PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Department of Health Services for year 2023.

Bid Number	Closing Date & Time	Item Description	Date of issue of Bidding Documents from	Non-refundable Bid Fee
DHS/P/WW/27/23	29.12.2022 at 9.00 a.m.	**40,000 Sets of Etonogestrel Implant single rod**	15.11.2022	Rs. 20,000/= + Taxes

Bids should be prepared as per particulars given in the Bidding Documents available to prospective bidders on working days between 0930 hours to 1500 hours at the Head Office of the State Pharmaceuticals Corporation of Sri Lanka, "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5. These could be purchased on cash payment of a non-refundable Bid Fee per set as mentioned above. Offers received without enclosing original payment receipt are liable to be rejected.

Wherever applicable potential bidder/bidders should get registered in terms of the Public Contract Act No.3 of 1987 before collecting the Bidding Documents and also should get the contract registered after the tender is awarded.

All Bids should be accompanied by a Bid Bond as specified in the Bidding Documents.

Sealed Bids may be sent by post under registered cover or may be personally deposited in the box available for this purpose at Administration Department of the State Pharmaceuticals Corporation at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 5, Sri Lanka.

Bids will be closed at the Head office of the State Pharmaceuticals Corporation on the dates and time mentioned above and will be opened immediately thereafter.

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

Bidding Documents are being sent to Sri Lanka missions abroad and foreign missions in Sri Lanka.

CHAIRMAN DEPARTMENTAL PROCUREMENT COMMITTEE
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
"MEHEWARA PIYASA", 16TH FLOOR
NO. 41, KIRULA ROAD
COLOMBO 5.
SRI LANKA.

FAX : 00 94-11- 2344082
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E-MAIL : pharma.manager@spc.lk

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

ANNEX-1

TENDER NO. : DHS/P/WW/27/23
DATE OF ISSUE : 15TH NOVEMBER 2022
CLOSING DATE & TIME : 29TH DECEMBER 2022 AT 09.00 HOURS SRI LANKA TIME

ORDER LIST NO. : 2023/SPC/N/R/P/00024

SR No.	Item Description/ Specification	Quantity	Delivery
01300501	**Etonogestrel Implant single rod** Single rod subdermal implant in a pre loaded, sterile and disposable applicator (blister pack) Each rod should contain Etonogestrel 68mg BP/USP. The rod should consist of non absorptive, clinically safe meterial for subdermal implantation. 1.The product should be stable under normal room temperature (28'C - 32'C) and humidity (75% - 100%) prevailling in Sri Lanka 2.The expiry date should not be less than 5 years from the date of manufacture. 3.The supply should be from freshly manufactured stocks and should reach Sri Lanka within 3 months of manufacture. Packing : One set in a pack	40,000 sets	20,000 Sets – April 2023 20,000 Sets – October 2023

Representative Tender samples to be submitted for the evaluation.

The amount of Bid Bond: LKR 1,502,496.00 or USD 4,134.00

Bid Bond should be submitted with valid up to 27.07.2023 together with the bid

Bid should be valid till 27.06.2023.

Non refundable Bid Fee Rs. 20,000.00 + Taxes should be paid in cash to SPC for each set of Tender Documents.

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

CONDITIONS OF SUPPLY

(a) Part A

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

2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Purchase Order (PO)/Indent of SPC and wherever applicable shall have a valid product registration or waiver of registration from NMRA.

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

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

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

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

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

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

Shelf life & Warrantees.

7. Freshly manufactured stocks of the product shall be supplied; thereby the residual Shelf Life (shelf life remaining at the time of delivery of goods at the MSD stores/ Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Indent/PO or as certified in the product registration certificate or indicated in any other way by NMRA.

   (a) When the shelf life is not specified in the indent/PO/item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for pharma. / laboratory items.
   The difference of the residual and requested product shelf life shall not exceed $1/6^{th}$ (one sixth) of the original product shelf life.

   (b) In the violation of the above tender condition, SPC/MSD reserves the right to accept a reduced quantity, that is usable (as per the consumption rate) up to three months before the expiry of same and will subject to application of a penalty (as clause No. 36).

Standards & Quality

8. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopoeial Standards that are indicated in the item specifications, other Pharmacopoeial Standards accepted in the product registration by the National Medicines Regulatory Authority.

9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items and the user manual/ instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.
   Any product deficient of or incompatible with, its sub components/ accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be rejected.

10. Withdrawal from use of items due to quality failure found as manufacturer/s fault:

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

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

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

12. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (to be selectively applied for Surgical & Lab items, depending on availability of testing methodology & facilities).
    If the sample is found to be substandard, random batch samples will be tested from all the batches/lots in the consignment, and entire expenses on such tests, like value of samples, transport, sampling & testing charges, etc, will be recovered from the supplier.

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

Pack size, Labeling & Packaging

14. Offers for pack sizes at a lower level (smaller quantity per pack) than the pack size specified in the item description/specification and MSD order List, are also acceptable, but higher level (larger quantity per pack) pack sizes will not be entertained unless otherwise offered with the original bid and accepted by the procurement committee, with the concurrence of MSD.

