipt of this invitation with the reason for not quoting.

#### 48. BIDS FROM THOSE OTHER THAN MANUFACTURERS

Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacturer 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.

#### Special Conditions for Surgical Consumables item

- a. The product should have minimum of 36 months shelf life at the time of delivery to Medical Supplies Division. Requested shelf life for Surgical Consumable is 36 months unless specified in the special order conditions/specifications/order list remarks.
- b. General condition 7 and 16 are not applicable or Surgical Consumable Items.
- c. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided.
- d. Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)
- e. Further to the condition 33, Tender Sample of the selected bid shall be forwarded to MSD to use as reference sample to check the consignment supplied on the indent/PO.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the total Tendered Price exceeds LKR 1 million. Bid Bond should be submitted with valid up to 31/12/2020 together with the tender.

Sufficient quantity of samples should be forwarded for evaluation.

## CONTRACT AND ARBITRATION (A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement is applicable normally for awards which are over LKR 500,000.00 (Five Hundred Thousand).

## (NEW PROCEDURES TO BE ADOPTED TO FACILITATE THE IMPLEMENTATION OF MSMIS PROJECT)

(a) In respect of multi-component items that are ordered as kit items under single SR number, representing all components as one assembled unit, all deliveries of such items to MSD should be in the form of kits (all its components assembled together) with a commercial invoice indicating the number of kits and its S.R. number, describing & quantifying the individual components that forms the kit.

MSD will not accept parts of the full complement of components making the kit, that are delivered by different suppliers at different times and such deliveries will be rejected, even when the different components are sourced from different suppliers.

### DHS/RSS/RQ/183/19

#### 2019/SPC/N/C/S/00171 CLOSING ON: 04<sup>TH</sup> JUNE, 2020 AT 2.00 pm

ITEM/ SR NO	ITEM	QTY	DELIVERY
01/14000205	Hypodermic Syringes, 2.5ml/3ml with Needle, single use plastic, conforming tosterile single use plastic syringes BP1993 complying with international standard ISO 7886 -1984(E) for hypodermic syringes for single use and British Standard BS 5081: Part 1 and 2 1987 for sterile hypodermic syringes andneedles), with 0.1ml graduations, with double seal piston (3 part) or medicalgrade plastic plunger (2 part), with mounted needle of size 30G x 31mm long.Sterile, non toxic and pyrogen free, for dental use.	10,000 Nos	50,000 Nos- Immediately 50,000 Nos – 3 months after 1 <sup>st</sup> lot
02/14102901	Venous Blood Sampling Set for new born and infants, conforming to ISO standards, with winged needles, luer lock fitting, sterile.	1,200 Nos	600 Nos- Immediately 600 Nos – 2 months after 1 <sup>st</sup> lot

Packing: 1 Nos

#### NB:

If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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.

#### Samples Catalogue/Literature should be submitted for evaluation

#### **General Conditions:**

Offers should be submitted in the format as per annexure.

#### General (Product & Consignments)

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

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

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

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

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

#### **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. (Not applicable for Surgical Non Consumables)

In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty(as clause No. 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. (Not applicable for Surgical Non Consumables)

#### **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.
- 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 from the supplier.
  - (b).In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of **the quality failed supplies** with 25% administrative surcharge of the same.
- 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.(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 quality failed (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 for surgical Non-Consumables
- 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 at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.

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

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

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 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°c +/- 2°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 **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
- d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
- e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

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

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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. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 38. To be supplied as per the delivery schedule indicated in the order list.
- 39. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.
- 41. Where a purchase for a particular item is being made for the first time from a supplier or where there are previous quality failures on goods supplied by a particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.

- 42. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement
- 43. This tender is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Tender or shall register himself and such public contract act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of Registration with the tender.
- 44. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 45. Offer validity should be 01/12/2020.
- 46. When the time of arrival of goods to Sri Lanka, the residual shelf life should be remained 85% or more out of total product shelf life as per the regulation of Import & Export Controller of Sri Lanka.
- 47. If you are not interested in participating, please acknowledge the receipt of this invitation with the reason for not quoting.

#### 48. BIDS FROM THOSE OTHER THAN MANUFACTURERS

Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacturer 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.

