STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(ESTABLISHED UNDER THE STATE INDUSTRIAL CORPORATIONS ACT, NO. 49 OF 1957)
16th Floor, "Mehewara Piyasa" 41, Kirula Road, Colombo 05 Sri Lanka
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E-Mail: .mgrsurgical@spc.lk

Date: 21ST SEPTEMBER, 2022

M/S

Dear Sirs/ Madam,

BIDDING DOCUMENT FOR INVITATION OF RESTRICTED BIDS (DPC) FOR THE SUPPLY OF SURGICAL CONSUMABLES /NON-CONSUMABLES FOR EMERGENCY PURCHASE FROM INDIA WITH FACILITY OF INDIAN CREDIT LINE

BID NO. : DHS/ICL/X/RSS/055/2022
CLOSING AT 9.00 am SRI LANKA TIME ON : 28TH SEPTEMBER , 2022

State Pharmaceuticals Corporation hereby invite your C&F prices in USD for the supply of the item(S) listed in the Annex I, which is for use in Government Medical Institutions.

TERMS AND CONDITIONS OF BID/INSTRUCTIONS TO BIDDERS

1. SUBMISSION OF BID.

1.1 Bid shall be submitted in one Original and One Duplicate sealed separately and marked as "Original " and "Duplicate" respectively. Both envelopes shall together be enclosed in one envelope sealed and addressed to 'Chairman/ Departmental Procurement Committee, State Pharmaceuticals Corporation of Sri Lanka, 16th Floor, "Mehewara Piyasa" 41, Kirula Road, Colombo 05 Sri Lanka.

1.2 Bids, if sent through the Post, should be sent under registered cover. A Bidder may also personally deposit sealed Bids in the Tender Box provided for this purpose at Administration Department of the State Pharmaceuticals Corporation of Sri Lanka, 16th Floor, "Mehewara Piyasa" 41, Kirula Road, Colombo 05 Sri Lanka.

The left-hand top-corner of the envelopes should indicate the Bid Reference and the closing date of Bid. Bids should be received on or before the closing date and time of Bid. Late Bids will not be entertained under any circumstances. The Corporation shall not accept responsibility for the Bid misplacement or premature opening of Bids if the envelopes have not been marked as given above.

2. FORMAT OF BID/ BID SUBMISSION FORM & PRICE SCHEDULE

02.1 Bids should be submitted according to the format given in **Annex IIA & IIB.**
02.2 Bids which are not in the prescribed format or are not in strict conformity with the terms, conditions and specifications laid-down in this Bid shall be rejected.

02.3 The Bid shall contain no interlineations, or even writing except as necessary to correct errors made by the Bidder - in which case such corrections shall be initialled by the person or persons signing the bid.

02.4 All Bids, literature etc., should be in the English Language.

02.5 The bid submitted should be duly signed and endorsed by the Bidder himself (the name and designation of the signatory, should be indicated).

3. VALIDITY OF OFFER

Bidders should keep their offers valid for acceptance for a period of at least 180 days from the date of closing of tender. No increase in price will be permitted after tender awarded.

4. ELIGIBLE GOODS AND REGISTRATION

4.1 WITH THE NATIONAL MEDICINES REGULATORY AUTHORITY (NMRA)

(a) All Surgical /Lab items imported to Sri Lanka should be registered with the NMRA of Sri Lanka.

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

5. FRESH STOCKS AND SHELF LIFE

5.1 Supplies should be conformed to the stipulated specifications and shelf life as stated in Annex-1, Residual shelf life should be at least 75% at the time of receipt of goods at MSD.

5.2 Corporation reserves the right to call for free replacement of goods supplied with inadequate residual shelf life, reimbursement the cost of goods or reject such deliveries.

6. COUNTRY OF ORIGIN AND NAME OF MANUFACTURER

The Country of Origin should be India and Name of Manufacturer should be indicated in the Bid Form at Annex- II B.

7. BID OPENING

7.1 Bids will be opened immediately after closing, at the Head Office of the State Pharmaceuticals Corporation at 16th Floor, "Mehewara Piyasa" 41, Kirula Road, Colombo 05 Sri Lanka at the date and time specified in **Annex- 1**.

7.2 The bidder or their authorized representatives will be permitted to be present at the opening of Bids.

7.3 Only the copy of the bid marked 'Original' will be opened at the time of opening of Bids.

7.4 The Bid Opening Committee who opens the bids will read out (or cause to be read out) to those present, the name of each Bidder as well as the amount quoted together with discounts, if any.

7.5 Any other detail which the Bid Opening Committee determines as necessary will be read out.

8 REIMBURSEMENT

8.1 Corporation reserves the right to call for reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf-life, also for packs which cannot be identified due to labels falling off or items with incorrect labelling.

8.2. All quality problems/complaints should be confirmed by the NMRA/ Technical Advisory Committee (TAC) of Sri Lanka/ SPC Quality Assurance Laboratory or any other Authority as decided by the Ministry of Health of Sri Lanka.

a. In the event of receipt of a complaint sample will be tested by NMQAL, and follow the recall procedure approved by the Ministry of Health and will be destroyed according to section 72 of Drug regulations.

b. In case of withdrawals due to quality failure Suppliers should ensure that the value of entire quantity of either the withdrawn batches or products would be totally reimbursed with an additional 25% of the total value concerned as an Administrative Cost.

9. PERFORMANCE BOND

9.1 The successful Bidder shall within 07 days from the notification of award should submit an unconditional Performance Bond up to 25% of the total value of award and should be valid 3months beyond the last delivery date.

Failure to comply with this request shall constitute sufficient grounds for the Corporation to cancel such award and forfeit the Bid Bond/Security.

9.2 However, the **Departmental Procurement Committee** reserves the Right to increase/decrease the required Performance Bond at their discretion.