15. In respect of bulk packs (not applicable for blister/strip packs), 'DHS' mark shall be ;
    (a). embossed or printed in case of tablets
    (b). printed in case of capsules
    Above condition can be waved off, if the quantity in the purchase order is less than 100,000 tablets/capsules, (any exemptions to this condition, is notified in the relevant MSD order list)

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

    It is essential to include and exactly match the dates of Expiry (& date of Manufacture (in any form as 'Year & Month' or 'No Exp.'), in the innermost pack and supplier's invoice.
    (Applicability of the innermost pack mentioned in this clause shall be adapted as per the pack specified in the specification.)

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

18. All outer most cartons (shipping packages) shall bear the MSD Purchase Order No, SPC Indent No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

19. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
    Format shall be according to Code 128 or 2D standards.

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

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

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

Storage Conditions & Temperature

21. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30 ^{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.

22. Maintenance of Cold Chain;
    a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.

    b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colours and sizes for easy identification of cold cargo. Supplier shall use standardized USB Devices for temperature data logging inside the packages and shall provide free of charge, data logger readers &/ software (reading apps compatible with Windows-07/latest) to wharf department of SPC in advance, to enable examining the maintenance of cold chain in transit, and before taking over the consignment by MSD.

    c. If the cold chain break is observed at the time of taking over the consignments by MSD, such consignments shall be rejected, indicating the reason on the relevant WDN or copy of the delivery documents. In such an event, the SPC shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

    d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
    e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

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

Delivery Requirements

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

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

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

26. Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described below ;

    (a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its? latest amended delivery schedules.

    (b). When the delay exceeds 60 days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, MSD reserve the right to recover liquidated damages or to revoke the cancellation (eg. if payments have been released prior to such a cancellation), and accept the consignment subject to a 25% admin surcharge.

27. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its' amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

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

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

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

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

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

Documents & Information

31. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.

32. One of the tender samples of the selected bid shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO.(applicable for all surgical items and regular category of laboratory items, when specified in respective order lists).

The artwork of the; specimen labels, minimum pack and outer most box/shipper carton, that satisfies the above mentioned labeling conditions, shall also be provided before signing the contract with the performance bond.

33. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) SPC Imports department and MSD by e-mail (follow instructions in website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.

34. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD by the supplier. (follow instructions in the website www.msd.gov.lk)
    If it is not complied or the information so provided are found to be incomplete/false, the grace period (for supply delays) mentioned in the clause 26 will not be applicable.

Common conditions

35. In addition to the general conditions of supply given herein, item/order-list specific amendments, exclusions or additions to the same, stated in the covering letter of the order list and any other relevant conditions as per the tender document issued by SPC, are also applicable. The order/item specific; new conditions or amendments to General Order Conditions, will be included in the order list itself and as a remark entry in the MSMIS order records.

36. Administrative surcharge of 25% (on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. (eg. As in conditions No. 07,05,09,12)

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

(b) Part B

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

(i) Etonogestrel 68mg Single Rod Implant specification which was sent by FHB is attached herewith.

<u>Special Conditions for Bidding :</u>

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

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

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

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

6. If the shipment is being effected on FCL basis both FOB and Freight charges should be quoted separately against each item in addition to quoted C & F price. The volume of the total quantity of each item should be given in cubic meters (m^3).

7. Representative samples in respect of items offered should be submitted to reach SPC on or before the **closing time on the closing date** of tender and acknowledgement receipt to be obtained from Administration Department of SPC.
   Sufficient quantity of Samples should be forwarded for evaluation

8. The original payment receipt for purchasing the bidding document has to be annexed to the offer. Offers without same will be rejected.

9. Procurement Committee has the authority to decide whether pre-shipment/ pre delivery/post delivery samples to be tested. In such cases the supplier will have to bear the cost of testing samples.

10. The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer himself (with the name and designation of the signatory) or by the representative. Representatives submitting offers on behalf of their principals should submit a letter of authorization and power of attorney (if signing on behalf of the principals) and also should submit documentary proof on their registration as per the Act. No. 03 of 1987 with the Department of the Registrar of Companies – Sri Lanka (where applicable).

11. The successful supplier should agree to dispatch by fax/courier a full set of copy document to SPC at least 3 days prior to arrival of consignment in Sri Lanka to prevent any delay in clearance.

    Demurrage /additional charges if any which become payable due to supplier's failure to comply with this requirement will be claimed from the supplier.

12. In the event of an award made to you on this tender, SPC reserves the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.

13. This bid is administered by the provisions of the "Public Contract Act No. 3 of 1987" and therefore, in the event bidder is to retain an agent, representative, nominee for and on behalf of Bid or shall register himself and such public contact act in accordance with the section 10 of the Public Contract Act and produce such valid original certificate of registration with the bid.

14. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly showed on Bill of Lading/Airway Bill and invoice.