#### **Special conditions for Surgical Non Consumable Item**

- a. No. -17, under general condition for Non Consumable item shelf-life is not applicable.
- b. No. -17, under general condition for Non Consumable- Freshly manufactured product should be supplied.
  - Warranty document should be address to SPC with a copy to D/MSD and Warranty period is consider from the date of acceptance the consignment by MSD. Each individual items should be included a Warranty card with contact details of authorized local agent. Warranty details/period should be included in label and invoice.
- c. General condition 8 and 16 are not applicable for Surgical Non-Consumables.
- d. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided, if requested by MSD.
- Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)
- f. Provide copy of quotation with catalogue numbers for all article/components including special instrument sets at the stage of offered item acceptance.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the total Tendered Price exceeds LKR 1 million. Bid Bond should be submitted with valid up to 03/12/2020 together with the tender.

Sufficient quantity of samples should be forwarded for evaluation.

### CONTRACT AND ARBITRATION (A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement is applicable normally for awards which are over LKR 500,000.00 (Five Hundred Thousand).

## (NEW PROCEDURES TO BE ADOPTED TO FACILITATE THE IMPLEMENTATION OF MSMIS PROJECT)

(a) In respect of multi-component items that are ordered as kit items under single SR number, representing all components as one assembled unit, all deliveries of such items to MSD should be in the form of kits (all its components assembled together) with a commercial invoice indicating the number of kits and its S.R. number, describing & quantifying the individual components that forms the kit.

MSD will not accept parts of the full complement of components making the kit, that are delivered by different suppliers at different times and such deliveries will be rejected, even when the different components are sourced from different suppliers.

### DHS/RSS/RQ/184/19

#### 2019/SPC/N/C/S/00251 CLOSING ON: 04<sup>TH</sup> JUNE, 2020 AT 2.00 pm

ITEM/ SR NO	ITEM	QTY	DELIVERY
26/20509801	Retractor, Valve Leaflet, Cleland type or similar, (UK pattern), 250mm (approx.) length, stainless steel.	01 No	100% - Immediately
27/20509901	Retractor, Valve, for Off Pump Coronary Bypass Graft (OPCABG) Surgery, Octopus type or similar, with flexible arm, stainless steel.	01 No	100% - Immediately

Packing: 1 Nos

#### NB:

If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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.

#### Samples Catalogue/Literature should be submitted for evaluation

#### **General Conditions:**

Offers should be submitted in the format as per annexure.

#### General (Product & Consignments)

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

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

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

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

#### **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. (Not applicable for Surgical Non Consumables)

In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty(as clause No. 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. (Not applicable for Surgical Non Consumables)

#### **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.

- 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 from the supplier.
  - (b).In case of product withdrawal, **value of entire product quantity** supplied shall be recovered from the supplier.
  - (c). In the event of either a) or b) above, supplier shall be surcharged the total **cost involved for MSD**, of **the quality failed supplies** with 25% administrative surcharge of the same.
- 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.(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 quality failed (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 for surgical Non-Consumables
- 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 at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
  - Format shall be according to Code 128 or 2D standards.
  - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).
- 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.
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    - c.If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
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  - 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. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 38. To be supplied as per the delivery schedule indicated in the order list.
- 39. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.
- 41. Where a purchase for a particular item is being made for the first time from a supplier or where there are previous quality failures on goods supplied by a particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- 42. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement
- 43. This tender is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Tender or shall register himself and such public contract act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of Registration with the tender.

- 44. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 45. Offer validity should be 01/12/2020.
- 46. When the time of arrival of goods to Sri Lanka, the residual shelf life should be remained 85% or more out of total product shelf life as per the regulation of Import & Export Controller of Sri Lanka.
- 47. If you are not interested in participating, please acknowledge the receipt of this invitation with the reason for not quoting.

#### 48. BIDS FROM THOSE OTHER THAN MANUFACTURERS

Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacturer 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.

#### Special conditions for Surgical Non Consumable Item

- a. No. -17, under general condition for Non Consumable item shelf-life is not applicable.
- b. No. -17, under general condition for Non Consumable- Freshly manufactured product should be supplied.
  - Warranty document should be address to SPC with a copy to D/MSD and Warranty period is consider from the date of acceptance the consignment by MSD. Each individual items should be included a Warranty card with contact details of authorized local agent. Warranty details/period should be included in label and invoice.
- c. General condition 8 and 16 are not applicable for Surgical Non-Consumables.
- d. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided, if requested by MSD.
- e. Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)
- f. Provide copy of quotation with catalogue numbers for all article/components including special instrument sets at the stage of offered item acceptance.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the total Tendered Price exceeds LKR 1 million. Bid Bond should be submitted with valid up to 31/12/2020 together with the tender.

Sufficient quantity of samples should be forwarded for evaluation.

## CONTRACT AND ARBITRATION (A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement is applicable normally for awards which are over LKR 500,000.00 (Five Hundred Thousand).