9.3 The Performance Bond shall be as per specimen **Annexure- IV -** and shall be issued by one of the Bank /institutions approved by the Central Bank of Sri Lanka.

9.4 Claims on the Performance Bond will be made by the Corporation on the very first instance the supplier fails to comply with the terms and conditions of the Bid or Purchase Order.

10. CONTRACT AND ARBITRATION

(A) CONTRACT

The successful supplier should agree to enter into a Contract/Agreement with the State Pharmaceuticals Corporation.

(B) ARBITRATION

If during the continuance of this Contract or at any time after the termination thereof, any difference or disputes which may arise between the parties hereto in regard to this interpretation of any of the provisions herein, contained or any other matter or thing relating to this contract (other than any difference or dispute in respect of which a decision of the Chairman of the State Pharmaceuticals Corporation of Sri Lanka, is declared to be final and binding on the parties hereto) such difference or dispute shall be forthwith referred to an Arbitral Tribunal in Sri Lanka. Composition of the Arbitral Tribunal, Jurisdiction of the Arbitral Tribunal, Conduct of Arbitration Proceedings, awards and any other matters relating

to the Arbitration shall abide by Arbitration Act No. 11 of 1995 of the Democratic Socialist Republic of Sri Lanka. The place of Arbitration shall be in Sri Lanka.

11. PACKING AND STORAGE CONDITIONS

i. Pack Size offered should conform to requirements. Bids for alternate pack sizes may be rejected. Export-worthy packing which will prevent damage in transit should be used. Details of nature of packing should be given.

ii. Packing of all items should be suitable for storage and use under tropical conditions. Final packing should indicate the required storage temperature for goods which require Refrigeration/ Cool Room/ Freezer Storage enabling the cargo handling staff to arrange proper storage for such goods immediately on receipt.

iv. Containers and closures used should be of such quality so as not to react with the contents while in storage under tropical conditions.

v. Final export packing should be in seaworthy strong cases or cartons, stenciled with blue bands in the form of a cross on each face and in addition carrying the shipping marks, details of which will be provided with order. Such export packing should be suitable to withstand the long sea Journey and rough handling at ports of loading and unloading. Bag cargo should be palletized and shrink wrapped. All bulk packs containing tablets or capsules should include a pouch of Silica Gel, which has a colour guide. This is important to maintain the shelf life of the product under high humidity conditions which prevail in Sri Lanka.

vi. Sri Lankan ambient storage conditions are in the ranges of 30^0C +/- 2^0C temperature and 75% +/-5% relative humidity.

vii. The items which have to be stored between 2^o C – 8^o C should be delivered with cold chain monitors.

viii. The Recommended storage mentioned on the Product label should be maintained at all levels including in transit and storage condition should be clearly shown on Invoice. All outer carton and inner box should contain the following information.

(a) Description of the Item
(b) Date of Manufacturer
(c) Date of Expiry
(d) Batch No.
(e) Name and Address of manufacturer

ix. If any damage (s) caused due to non-compliance of packing to the above-mentioned conditions, supplier should bear the full cost of damages.

12. LABELLING

12.1 All labels should be printed in English Language and the labeling requirements should be according to the specifications required for registration at **NMRA** as follows;

c. Description of the item in generic form.
d. The Brand Name.
e. List of contents.
f. A statement of the net contents (e.g., number of units, weight or volume).
g. Any special storage conditions that may be necessary.
h. Warnings and precautions that may be necessary.
i. The Date of Manufacture, where applicable.
j. The Date of expiry, where applicable.
k. The batch or lot number assigned by the manufacturer.

l. The name and Address of the manufacturer.

12.2 Size of the letters of the above (f), (g), (h) and the SR Number on the outer carton should not be less than 1.5 cm.

12.3. Name of the manufacturer or identification mark should be imprinted in a permanent manner on surgical consumable items.

13. PAYMENTS

Will he arrange as per the terms and condition of Indian credit Line facility agreement with The Government of Sri Lanka. Payment will be made in Indian Rupee (INR) equivalent to offer price in USD.

14. TENDER AWARD

Awards are made to suppliers taking into consideration among other factors, prices quoted, past performance, quality of samples, delivery offered, product registration etc. And the decision of the Procurement Committee is final.
The Procurement Committee reserves to itself the right without question to:-

(a) Accept any bid, or portion of a bid,
(b) Accept portions of more than one bid
(c) Reject all or any bids
(d) Direct that fresh bids be called for
(e) Cancel the bid

The relevant **Procurement Committee** reserves the right, at time of award to decrease/increase the quantity required, by 25% without any change in price or other terms and conditions.

In case lowest evaluated responsive supplier is Bidding for a product which has not been supplied before, the relevant **Procurement Committee** reserves the right to purchase only part quantity from such supplier and to get a feedback from the end users to decide on the balance quantity.

However, in such cases the price offered for the total amount should be maintained for the smaller quantity.

15. DELIVERY

Reference **Annex I** - Successful bidders should conform strictly to delivery dates. Failure to do so will result in forfeiture of the Performance Bond and/or cancellation of the award.

If awarded supplier is unable to adhere to the delivery schedule due to no fault of the SPC would result in the supplier being surcharged as per the condition mentioned under "condition of supply" in Annex I.

16. TESTING OF BATCH SAMPLES

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

an administrative cost within 30 days from the date of intimation.

17. **QUALITY CERTIFICATE**

(a) Corporation reserves the right to nominate Independent Competent Authorities for the issue of pre-shipment Certification (Certificate of Quality, Quantity and Loading). In such an event, the cost of **such certification** must be borne by the supplier and should be included in the Bid (**Annex 11B).**

(b) The Secretary, Ministry of Health, Sri Lanka reserves the right to nominate suitable persons to inspect the production and quality control facilities of bidders and manufacturers and their records. Bidders, who refuse permission to our nominees to carry out such an audit will be automatically disqualified.