15. **Destination Terminal Handling charges (THC) should be borne by the supplier at the Port of Loading. Hence when the C&F prices are quoted this should be inclusive of THC.**

16. All shipments should be made exclusively on vessels belonging to the Ceylon Shipping Corporation or those chartered by CSC. Shipments on other vessels will be permitted in instances where vessel of the Ceylon Shipping Corporation do not call at the Port of shipment or if they are not available for time by shipment of cargo, in which event the supplier should attached a waiver certificate issued by Ceylon Shipping Corporation or their Authorized Agent in the Supplier's Country.

17. SPC reserves the right to reject offers which do not comply with above conditions.

18. In case of an offer of product not registered with NMRA, bidders should submit documents in the annexure 1 (checklist for WOR) along with the offer to consider under exceptional circumstances.

    Checklist for Waver of Registration,
    - Certificate of Analysis (COA) of the relevant product
    - Certificate of Pharmaceutical Product
    - Label of the Product
    - Product Information Leaflet (PIL)
    - Pro-forma Invoice.

    In the event of an award of an un registered product, SPC will apply for a WOR from NMRA and the supplier shall submit corresponding samples of the product; upon the demand of SPC; for onward submission to NMRA.

    However, NMRA may request for additional information/documentation to consider allowing the WOR and the suppliers may refer the official website of NMRA (www.nmra.gov.lk) for more details on the documentation required.
    The payment due to NMRA for issuance of WOR; shall be borne by the supplier/Local Agent.

SR 1300501

Annex - I,

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Specifications for Subdermal Implants-Single Rod: Etonogestrel 68mg x 1

2023 Order

Product	Implant - Etonogestrel 68 mg USP/BP
Quantity	• **40,000 (Forty thousand) sets**
Description	Single Rod Subdermal Implant in a preloaded, sterile and disposable applicator (blister pack). Each rod should contain Etonogestrel 68 mg USP/BP. The rod should consist of non absorptive, clinically safe material for subdermal implantation. • The product should be stable under normal room temperature (30°C - 35°C) and humidity (75%-100%) prevailing in Sri Lanka. • The expiry date should not be less than 5 years from the date of manufacture. • The supply should be from freshly manufactured stocks and should reach Sri Lanka within 3 months of manufacture.
Pre-qualifications	The manufacturer should have the following documents 1. Good Manufacturing Practices (GMP) certification in accordance with recommendations of WHO, from the country of manufacture. 2. Evidence of pre-qualification by WHO, UNFPA, USAID, Population Council or IPPF. 3. Registration with National Medicines Regulatory Authority of Sri Lanka (NMRA). 4. Certificate of the Pharmaceutical Product (COPP). 5. Registration for product to be marketed in the country of manufacture. 6. Evidence of use in the country of manufacture. 7. List of countries that are currently using the product with documentation of evidence of use such as copy of registration certificate & sales data for at least 2 years, preferably 5 years. The list must include one or more of the following countries: Australia, Canada, European Union countries, Japan, Malaysia, Singapore, Switzerland, Sweden, Thailand, USA. 8. Real time stability data at recommended storage conditions for 5 years. 9. A certificate of analysis from a WHO accredited laboratory for all batches prior to shipment, on the onus of the supplier. The test result should conform to the specifications declared by the manufacturer. **N.B.** Even after delivery of goods, samples of the product will be sent to a WHO accredited laboratory at the supplier's expense if there is any suspicion of quality failure or complaint regarding the product.

Labelling	Should contain the following information: **Blister pack individual cover box:** • Date of manufacture, date of expiry and batch/lot No: to be printed in black. • The logo of the Family Health Bureau, logo of Government of Sri Lanka and the wordings Family Health Bureau, Ministry of Health, Sri Lanka should be clearly printed in black. • Storage condition, Name of manufacturer, Country of origin • The wording "NOT FOR SALE" should be printed in red. **Note:** As the blister pack comes in a sealed unit labelling to be on individual cover box. **Inner Box:** • Date of manufacture, Date of expiry and batch/lot no • The logo of the Family Health Bureau, logo of Government of Sri Lanka • The wordings Family Health Bureau, Ministry of Health, Sri Lanka should be clearly printed in black. • Storage condition, Name of manufacturer, Country of origin • The wording "NOT FOR SALE" should be printed in red **Outer (Corrugated) box:** A label should be pasted or printed on all four sides of the box with the following information. • Generic name and strength (also Brand name if applicable) • Logo of the Family Health Bureau/Logo of Government of Sri Lanka • Wordings 'Family Health Bureau, Ministry of Health, Sri Lanka' • Quantity (in each box)/Batch/Lot no • Date of manufacture/Date of expiry • Storage condition, Name of manufacturer, Country of origin
Packaging	• 1 rod and the applicator should be in a blister pack, 10 blister packs per inner box, 200 inner boxes per carton. The carton should be made of corrugated cardboard with double wall, Strength 1400 g/sqm. • The corrugated box should be strong and should not lose its shape when stacked (up to 8 feet), during storage.
Delivery/Shipment	• The total quantity should be delivered as one consignment. • **Director MCH, Family Health Bureau should be informed 10 days prior to the arrival of shipment.**

Note: All normal conditions of supply will apply.

Please refer Global Bid Document

B: Global Tender - Bid Document for Pharmaceutical DPC