KARADENİZ İHRACATÇI BİRLİKLERİ
GENEL SEKRETERLİĞİ

Sayı : 35649853-TİM.KİB.GSK.TEŞVİK.2023/1091-2548 Giresun, 21/08/2023

Konu : Sri Lanka İlaç Kurumu Tarafından Yayımlanan İhale Belgeleri

E-POSTA

KARADENİZ İHRACATÇI BİRLİKLERİ ÜYELERİNE SİRKÜLER
2023 / 447

Sayın üyemiz,

T.C. Ticaret Bakanlığının bir yazısına atfen, Türkiye İhracatçılar Meclisinden alınan 18/08/2023 tarih 744-2321 sayılı yazıda;

Sri Lanka İlaç Kurumunun tıbbi malzeme temini için yayımladığı ve örnekleri Ek.1'de yer alan ihalelerin kapanış tarihleri **29 Ağustos – 7 Eylül 2023**, Ek.2'de yer alan ihalelerin kapanış tarihleri **4 – 5 Eylül 2023** olarak belirtilmekte olup Ek.3, Ek.4, Ek.5 ve Ek.6'da Sri Lanka İhale Şartnameleri ile Ek.7'de Sri Lanka Tedarik İlamı yer almaktadır.

Bilgilerinize sunarız.

e-imzalıdır
Şahin KURUL
Genel Sekreter a.
Şube Müdürü

EKLER:
Ek.1- 1A Sri Lanka Sağlık Ürünleri için İhale İlamı (168 sayfa)
Ek.2- 1B Sri Lanka Sağlık Ürünleri İhale İlamı (168 sayfa)
Ek.3- 2A Sri Lanka İhale Şartnamesi (17 sayfa)
Ek.4- 2B Sri Lanka İhale Şartnamesi (18 sayfa)
Ek.5- 2C Sri Lanka İhale Şartnamesi (19 sayfa)
Ek.6- 2D Sri Lanka İhale Şartnamesi (18 sayfa)
Ek.7- 2E Sri Lanka Tedarik İlamı (3 sayfa)

Şahin KURUL tarafından 5070 sayılı kanun gereğince güvenli elektronik imza ile imzalanmıştır.

Karadeniz İhracatçı Birlikleri Genel Sekreterliği
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Telefon: 0.454.2162426 (PBX)
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Web : www.kib.org.tr

Ayrıntılı bilgi için: Şahin KURUL – Şube Müdürü

Request for Bids
Health Goods

Purchaser: *Ministry of Health, Sri Lanka*

Project: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*

Contract title: *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*

Country: *Sri Lanka*

Loan No. /Credit No. / Grant No.: *IBRD-9296*

RFB No: ***LK-SPC-370463-GO-RFB***

Issued on: 27th Jul. *2023*

1. The ***Government of Sri Lanka / Ministry of Health*** *has received* financing from the World Bank toward the cost of the *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*], and intends to apply part of the proceeds toward payments under the contract for *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial* "For this contract, the Borrower shall process the payments using the Direct Payment disbursement method, as defined in the World Bank's Disbursement Guidelines for Investment Project Financing, except for those payments, which the contract provides to be made through letter of credit."

2. The ***Ministry of Health, Sri Lanka*** now invites sealed Bids from eligible Bidders for *supply of 1,000,000 PFS/vials of Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*

3. Bidding will be conducted through international competitive procurement using a Request for Bids (RFB)as specified in the World Bank's "Procurement Regulations for IPF Borrowers" November 2020 ("Procurement Regulations"), and is open to all eligible Bidders as defined in the Procurement Regulations.

4. Interested eligible Bidders may obtain further information from *Mr. Saman Munasinghe, Manager Imports (DHS- Pharma) of Ministry of Health, Sri Lanka (pharma.manager@spc.lk)* and inspect the bidding document during office hours ***[8.00 to 15.00*** *hours]* at the address given below. *The Bidding Document is published on the website www.spc.lk for reference only.*

5. The bidding document in **English** may be purchased by interested Bidders upon the submission of a written application to the address below and upon payment of a nonrefundable fee of [*LKR. 100,000.00 + Taxes*]. The method of payment will be ***cash***. The document will be handed over to the representative. If no local representative for the interested Bidder the bidding document could be downloaded from the State Pharmaceuticals Corporation of Sri lanka (SPC) web site after submitting proof documents for the payment.

6. Bids must be delivered to the address below on or before 07th September 2023 at 10:00 Hour. Electronic Bidding ***will not*** be permitted. Late Bids will be rejected. Bids will be publicly opened in the presence of the Bidders' designated representatives and anyone who chooses to attend at the address below on 10:00 Hour, 07th September 2023.