(c) The expenses involved. In the inspections should be borne by the manufacturer/ supplier.

18. WHO CERTIFICATION SCHEME FOR QUALITY OF SURGICAL /LAB ITEMS MOVING IN INTERNATIONAL COMMERCE

(a) A certificate of Surgical/Lab items issued by the Competent Authority in the manufacturer's country confirming that the item bided has been authorized to be placed in the market for sale and use in the country of manufacture, should be submitted along with the Bid(s).

(b) The certificate of Surgical/Lab items should also certify that the Manufacturing Plant in which the product is produced is subject to inspection at suitable intervals, and that the manufacturer conforms to the requirement for Good Practices in manufacture and quality control as recommended by the World Health Organization in respect of products to be sold or distributed within the country of origin or to be exported.

(c) All batches offered should conform to the requirements of the Competent Authority for sale or distribution within the country of manufacture or where appropriate to established specifications provided by the manufacturer. These certificates should indicate the name and dosage form of the product, the batch number, the date of manufacture, date of expiry, storage conditions, date of packaging, labeling, nature of the container, date of sterilization, the method of the sterilization, results of analysis and other data (BATCH CERTIFICATES).

19. PRODUCT LIABILITY

In the event of an order being placed, the supplier should indemnify the State Pharmaceuticals Corporation of Sri Lanka against all product liability claims arising out of the items supplied on his bid. E.g. due to incorrect labelling, deviation from agreed specifications etc.

20. PATENT RIGHTS (AND OTHER THIRD-PARTY RIGHTS) AND ROYALTIES

The suppliers shall at all times indemnify and keep this Corporation indemnified against any and all claims arising at any time on Account of Patent rights or other rights, whether from manufacturers or others, from the use of the supplied goods in Sri Lanka.

21. 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 at the time of submitting bidding documents indicating that the bidder has been duly authorized to supply the goods bided for. Failure to comply will result in the offer being rejected.

22. TERMS & CONDITIONS AND CLARIFICATION

Prospective Bidders should acquaint themselves, fully with these terms and conditions and if any further clarification is required please contact the undersigned, No plea of lack of information or insufficient information will be entertained at any stage.

This procurement is coming under Indian Credit Line facility therefore bidder required to furnish following document along with their bids as indicate below.

a. Form "A" -Supportive documents to be submitted with the Performa Invoice.
b. Form "B" -Format of Questionnaire
c. Form "C" -Applicant's JV Members information form
d. Form "D""D1" -Exporters Bank letter head
e. Form "E" -Affidavit
f. Form "F" - Bank details etc.

23. EXAMINATION, EVALUATION AND COMPARISON OF OFFERS

23.1 The purpose of bid evaluation is to determine the lowest evaluated bid from the substantially responsive bids received.

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.

i. Preliminary examination

The Bid received will be examined by the Technical Evaluation Committee appointed for each bid to determine whether they are complete, whether they are from eligible bidders, whether required bid bond has been furnished in required format, whether the document has been properly signed, whether any computational errors and whether the samples are provided if required and whether the specimen Bid form at **Annex 11 (A)** has been followed and the price schedule as per **Annex 11 (B**) has been followed.

ii. Prior to detailed evaluation

The TEC will determine the substantial responsiveness of each offer to the bidding documents as pursuant to clause 26.1.(i). A substantially responsive bid is one, which conform to all the conditions described in clause 26.1 (i) without any deviation. A bid determined as not substantially responsive will be rejected and may not subsequently be made responsive by the bidder by correction of the non-conformity.

The offers, which are previously determined to be substantially responsive to clauses.

23.2 (i), (ii) will be further evaluated.

iii) The TEC and the Corporation will also examine the Bids in order to ensure the correctness of the Bids. Arithmetical errors, if any, will be corrected on the following basis;

a) If Discrepancy is between Unit Price and Total Price, then the Unit Price shall prevail and the Total Price will be corrected.

b) If Discrepancy is between words and figures, the amount in words will prevail.

c) If a Discrepancy appears between the original bid and the duplicate, the original will prevail.

iv) All the items offered in Annex 11B should conform strictly to the technical specifications set out in the Annex 1 of this document and will be taken in to account at the time of evaluation.

- Unless specifically stated in this document any other relevant Terms & Conditions of Bid/Instructions to Bidders any annexures mentioned in 'Global Bid Document Surgical & Laboratory Items DPC' available for perusal at web site of SPC under emergency tenders, Home page, main menu under the Tab 'Tenders' in www.spc.lk and Guide Lines for Procurement of Pharmaceuticals issued by the Government with its subsequent amendments/revisions will be applicable.

- In the event of conflict between Global Bid Document Pharmaceutical DPC, Procurement Guide Line for Procurement of Pharmaceuticals and Medical Devices Procurement Guide Lines issued by the Government 2007, and subsequent Amendments/Supplements this 'Bidding Document for Invitation of Restricted Bids' shall prevail.

