ANNEX - 1

BID NO. : DHS/P/M/WW/08/22
DATE OF ISSUE : 20TH JULY 2021
CLOSING DATE & TIME : 31ST AUGUST 2021 AT 1100 HOURS SRI LANKA TIME

Order List No. 2022/SPC/N/C/P/00025

SR no.	Item Description/Specifications	Quantity	Delivery
00206101	**Dried factor VIII Fraction 200-350 IU vial** Dried factor VIII Fraction BP (Dried Human Antihaemophilic Fraction) OR Human Coagulation Factor VIII Ph Eur. OR Antihemophilic Factor USP OR Dried Human Antihaemophilic Fraction IP Each vial to contain 200 - 350 IU of concentrated, monoclonal purified and detergent treated dried factor VIII Fraction BP,Ph Eur,USP or IP. Note: 1. The item should be stable at temperature 2'C - 8'C. 2. The product should have minimum 24 months shelf life at the time of delivery to MSD. 3. Tenderer should submit detailed specifications of the product offered. 4. The product should ensure, at least two steps on virus inactivation as recommended by WHO/US.FDA 5. The donor selection process should be specified by the manufacturer. 6. Each batch should be certified as free from HIV and hepatitis viruses. 7. Anti viral test methods used for screening for HIV and Hepatitis viruses should be declared by the manufacturer. The test methods used should be approved by WHO/US.FDA. 8. Each vial to be supplied with suitable diluent. 9. The product should be protected from light. Packing : 10 Vials in a box	28,000 Vials	14,000 Vials - August 2022 14,000 Vials - October 2022

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

The amount of Bid Bond: LKR 6,875,954.00 or USD 34,397.00

Bid Bond should be submitted with valid up to 28.03.2022 together with the bid

Bid should be valid till 26.02.2022.

Non refundable Bid Fee Rs. 60,000.00 + Taxes.

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

CONDITIONS OF SUPPLY

(a) Part A

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

   a.) 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.
   b.) 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. 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 unless otherwise mentioned in this document

Shelf life & Warrantees

6. 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 an administrative charge.

   a.) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 24 months for pharmaceuticals.

Standards & Quality

7. 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.

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

9. 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 charge of the same.

10. 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.

    a.) The bidder 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.

11. 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. If the sample/s 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.

12. 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.09).

Pack size, Labeling & Packaging

13. 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.

14. Each pack 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. Product Information Leaflet (PIL) to be included with each pack.

    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.

15. 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..
    The format of Date of Manufacture / Date of Expiry should be declared in the offer and it shall consist at least the YEAR & MONTH.

16. 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.

17. 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).

18. 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.

    a.) 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

19. 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 ^{o}C +/- 2 ^{o}C temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

20. 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.

21. 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.10)

Delivery Requirements

22. 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. 24 on delayed deliveries, shall be applied.

23. All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However sending consignments **to reach Sri Lanka from 15th December to 10th January** shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries.

24. 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 surcharge 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% administrative charge.

25. (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.

26. 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. 24 (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.

27. 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. 24 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

28. 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. 24, 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

29. 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.

30. 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.

    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. Reference sample will be sent by State Pharmaceuticals Corporation (SPC) to MSD.

31. 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.

32. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier.(follow instructions in the website www.msd.gov.lk)

    If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 25 will not be applicable.

Common conditions

32. In addition to the general conditions of supply given herein any other relevant conditions as per the tender document issued by SPC, are also applicable.

Special Conditions for Tendering

1. Each vial should be labeled accordingly and shall be individually packed inside cardboard boxes and each individually packed vial shall bear a leaflet containing chemical composition, pharmacokinetics, pharmacodynamics, therapeutic indications, dosage, method of administration including directions for reconstitution and compatible solutions for infusions, adverse effects, instructions for storage of vials and directions for storage of reconstituted drug, safety data and warning, drug interactions and clinical trial data.

2. The product should conform to bio equivalence criteria of the WHO.

3. Certificate of conformity with the requested Pharmacoepial Standards and relevant product evaluation literature should be submitted along with the bid.

Abbreviations :*NMRA ; National Medicines Regulatory Authority/Sri Lanka,* SPC ; State *Pharmaceuticals Corporation, MSD; Medical Supplies Division, WDN; Wharf Delivery Note.*

(b) Part B

Conditions of Supply specifically applicable for the order list (with SR)

"These products should be revised along with experts in order to meet the efficacy of this life saving antibiotics. All the registered companies who import Meropenem Injection 1g vial should have certificate of standards after obtaining an efficacy test (MIC - Minimal Inhibitory Concentrations and other internationally approved sensitivity standards) as per BP/USP and tested at NDQAL in Sri Lanka. In addition should produce pre shipment test certificate. Further should be adhered to random sample testing and tests following end users complaints."