# (NEW PROCEDURES TO BE ADOPTED TO FACILITATE THE IMPLEMENTATION OF MSMIS PROJECT)

(a) In respect of multi-component items that are ordered as kit items under single SR number, representing all components as one assembled unit, all deliveries of such items to MSD should be in the form of kits (all its components assembled together) with a commercial invoice indicating the number of kits and its S.R. number, describing & quantifying the individual components that forms the kit.

MSD will not accept parts of the full complement of components making the kit, that are delivered by different suppliers at different times and such deliveries will be rejected, even when the different components are sourced from different suppliers.

### DHS/RSS/RQ/186/19

#### 2019/SPC/N/C/S/00308 CLOSING ON: 27<sup>TH</sup> MAY, 2020 AT 2.00 pm

ITEM/ SR NO	ITEM	QTY
09/13512202	Coronary Guiding Catheter, Ikari Left Curve, size 7F, Inner diameter > 0.081", curve style IL 2, 90cm - 100cm length, sterile.	25 Nos
10/13512102	Coronary Guiding Catheter, Ikari Left Curve, size 7F, Inner diameter > 0.081", curve style IL 1.5, 90cm - 100cm length, sterile.	20 Nos

**Delivery: Immediately** 

Packing: 01 Nos

NB:

If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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.

#### Samples Catalogue/Literature should be submitted for evaluation

#### **General Conditions:**

Offers should be submitted in the format as per annexure. General (Product & Consignments)

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

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

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

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

#### **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. (Not applicable for Surgical Non

In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty(as clause No. 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. (Not applicable for Surgical Non Consumables)

#### **Standards & Quality**

Consumables)

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

- 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.(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 quality failed (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 for surgical Non-Consumables
- 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 at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
  - Format shall be according to Code 128 or 2D standards.
  - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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 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°c +/- 2°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 **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
- 24. In respect of the products requiring controlled temperature storage (Eg. < 25°c, 2-25°c, 15-20°c/30°c, 2-8°c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30°c +/- 2°c & 75% +/- 5% RH for **AC stored** items and at 25°c +/- 2°c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.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 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.
- 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.(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 <a href="www.msd.gov.lk">www.msd.gov.lk</a>), 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. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 38. To be supplied as per the delivery schedule indicated in the order list.
- 39. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.
- 41. Where a purchase for a particular item is being made for the first time from a supplier or where there are previous quality failures on goods supplied by a particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- 42. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement
- 43. This tender is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Tender or shall register himself and such public contract act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of Registration with the tender.
- 44. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 45. Offer validity should be 23/11/2020.
- 46. When the time of arrival of goods to Sri Lanka, the residual shelf life should be remained 85% or more out of total product shelf life as per the regulation of Import & Export Controller of Sri Lanka.
- 47. If you are not interested in participating, please acknowledge the receipt of this invitation with the reason for not quoting.

#### 48. BIDS FROM THOSE OTHER THAN MANUFACTURERS

Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacturer 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.

#### Special conditions for Surgical Non Consumable Item

- a. No. -17, under general condition for Non Consumable item shelf-life is not applicable.
- b. No. -17, under general condition for Non Consumable- Freshly manufactured product should be supplied.
  - Warranty document should be address to SPC with a copy to D/MSD and Warranty period is consider from the date of acceptance the consignment by MSD. Each individual items should be included a Warranty card with contact details of authorized local agent. Warranty details/period should be included in label and invoice.
- c. General condition 8 and 16 are not applicable for Surgical Non-Consumables.
- d. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided, if requested by MSD.
- e. Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)
- f. Provide copy of quotation with catalogue numbers for all article/components including special instrument sets at the stage of offered item acceptance.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the total Tendered Price exceeds LKR 1 million. Bid Bond should be submitted with valid up to 23/12/2020 together with the tender.

Sufficient quantity of samples should be forwarded for evaluation.

## CONTRACT AND ARBITRATION (A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement is applicable normally for awards which are over LKR 500,000.00 (Five Hundred Thousand).

# (NEW PROCEDURES TO BE ADOPTED TO FACILITATE THE IMPLEMENTATION OF MSMIS PROJECT)

(a) In respect of multi-component items that are ordered as kit items under single SR number, representing all components as one assembled unit, all deliveries of such items to MSD should be in the form of kits (all its components assembled together) with a commercial invoice indicating the number of kits and its S.R. number, describing & quantifying the individual components that forms the kit.

MSD will not accept parts of the full complement of components making the kit, that are delivered by different suppliers at different times and such deliveries will be rejected, even when the different components are sourced from different suppliers.