Yours faithfully

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

PROCUREMENT OFFICER
DHS – [SURGICAL SPECIAL)

Telephone : (00) 94- 11 - 2582509
Fax : (00) 94 – 11 – 2582495
E-MAIL address: dgmsurgical@spc.lk and mgrsurgical@spc.lk

ANNEX I

BID NO./BID REFERENCE : DHS/ICL/X/RSS/055/2022

O.L. No. 2022/SPC/ X/C/S/00567 CLOSING ON: 28TH SEPTEMBER , 2022 AT 9.00 am

Item No./SR No	Item Specification	Quantity	Delivery
01/13901401	Connector Double Swivel 360 degrees, with suction port, with 15mm male and 15mm female fittings, sterie. Paediatric angle piece.	700 Nos.	100% -Immediately
02/13901602	Suction Tube, paediatric, Baby - Yankeur type or similar, 8mm diameter, with luer hub, 210mm (approx.) length, clear transpaent, sterile.	10,000 Nos.	5,000-Immediately 5,000 - 02 months after 1st lot
03/13903101	Closed System Suction Catheter for ventilated patients, single lumen 4FG, 45cm to 65cm length. Sterile.	1,300 Nos	100%-Immediately
04/13903102	Closed System Suction Catheter for ventilated patients, single lumen 6FG, 45cm to 65cm length. Sterile.	800 Nos	100%-Immediately
05/13903200	Closed System Suction Catheter for ventilated patients, double lumen 12FG, 45cm to 65cm length. Sterile.	6,000 Nos.	3,000-Immediately 3,000 - 02 months after 1st lot

Packing : 1 Nos

Sufficient quantity of Representative samples for the item to be submitted for the evaluation as tender samples.

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

MSD CONDITIONS OF SUPPLY

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.

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

3. Maintaining the validity of th 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 surcharge. (as clause No. 37)

6. The specifications of the product offered by the suppliers in the tender, 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. In respect of Non Consumable; laboratory items and surgical items: Manufacturer or supplier or local agent shall provide a warranty for a period, not less than as specified in the specification of the item and/or it's sub components/articles supplied (eg. Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

The supplier's invoice shall indicate, the validity period of the warrantee from the date of receiving goods at MSD and a warrantee card with all details, including the local contact details of warrantee services provider, shall also be inserted in each individual pack.

Foreign suppliers of all such items shall have their own local agent in Sri Lanka, capable of providing technical support, repairs & spares, when necessary. **(This clause No. 07 is not applicable for all Pharmaceuticals and all Consumable Surgical & Laboratory 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 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 Laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.

(b) In the violation of the above tender condition, Director/MSD reserves the right to accept a reduced quantity, that is usable (as per the actual consumption rate) up to three months before the expiry of same and will subject to application of a penalty. (as clause No. 37 and footnote 01).

Standards & Quality

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

10. 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.

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. Description of the Item, 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.

17. 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.

18. 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)

19. 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 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

20. 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 30^0c +/- 2^0c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

21. 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.

22. In respect of the products requiring controlled temperature storage (Eg. < 25^0c, 2-25^0c, 15-20^0c/30^0c, 2-8^0c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment. (Report shall include studies; at 30^0c +/- 2^0c & 75% +/- 5% RH for **AC stored** items and at 25^0c +/- 2^0c & 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

23. 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 DP. Any deviation from this agreed delivery scheduled shall be treated as 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.

24. 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.

25. 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 [8] 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.

26. (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.

27. 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 consignments) 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 additions expenses (i.e. staff OT, forklift charge, etc) of MSD, by the supplier.

28. 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. 23 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C .

29. 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

30. 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.

31. 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 consumable surgical items and laboratory regular items, except when stated otherwise in the relevant order list.)

The product artwork or dimensional detail diagrams, product Catalogs and Catalog No's as necessary for the surgical items (**not relevant to Pharmaceutical & Laboratory items)**, shall be provided with the bid document, for reference in the ; tender evaluation by SPC, ascertaining (before awarding) user acceptance of deviations from the spec by MSD and inspecting the consignments delivered to MSD.

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

32. 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.

33. After releasing the Indent/PO 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 27 will not be applicable.

Common conditions

34. 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.

35. 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).**

36. Offer validity should be 27/03/2023.

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

(b) Part B- Special Order Condition (SOC) of supply

Note:

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

(i) -
(ii) -
(iii) -

Annex II A

SPECIMEN FORM OF BID (SUPPLIES)

Chairman,
Departmental Procurement Committee
……

……

BID FOR THE SUPPLY OF

……

BID NO./BID REFERENCE ……..

1. I/ We, the undersigned, having read and fully acquainted myself/ourselves with the contents of the Terms and Conditions of Bid/Instructions to Bidders and Contract and Annex I where specifications and delivery of items required pertaining to the above Bid, hereby undertake to supply the goods referred to therein, in accordance with the aforesaid Instructions, Terms and Conditions as per price quoted in the attached Annex II B.

2. I/ We confirm that this offer shall be open for acceptance until…… and that it will not be withdrawn or revoked prior to that date.

3. I/We attach hereto the following documents as part of my/our Bid:

   (I) Price schedules (as per Annex II B – Bid Form
   (II) Documentary evidence to establish Registration of product with the National Medicines Regulatory Authority Certificate No …….
   (III) Documentary evidence to establish that goods offered are from an eligible source and origin.
   (Document as required in Para. 4 of the Terms & conditions of the Bid).

   (IV) Any other documents (give details).

4. I/We understand that you are not bound to accept the lowest bid and that you reserve the right to reject any or all Bids or to accept any part of a Bid without assigning any reasons thereof.

5. We undertake to adhere to the Delivery Schedule indicated.

6. My/Our Bank Reference is as follows: ……..
   ……

Signature: ……..

Name of Bidder : ……..
Address: ……..

E-mail: . ……..
Telex - ……..
Fax:. ……..
Date ……

STATE PHARMACEUTICALS CORPORATION – BID FORM

ANNEX 11 (B)

(To be submitted in duplicate)

BID NO./BID REFERENCE..... CLOSING ON: .....