7. All Bids must be accompanied by a *"Bid Security"* of *LKR. 19,588,000.00 or equivalent value in USD according to the exchange rate on Bid issuing date.*

8. Attention is drawn to the Procurement Regulations requiring the Borrower to disclose information on the successful bidder's beneficial ownership, as part of the Contract Award Notice, using the Beneficial Ownership Disclosure Form as included in the bidding document.

9. The address referred to above is:

Ministry of Health, Sri Lanka of Sri Lanka
Mr. Sarath Liyanage, Chairman
State Pharmaceuticals Corporation of Sri Lanka.
16th Floor, No. 41, "Mehewara Piyasa", Kirula Road, Colombo 05, Sri Lanka
Tel. : +94 11 2338500
Fax : +94 11 2055800
Email :chairman@spc.lk
Web : www.spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
"MEHEWARA PIYASA" 26TH FLOOR,
NO. 41, KIRULA ROAD, COLOMBO 05.

STANDARD PROCUREMENT DOCUMENT

Request for Bids
Health Sector Goods
(Pharmaceuticals)

Standard Procurement Document

Summary

Specific Procurement Notice

Specific Procurement Notice - Request for Bids (RFB)

The template attached is the Specific Procurement Notice for Request for Bids method, one-envelope Bidding process. This is the template to be used by the Borrower.

Bidding Document: Request for Bids – Health Sector Goods

PART 1 – BIDDING PROCEDURES

Section I - Instructions to Bidders (ITB)

This Section provides information to help Bidders prepare their Bids. Information is also provided on the submission, opening, and evaluation of Bids and on the award of Contracts. **Section I contains provisions that are to be used without modification.**

Section II - Bid Data Sheet (BDS)

This Section includes provisions that are specific to each procurement and that supplement Section I, Instructions to Bidders.

Section III - Evaluation and Qualification Criteria

This Section specifies the criteria to determine the Most Advantageous Bid.

Section IV - Bidding Forms

This Section includes the forms for the Bid submission, Price Schedules, Bid Security, and the Manufacturer's Authorization and Certificate of a Pharmaceutical Product to be completed and submitted by the Bidder as part of its Bid.

Section V - Eligible Countries

This Section contains information regarding eligible countries.

Section VI - Fraud and Corruption

This Section includes the fraud and corruption provisions which apply to this Bidding process.

PART 2 – SUPPLY REQUIREMENTS

Section VII - Schedule of Requirements

This Section includes the List of Goods and Related Services, the Delivery and Completion Schedules, the Technical Specifications and the Drawings that describe the Goods and Related Services to be procured.

PART 3 – CONDITIONS OF CONTRACT AND CONTRACT FORMS

Section VIII - General Conditions of Contract

This Section includes the general clauses to be applied in all contracts. **The text of the clauses in this Section shall not be modified.**

Section IX - Special Conditions of Contract

This Section contains the Special Conditions of Contract (SCC). The contents of this Section modify or supplement, but not over-write, the General Conditions and shall be prepared by the Purchaser.

Section X - Contract Forms

This Section contains the Letter of Acceptance, Contract Agreement and other relevant forms.

Request for Bids
Health Goods

Purchaser: *Ministry of Health, Sri Lanka*

Project: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*

Contract title: *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*

Country: *Sri Lanka*

Loan No. /Credit No. / Grant No.: *IBRD-9296*

RFB No: ***LK-SPC-370463-GO-RFB***

Issued on: 27th Jul. *2023*

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9. The address referred to above is:

Ministry of Health, Sri Lanka of Sri Lanka
Mr. Sarath Liyanage, Chairman
16th Floor, No. 41, "Mehewara Piyasa", Kirula Road, Colombo 05, Sri Lanka
Tel. : +94 11 2338500
Fax : +94 11 2055800
Email :chairman@spc.lk
Web : www.spc.lk

Request for Bids
Health Sector Goods

Procurement of:
Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vials

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Purchaser: *Ministry of Health, Sri Lanka*

Project: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*

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Issued on: 27th July *2023*

Table of Contents

PART 1 – Bidding Procedures

Section I - Instructions to Bidders

Contents

Section I - Instructions to Bidders

A General

1. Scope of Bid

1.1 In connection with the Specific Procurement Notice - Request for Bids (RFB), specified **in the Bid Data Sheet (BDS),** the Purchaser, **as specified in the Bid Data Sheet,** issues this bidding document for the supply of Goods (pharmaceuticals, vaccines, contraceptives, or nutritional supplements) and Related Services incidental thereto as specified in Section VII, Schedule of Requirements. The name, identification and number of lots (contracts) of this RFB are specified **in the Bid Data Sheet.**

1.2 Throughout this bidding document:

(a) the term "in writing" means communicated in written form (e.g. by mail, e-mail, fax, including if specified **in the Bid Data Sheet**, distributed or received through the electronic-procurement system used by the Purchaser) with proof of receipt;

(b) if the context so requires, "singular" means "plural" and vice versa; and

(c) "Day" means calendar day, unless otherwise specified as "Business Day." A Business Day is any day that is an official working day of the Borrower. It excludes the Borrower's official public holidays.