### DHS/RSS/RQ/187/19

#### 2019/SPC/A/C/S/00254 CLOSING ON: 27<sup>TH</sup> MAY, 2020 AT 2.00 pm

ITEM/ SR NO	ITEM	QTY
16/13400300	Arterial Cannula for ECMO (Extracorporeal Membrane oxygenation), for neonate, size 6Fr, sterile.	04 Nos
17/13400303	Arterial Cannula for ECMO (Extracorporeal Membrane oxygenation), for paediatric, size 10Fr, sterile.	02 Nos
19/13400305	Arterial Cannula for ECMO (Extracorporeal Membrane oxygenation), for paediatric, size 14Fr, sterile.	02 Nos

Delivery: 100% Immediately

Packing: 1 Nos

#### NB:

If offers are received on Import & Supply basis from local suppliers, those offers should be in LKR. All local suppliers/manufacturers should quote in LKR for the total delivery price to MSD stores.

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.

#### Samples Catalogue/Literature should be submitted for evaluation

#### **General Conditions:**

Offers should be submitted in the format as per annexure.

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

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

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

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

#### **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. (only applicable for Non Consumable Items)
- 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 life, 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 (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 quality failed (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) (only applicable for Pharmaceutical Products)
- 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 at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
  - Format shall be according to Code 128 or 2D standards.
  - Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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°c +/- 2°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 **WDN or copy of the delivery documents.** In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses bone by MSD / SPC in arranging the cold storage shall be recovered from the supplier.
  - d.The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
  - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.
  - 24. In respect of the products requiring controlled temperature storage (Eg. < 25°c, 2-25°c, 15-20°c/30°c, 2-8°c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment.(report shall include studies; at 30°c +/- 2°c & 75% +/- 5% RH for **AC stored** items and at 25°c +/- 2°c & 60% +/- 5% RH for **Cold stored** items. It shall be a true copy of the latest report submitted to NMRA or a report issued within last 05 years). (refer clause No.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 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 other 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.
- 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.(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 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. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.
  - Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.
- 38. To be supplied as per the delivery schedule indicated in the order list.
- 39. In addition to the condition given herein any other relevant conditions as per the tender document issued by SPC are also applicable.
- 41. Where a purchase for a particular item is being made for the first time from a supplier or where there are previous quality failures on goods supplied by a particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.

- 42. In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement
- 43. This tender is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Tender or shall register himself and such public contract act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of Registration with the tender.
- 44. Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.
- 45. Offer validity should be 23/11/2020.
- 46. When the time of arrival of goods to Sri Lanka, the residual shelf life should be remained 85% or more out of total product shelf life as per the regulation of Import & Export Controller of Sri Lanka.
- 47. If you are not interested in participating, please acknowledge the receipt of this invitation with the reason for not quoting.

#### 48. BIDS FROM THOSE OTHER THAN MANUFACTURERS

Bids for supply of goods which are not manufactured by the Bidder should be supported by a Certificate of Authority issued by the Manufacturer 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.

#### Special Conditions for Surgical Consumables item

- a. The product should have minimum of 36 months shelf life at the time of delivery to Medical Supplies Division. Requested shelf life for Surgical Consumable is 36 months unless specified in the special order conditions/specifications/order list remarks.
- b. General condition 7 and 16 are not applicable or Surgical Consumable Items.
- c. Art works and diagrams with dimensions for relevant products with catalog numbers should be provided.
- d. Usage instruction pamphlet/user manuals in print/pdf/video format should be provided. (Such instructions should carry details on maintenance, compatibility and storage)
- e. Further to the condition 33, Tender Sample of the selected bid shall be forwarded to MSD to use as reference sample to check the consignment supplied on the indent/PO.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value of 2% of the total Tendered Price exceeds LKR 1 million. Bid Bond should be submitted with valid up to 23/12/2020 /2020 together with the tender.

Sufficient quantity of samples should be forwarded for evaluation.

## CONTRACT AND ARBITRATION (A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement is applicable normally for awards which are over LKR 500,000.00 (Five Hundred Thousand).

# (NEW PROCEDURES TO BE ADOPTED TO FACILITATE THE IMPLEMENTATION OF MSMIS PROJECT)

(a) In respect of multi-component items that are ordered as kit items under single SR number, representing all components as one assembled unit, all deliveries of such items to MSD should be in the form of kits (all its components assembled together) with a commercial invoice indicating the number of kits and its S.R. number, describing & quantifying the individual components that forms the kit.

MSD will not accept parts of the full complement of components making the kit, that are delivered by different suppliers at different times and such deliveries will be rejected, even when the different components are sourced from different suppliers.