NAME & ADDRESS OF MANUFACTURER :

NAME & ADDRESS OF BIDDER :

(Bidders should prepare their own forms as per this format. Offers which are not as per the format are liable to be rejected)

1	2	3	4	5	6	7	8	9	10
SR NO./ITEM NO.	FULL DESCRIPTION OF ITEM OFFERED, THE STANDARD AND THE STORAGE TEMPERATURE	PACK SIZE OFFERED	QTY OFFERED	PROBABLE SHIPMENT/DELIVERY DATE	UNIT PRICE & CURRENCY (DELIVERY PRICE TO MSD STORES)	TOTAL DELIVERY PRICE TO MSD STORES	NMRA REGISTRATION CERTIFICATE NO. & DATE OF EXPIRY	SHELF LIFE	COUNTRY OF ORIGIN

1. Cost of Inspection Certificate (If not included in the unit delivered price).....
   Indicate from whom independent Pre-shipment Certificate of Quality, Quantity and Loading will be submitted.

2. Indicate date when samples were submitted: - .....
3. Quotation Valid upto :-.....
4. Local manufacturers/ Importers should indicate in column No. 10 Local /Total delivery price to Stores at Medical Supplies Division, No. 357, Baddegama Wimalawansa Thero Mawatha, Colombo 10.

We confirm that we have read and understood the terms, conditions and specifications covering this tender and submitted our offer accordingly. We are not listed as defaulted/ black-listed Bidder in any Government Institution in Sri Lanka. "In the event of goods being rejected due to un-acceptable quality, reimbursement of its value and an additional 25% of the total value at landed cost as an administrative charge will be made".

Name of Bidder :

Signature of Bidder :
(With Name and Designation of Signatory)

Official Stamp of Bidder :

Postal Address of Bidder :

Telephone No. :

E-mail :

Fax No. :

Name of Bankers with Account No.
Beneficiary :

(Inform your terms and conditions and special instructions for opening Letters of Credit in the event of an award in your favour) .

NOTE
1.Storage temperature of the offered items should be prominently indicated in the column No. 2.

Annex IV

SPECIMEN FORM OF PERFORMANCE BANK GUARANTEE

(UNCONDITIONAL)

BOND NUMBER: …….. **DATE: ……..**

SUM GUARANTEED: ……..

To:…….. (Name of employer)

…….. (Address of employer)

Whereas ……name and address of contractor)
(hereinafter called "the contractor") has undertaken, in pursuance of contract No…….. dated
to execute ……(name of contract) (hereinafter called "the contract");

And whereas it has been stipulated by you in the said Contract that the Contractor shall furnish you with a Bank Guarantee by a recognized Bank for the sum specified therein as security for compliance with his obligations in accordance with the Contract;

And whereas we have agreed to give the Contractor such a Bank Guarantee;

Now therefore we hereby affirm that we are the Guarantor and responsible to you, on behalf of the Contractor, up to a total of …… (amount of Guarantee) …….. (amount in words), such sum being payable in the type and proportions of currencies in which the Contract Price is payable, and we undertake to pay you, upon your first written demand and without cavil or argument, any sum or sums within the limits of …….. (amount of Guarantee) as aforesaid without your needing to prove or to show grounds or reasons for your demand for the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the contractor before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the Contract or of the Works to be performed thereunder or of any of the Contract document which may be made between you and the Contractor shall in any way release us from any liability under this guarantee, and We hereby waive notice or any such change, addition or modification.

This guarantee shall be valid until a date 28 days from the date of issue of the taking over Certificate.

Signature and the Seal of the Guarantor: ……..

Name of the Bank: ……

Address ……

Date: ……

Witness : …….. ……..

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

AGREEMENT

DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

Our Ref No. : ---------- Date : [ ]
Tender No : ----------

This AGREEMENT made and entered into between the State Pharmaceuticals Corporation established under the act. No. 49 of 1957 and having a its Registered office at 75, Sir Baron Jayatilaka Mawatha, Colombo 01, Sri Lanka (hereinafter called the "SPC" which term or expression shall mean and include the said State Pharmaceuticals Corporation and its successors and permitted assigns) of the One Part and ---------- business under the time, style and firm of a company duly registered and carrying business (hereinafter called "the supplier" and which term or expression shall mean and include the said and its/their/its heirs executors administrator and permitted assign/successors in business or permitted assigns) of the Other – Part.

Whereas the State Pharmaceuticals Corporation has accepted the tender of ---------- ------- of ---------- for the supply and delivery of ---------- of ---------- in the manner and quantities as per the attached order for **LKR** ---------- marked ---------- hereof.

NOW IT IS HEREBY AGREED AS FOLLOWS :

1. The following documents :-
   (a) Conditions of contract marked 1
   (b) Bid documents marked 2
   (c) Copy of Purchase Order marked 3

(hereinafter called "the Contract Documents") showing and describing the nature and scope of the Agreement duly signed by both parties shall be deemed to form and be read and construed as part and parcel of this Agreement.

2. In consideration of the payment to be made by SPC to the supplier the contract sum hereinafter mentioned the supplier hereby covenants with SPC to supply and deliver the goods in conformity in all respects with the provisions of this contract.

   The supplier shall be paid for such supply and delivery of the goods according to the **Indent No.** ---------- .marked 3 and in the manner and at the times hereinafter specified.

This contract as herein before defined constitutes the entire agreement between SPC and the supplier and may only be modified or repealed by formal agreement in writing duly executed by the parties or their authorized representatives.

In witness whereof the official Seal to be affixed and the signature of the Authorized officers of the State Pharmaceuticals Corporation of Sri Lanka have set their hands and Suppliers has placed its hand/caused its Common Seal to be affixed hereunto and to two other of the same tenor on this ……..2020.

The Common Seal of **---------- of ----------** herein.

1. ……..
   President/Managing Director/C.E.O.

2. ……..
   Director

Witnesses

Signature	Name, Address and ID No.
1. …….	…….
2 ……..	…….

Annex 1

CONDITIONS OF CONTRACT

1. SCOPE OF CONTRACT

Provide Pharmaceuticals for the Department of Health Services as per the Tender No**.** ---------- closed on ---------- thereof.