2. Source of Funds

2.1 The Borrower or Recipient (hereinafter called "Borrower") specified **in the Bid Data Sheet** has applied for or received financing (hereinafter called "funds") from the International Bank for Reconstruction and Development or the International Development Association (hereinafter called "the Bank") in an amount specified **in Bid Data Sheet,** toward the project named **in Bid Data Sheet.** The Borrower intends to apply a portion of the funds to eligible payments under the contract for which this bidding document is issued.

2.2 Payment by the Bank will be made only at the request of the Borrower and upon approval by the Bank in accordance with the terms and conditions of the Loan (or other financing) Agreement. The Loan (or other financing) Agreement prohibits a withdrawal from the Loan (or other financing) account for the purpose of any payment to persons or entities, or for any import of goods, equipment, plant or materials if such payment or import, to the knowledge of the

Bank, is prohibited by decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. No party other than the Borrower shall derive any rights from the Loan (or other financing) Agreement or have any claim to the proceeds of the Loan (or other financing).

3. Fraud and Corruption

3.1 The Bank requires compliance with the Bank's Anti-Corruption Guidelines and its prevailing sanctions policies and procedures as set forth in the WBG's Sanctions Framework, as set forth in Section VI.

3.2 In further pursuance of this policy, Bidders shall permit and shall cause their agents (where declared or not), subcontractors, subconsultants, service providers, suppliers, and personnel, to permit the Bank to inspect all accounts, records and other documents relating to any initial selection process, prequalification process, bid submission, proposal submission, and contract performance (in the case of award), and to have them audited by auditors appointed by the Bank.

4. Eligible Bidders

4.1 A Bidder may be a firm that is a private entity, a state-owned enterprise or institution subject to ITB 4.6 or any combination of such entities in the form of a joint venture (JV) under an existing agreement or with the intent to enter into such an agreement supported by a letter of intent. In the case of a joint venture, all members shall be jointly and severally liable for the execution of the entire Contract in accordance with the Contract terms. The JV shall nominate a Representative who shall have the authority to conduct all business for and on behalf of any and all the members of the JV during the Bidding process and, in the event the JV is awarded the Contract, during contract execution. Unless specified **in the Bid Data Sheet**, there is no limit on the number of members in a JV.

4.2 A Bidder shall not have a conflict of interest. Any Bidder found to have a conflict of interest shall be disqualified. A Bidder may be considered to have a conflict of interest for the purpose of this Bidding process, if the Bidder:

(a) directly or indirectly controls, is controlled by or is under common control with another Bidder; or

(b) receives or has received any direct or indirect subsidy from another Bidder; or

(c) has the same legal representative as another Bidder; or

(d) has a relationship with another Bidder, directly or

through common third parties, that puts it in a position to influence the Bid of another Bidder, or influence the decisions of the Purchaser regarding this Bidding process; or

(e) or any of its affiliates participated as a consultant in the preparation of the design or technical specifications of the goods that are the subject of the Bid; or

(f) or any of its affiliates has been hired (or is proposed to be hired) by the Purchaser or Borrower for the Contract implementation; or

(g) would be providing goods, works, or non-consulting services resulting from or directly related to consulting services for the preparation or implementation of the project specified in the BDS ITB 2.1 that it provided or were provided by any affiliate that directly or indirectly controls, is controlled by, or is under common control with that firm; or

(h) has a close business or family relationship with a professional staff of the Borrower (or of the project implementing agency, or of a recipient of a part of the loan) who: (i) are directly or indirectly involved in the preparation of the bidding document or specifications of the Contract, and/or the Bid evaluation process of such Contract; or (ii) would be involved in the implementation or supervision of such contract unless the conflict stemming from such relationship has been resolved in a manner acceptable to the Bank throughout the Bidding process and execution of the Contract.

4.3 A firm that is a Bidder (either individually or as a JV member) shall not participate in more than one Bid, except for permitted alternative Bids. This includes participation as a subcontractor. Such participation shall result in the disqualification of all Bids in which the firm is involved. A firm that is not a Bidder or a JV member, may participate as a subcontractor in more than one Bid.