2. GOODS

2.1 Supply should be from fresh stocks of recent manufacture conforming to the stipulations in the schedule marked 3 and the samples submitted.

2.2 The goods supplied should have at least 75% residual shelf life at the time of receipt in Sri Lanka.

2.3 Goods supplied should meet the Dissolution Bio equivalence test requirements where applicable.

2.4 SPC reserves the right to :-

(a) Reject goods supplied with an inadequate shelf life

(b) Call for free replacement of goods or reimbursement of cost so supplied which do not conform to required standards.

3. FREE REPLACEMENT AND /OR REIMBURSEMENT DUE TO QUALITY ISSUE

3.1 SPC reserves the right to call for the replacement or reimbursement in the event of

3.1.1 Short packing

3.1.2. Loss damage or deterioration of goods supplied (within Shelf Life)

3.1.3. Packs which cannot be identified due to labels falling off.

3.1.4. Goods supplied fails to perform or meet requirements of the specification to the satisfaction of SPC. (quality/standard)

3.2 In the event of quality problem, Batch samples would be tested by SPC/its authorized personnel at the NMQAL or its fitness for use will be determined by an expert committee appointed by the relevant Authority.

Samples from the available batches will be **retained** by SPC and the balance will be destroyed by authorized officers in the presence of **supplier** and a certificate of destruction issued by SPC following destruction.

In case of Batch/Product withdrawals due to quality failure the supplier should reimburse SPC the total value of the entire quantity of either withdrawn batches of withdrawn product with an additional 25% of the total value concerned as an Administrative Cost.

3.3 Withdrawal form 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

4 **VARIATION**

4.1 The SPC may at the time of Award increase or decrease the order by up to 25% without being subject to any change to price or terms and conditions hereof.

. **5. <u>PACKING AND STORAGE</u>**

5.1 Packing of all items should be suitable for storage and use under tropical conditions and sufficient marking should be made on the cases or containers in order to prevent possible mistakes regarding proper storage during transit, particularly for items requiring refrigeration or cool storage.

5.2 Containers and closures used should be of such quality so as not to react with the contents while in storage under tropical conditions.

5.3 Approved packing material as per bid document should be used. Use of Rice Straw or other vegetable matter as packing is strictly prohibited (as per regulations passed under the Plant Protection Ordinance Chapter 447).

6. LABELLING

6.1 All labels should be printed in English Language and the labeling requirements should be according to the specifications required for registration at NMRA as follows.

a) The approved name found in official pharmacopoeias or formularies. (The source should be stated in abbreviations; e.g. BP or USP etc…)
b) The brand name

c) List of the active ingredients showing;
   a) The amount of each present in each dosage unit (e.g. per 5ml etc…)
   b) A statement of the net contents (e.g. number of dosage units, weight or volume)
d) Any special storage conditions that may be necessary
e) Warning and precautions that may be necessary
f) The Date of manufacture
g) The Date of expiry where applicable
h) The batch or lot number assigned by the manufacturer and
i) The Name and address of manufacturer
j) Name and address of supplier, if supplier is not the manufacturer

6.2 Labeling of the products ordered under this range of indents, in addition to the labeling requirements stipulated in the BP/USP relevant standards

7. TERMS OF DELIVERY

7.1 All items should be **<u>delivered to the warehouse of Medical Supplis Division</u>** and strictly conform to the delivery dates as Copy of Purchase Order marked hereto marked

[Indent Number].

7.2 Requests may be made for supply of goods in more installments than indicated **in the Purchase Order**

7.3 Delivery of all goods should be within the time period/delivery schedule indicated in the Purchase Order

8. PAYMENTS

Payment will be arranged as per the terms and condition of Indian credit facility agreement with Government of Sri Lanka.

9. PERFORMANCE BOND

As security for the due and punctual performance and fulfillment of the terms of this Agreement by the satisfactory completion of the supply and delivery, for the payment of all claims to which SPC may be entitled under the provisions of this Agreement. The supplier has furnished the State Pharmaceuticals Corporation with a Bank Guarantee from a Bank approved by the SPC in the sum **Sri Lankan Rupees [----------] only (LKR ----------).**

10. ARBITRATION

10.1 If any dispute or difference or claim shall arise between the parties as to any point in any agreement or contract arising of the invitation to Bid, or as to any matter or thing of whatsoever nature arising there-under or in connection therewith, then either party shall within 30 days give to the other, notice in writing of such dispute or difference. Such notice shall specify the matters which are in dispute. Such dispute shall be referred to a single arbitrator in case the parties agree upon one; otherwise to three arbitrators; one to be appointed by each party and the third arbitrator by the other two arbitrators. If either party shall refuse or neglect to appoint an arbitrator within twenty days after the other party shall have appointed an arbitrator and given notice thereof requiring such appointment, then the arbitrator appointed as aforesaid shall proceed to hear and determine the matters as if he were and arbitrator appointed by both parties to the dispute.

10.2 The decision or award of the arbitrator or arbitrators (as the case may be) shall be final and binding upon the parties and shall be a prerequisite to any proceedings in a Court of Law.

10.3 The arbitrator or arbitrators shall determine by whom, and in what manner, the cost of arbitration (or any party thereof) shall be borne and paid.

10.4 The arbitration shall be governed by the Arbitration Act. No. 11 of 1995 Laws of Sri Lanka and shall be held in Sri Lanka.

10.5 Performance of the contract shall continue during arbitration proceedings as far as possible.

11. LAW

11.1 The Laws of the Democratic Socialist Republic of Sri Lanka shall govern the validity, performance and enforcement of this contract.

12. INDEMNITY

12.1 The supplier shall at all times keep indemnified the SPC against any and all claims at any time arising on account of -

(a) Patent right or other rights whether from manufacturer or others, from use in Sri Lanka of the goods supplied.

(b) Product liability claims against SPC arising out of the goods supplied under this contract e.g. due to incorrect labeling, deviation from agreed specifications etc.

13. WARRANTY

13.1 The supplier warrants that goods supplied shall be of good quality; shall have no defect in manufacture, shall meet all the requirements of the specifications and shall in all aspects suited for the purposes intended the warranty provided by the supplier shall be relied upon and strictly enforced by SPC.

14. WARRANTY AGAINST BENEFITS

14.1 The supplier warrants that he/it has not given or promised to give any money or gift to any officer or employee of SPC or any Government instrumentality or employee thereof with the intent or objective of securing the contract.

14.2 Any violation of this warranty shall be sufficient grounds for cancellation or revocation of the contract without any claim against SPC.

15. ASSIGNMENT

15.1 Supplier shall not without the prior written consent of the SPC assign his contract or part thereof to another.

16. FORCE MAJEURE

16.1 The supplier shall not be liable for any delay or failure in making delivery of the supplies if it was due to any event which interfered with performance and was beyond the control of the supplier. However, at every time the supplier faces a situation disturbing the due performance of the obligations under this contract due to conditions beyond his/ its control he/it should write to SPC and get its approval. Approval/disapproval will be notified within Seven (7) working days of receipt of same in writing. Parties however shall endeavors to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

17. NOTICE

17.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by **E-mail** addressed to the either party at the respective address` at the beginning hereof written.

INDENT NO : ----------
ITEM : ---------- OF ----------
SUPPLIER : M/s. ----------

MANUFACTURER: M/s. ----------

In witness whereof the official Seal and the signature of the Authorized officers of the State Pharmaceuticals Corporation of Sri Lanka was affixed hereto namely _____ **&** _____

-----(Signature)--------
(Designation)

-----(Signature)--------
(Designation)

Witnesses

Signature	Name, Address and ID No.
1. …….	……
2 ……..	……

Form A

Supportive documents to be submitted with the Performa Invoice.

The following documents should be submitted by the importer with respect to the prospective exporter in India.

	Description	Remarks
01	Nature of entity: Company/ Proprietorship firm/ Others;	Specify here
02	Certificate of Incorporation (or equivalent documents of constitution or association), and/or documents of registration;	Certified by company secretary/ a director/ partner/ lawyer.
03	IEC, PAN and GST Registration details (Copies);	Certified by company secretary/ a director/ partner/ a lawyer.
04	List of Board of Directors with their complete designation in case of nominee Directors;	Certified by company secretary
05	The beneficial ownership with respective shareholding and nationality of shareholders of the JV Member (in case of a JV);	Certified by the company secretary or a director
06	A copy (self-attested on all pages) of Power of Attorney in favour of the person who has been authorised, through an appropriate Company Board Resolution or equivalent document, to sign on behalf of the Applicant;	Certified by the company secretary/ a director/ a partner/ a lawyer.
07	Financial Status & Capacity, certified by the Statutory Auditors of the company/firm;	
08	In case of JV, Applicant's JV Member's Information (in the format attached);	Attach duly filled form "C"
09	Details of non-performed export contracts, if any;	Specify details
10	Copy of necessary Certificates regarding safety from relevant agencies in India such as Food Safety and Standards Authority of India (FSSAI) in case of food items; Drugs Controller General of India (DCGI) in case of medicines etc, wherever applicable;	Certified by the company secretary/ a director/ a partner/ a lawyer.
11	Details, as mentioned in the attached questionnaire;	Attach duly filled form "B"
12	Declaration / Affidavit to the effect that all the information provided in the prescribed format is correct and in case any figures or information given therein are found to be incorrect and/ or certificates/documents provided in support of the relevant information entered therein are found to be fabricated, the contract will not be considered for inclusion under the credit facility (in the format attached).	Attach duly filled form "E"
13	Agreement on Receiving Payments in Indian Rupees (INR) by the Indian Exporter's Bank	Attach duly filled form "D"

Form B

Format of questionnaire

S.No.	Information sought	Response
1.	Has your firm been suspended or debarred by any Multilateral Agency, or any government or government procuring entity, or a UN agency? If Yes, provide details, including date of reinstatement, if applicable. Attach additional sheets, if needed.	**Yes/No**
2.	Has your firm's account been classified as Non-Performing Asset (NPA) with any Bank/FI or your companies/ promoters/ directors appear in Reserve Bank of India (RBI) Caution List, RBI Wilful Defaulter List (Suit filed as well as non-suit filed), Credit Information Bureau India Ltd (CIBIL) Defaulter List or any other negative list of the Indian central or state government agencies, updated from time to time? If yes, please provide details in a separate sheet, as necessary.	**Yes/No**
3.	Has your firm/organization ever filed or petitioned for bankruptcy? If Yes, furnish details of the case including filing date and current status.	**Yes/No**
4.	Has your firm/ any JV partner been penalized for delay in contractual performance in the last 5 years prior to Application submission deadline. If yes, please provide details in a separate sheet, as necessary.	**Yes/No**
5.	Has there been a termination of your contract for nonperformance in the last 5 years prior to the month preceding the month of Application Submission Deadline? If yes, please describe in detail in a separate sheet, as necessary.	**Yes/No**
6.	Is there any pending litigation against the firm, involving the Government of India, State Governments or any Government agencies, on matters relating to financial impropriety, money laundering and/or tax evasion? If yes, please provide additional details.	**Yes/No**

The undersigned declares that all information, statements and description contained in this document is correct in all respects and complete to the best of my knowledge and belief.

Signature……..

Name of the signatory……

Company Name…….

Note: - In case any figures or information given therein are found to be incorrect and/ or certificates/documents provided in support of the relevant information entered therein are found to be fabricated, the contract will not be considered for inclusion under the credit facility.

Form C

Applicant's JV Member's Information Form

S.No.	Details required
1.	Applicant Name:
2.	Applicant's JV Member's name:
3.	Applicants JV Member's country of registration:
4.	Applicants JV Member's date of constitution:
5.	Applicants JV Member's legal address registered in India:
6.	Applicants JV Member's authorized representative information- **Name:** **Address:** **Telephone/Fax No:** **Email address:**

Form D_1

(Exporter's letter head)

----------(date)

(Importer's Name and Address)

Dear Sir

Agreement on Receiving Payments in Indian Rupees (INR)

Performa Invoice No – ……..

Date – ……..

Value in USD – …….

I do hereby agree to receive the payment for the aforementioned consignment of goods supplied to …… (importers name and address), in Indian Rupee terms (INR) under the Credit Facility extended by the State Bank of India to the Government of Sri Lanka vide the Agreement dated 17th March, 2022, subject to the order being approved for export under the said facility.

…….

(Signature)

(Seal)

Form E

AFFIDAVIT

The undersigned declares that all information, statements and description contained in the Application is correct in all respects and complete to the best of our knowledge and belief.

We understand that in case any figures or information given therein are found to be incorrect and/ or certificates/documents provided in support of the relevant information entered therein are found to be fabricated, the contract will not be considered for inclusion under the credit facility

Name of firm/company:

Signature(s) of authorized representative(s) of the Applicant:

Name of signatory:

In the capacity of:

Address:

Date:

Form F

EXPORTER NAME	ADDRESS	GOODS													BANK INFORMATION				
		DESCRIPTION OF GOODS EXPORTED	HS CODE	BILL NO/ INVOICE NO	AMOUNT OF INVOICE	AMOUNT PAYABLE INCLUDING MISC. CHARGES	CONTRY OF ORIGIN OF GOODS	SHIPMENT DATE	SHIPMENT FROM (country)	SHIPMENT FROM (PORT)	SHIPMENT TO (COUNTRY)	SHIPMENT TO (PORT)	COUNTRY OF ORIGIN (EXPORTER)	VESSEL NAME/IMO NO.	BANK NAME	BIC CODE	AD BANK NOSTRO A/C DETAILS	ACCOUNT NUMBER	IEC CODE OF THE EXPORTER

NATIONAL MEDICINES REGULATORY AUTHORITY

SRI LANKA.
120, Norris Canal Road, Colombo 10, Sri Lanka.

Application form for Waiver of Registration OF A MEDICAL DEVICE

For government institution ☐

For private institution ☐

1. Applicant Detail	
1.1 Name of the applicant	
1.2 Address of the applicant	
1.3 Telephone no.	
1.4 E – mail	

2. Details of the Product	
2.1 Official/Common name of the product	
2.2 Brand name (if applicable)	
2.3 Model (if applicable)	
2.4 Sizes (if applicable)	
2.5 Quantity	
2.6 Total cost	

3. Details of Manufacturer	
3.1 Name of the legal manufacturer & country	
3. 2 Name of physical manufacturer & country (If applicable)	

4. Details of the distributor (if applicable)	
4.1 Name of the Distributor	
4.2 Country	

5. Detail of local agent (If applicable)	
5.1 Name	
5.2 Address	
5.3 Contact detail	

6. Importer Detail (If applicable)	
6.1 Name	
6.2 Address	
6.3 Contact detail	

7. Past history of issued WOR of particular item (if applicable)	
7.1 WOR number (Letter No)	
7.2 Date of issue	

8. Reason for WOR (tick √)	
8.1 Registered sources not quoted	☐
8.2 Lowest price than registered item	☐
8.3 Registered product not complied with tender specification	☐
8.4 Manufacturer's name changed	☐
8.5 Government to Government agreement	☐
8.6 No registered sources	☐

8.7 Short shelf life of the product ☐

8.8 Research ☐

8.10Donation

8.11 Other (If so reason should be mentioned) ☐

Remarks

9. Evaluation detail (if applicable)

9.1Name of evaluator	
9.2 Designation	
9.3 Institution	

10. NMRA Registration Status (if applicable)

10.1 Application No	
10.2 Date of submission	
10.3 Certificate of Registration No	
10.4 Validity period	
10.5 Any other NMRA documents/ reference No (if available)	

Declaration of the applicant

I, …… the undersigned, hereby declare that all the information submitted with this application is true and correct and certify that all documents uploaded in support of this application are accurate and most recent as per to date.

Signature :

Date :		
Document required for Waiver of Registration (If available please tick "√") **Note : The NMRA may be required more data where necessary.**		
1.	Letter of Authorization from the manufacturer	☐
2.	Agency transfer letter issued by NMRA	☐
3.	Sample import licence issued by NMRA	☐
4.	Certificate of Registration issued by NMRA	☐
4.	Free sale Certificate issued by Health Authority of Country of Origin of the Product	☐
5.	ISO certificate for quality management system	☐
6.	CE self declaration by manufacturer/ EC certificate for full Quality Assursnce system	☐
7.	Labels of the product	☐
8.	Product Information Leaflet / Catalogs	☐
9.	Report of Technical Evaluation Committee (TEC)	☐
10.	Approval of Procurement Committee	☐
11.	Purchase order / Indent/Commercial invoice	☐
12.	Registration of Medical Council – Sri Lanka	☐
13.	Ethic review committee approval (Applicable for research items)	☐
14.	Research proposal (Applicable for research items)	
15.	No Objection Letter (NOL) from local agent	☐
16.	Sri Lanka Custom Detained Document	☐
17.	Recommendation of Professional bodies (Colleges/Institutions)	☐
18	Request of Professional bodies (Colleges/Institutions)	

NB/ad