4.4 A Bidder may have the nationality of any country, subject to the restrictions pursuant to ITB 4.8. A Bidder shall be deemed to have the nationality of a country if the Bidder is constituted, incorporated or registered in and operates in conformity with the provisions of the laws of that country, as evidenced by its

articles of incorporation (or equivalent documents of constitution or association) and its registration documents, as the case may be. This criterion also shall apply to the determination of the nationality of proposed subcontractors or subconsultants for any part of the Contract including related Services.

4.5 A Bidder that has been sanctioned by the Bank, pursuant to the Bank's Anti-Corruption Guidelines, and in accordance with its prevailing sanctions policies and procedures as set forth in the WBG's Sanctions Framework as described in Section VI paragraph 2.2 d., shall be ineligible to be prequalified for, initially selected for, bid for, propose for, or be awarded a Bank-financed contract or benefit from a Bank-financed contract, financially or otherwise, during such period of time as the Bank shall have determined. The list of debarred firms and individuals is available at the electronic address specified in the BDS.

4.6 Bidders that are state-owned enterprises or institutions in the Purchaser's Country may be eligible to compete and be awarded a Contract(s) only if they can establish, in a manner acceptable to the Bank, that they (i) are legally and financially autonomous (ii) operate under commercial law, and (iii) are not under supervision of the Purchaser.

4.7 A Bidder shall not be under suspension from Bidding by the Purchaser as the result of the operation of a Bid–Securing Declaration or Proposal-Securing Declaration.

4.8 Firms and individuals may be ineligible if so indicated in Section V and (a) as a matter of law or official regulations, the Borrower's country prohibits commercial relations with that country, provided that the Bank is satisfied that such exclusion does not preclude effective competition for the supply of goods or the contracting of works or services required; or (b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Borrower's country prohibits any import of goods or contracting of works or services from that country, or any payments to any country, person, or entity in that country.

4.9 A Bidder shall provide such documentary evidence of eligibility satisfactory to the Purchaser, as the Purchaser shall reasonably request.

4.10 A firm that is under a sanction of debarment by the Borrower from being awarded a contract is eligible to participate in this

procurement, unless the Bank, at the Borrower's request, is satisfied that the debarment; (a) relates to fraud or corruption, and (b) followed a judicial or administrative proceeding that afforded the firm adequate due process.

5. Eligible Goods and Related Services

5.1 All the Goods and Related Services to be supplied under the Contract and financed by the Bank may have their origin in any country in accordance with Section V, Eligible Countries.

5.2 For purposes of this ITB, the term "goods" includes any goods that are the subject of this Request for Bids, and "Related Services" includes services such as transportation, insurance, commissioning and training.

5.3 The term "origin" means the country where the goods have been mined, grown, cultivated, produced, manufactured or processed; or, through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

B. Contents of Bidding Document

6. Sections of Bidding Document

6.1 The bidding document consists of Parts 1, 2, and 3, which includes all the sections indicated below, and should be read in conjunction with any Addenda issued in accordance with ITB 8.

PART 1 Bidding Procedures

- Section I - Instructions to Bidders (ITB)
- Section II - Bidding Data Sheet (BDS)
- Section III - Evaluation and Qualification Criteria
- Section IV -Bidding Forms
- Section V - Eligible Countries
- Section VI -Fraud and Corruption

PART 2 Supply Requirements

- Section VII - Schedule of Requirements

PART 3 Contract

- Section VIII - General Conditions of Contract
- Section IX - Special Conditions of Contract
- Section X - Contract Forms

6.2 The Specific Procurement Notice - Request for Bids (RFB) issued by the Purchaser is not part of this bidding document.

6.3 Unless obtained directly from the Purchaser, the Purchaser is not responsible for the completeness of the document, responses to requests for clarification, or Addenda to the bidding document in accordance with ITB 8. In case of any contradiction, documents obtained directly from the Purchaser shall prevail.

6.4 The Bidder is expected to examine all instructions, forms, terms, and specifications in the bidding document and to furnish with its Bid all information or documentation as is required by the bidding document.

7. Clarification of Bidding Document

7.1 A Bidder requiring any clarification of the bidding document shall contact the Purchaser in writing at the Purchaser's address specified **in the Bid Data Sheet**. The Purchaser will respond in writing to any request for clarification, provided that such request is received prior to the deadline for submission of Bids within a period specified **in the Bid Data Sheet.** The Purchaser shall forward copies of its response to all Bidders who have acquired the bidding document in accordance with ITB 6.3, including a description of the inquiry but without identifying its source. If so specified **in the Bid Data Sheet**, the Purchaser shall also promptly publish its response at the web page identified **in the Bid Data Sheet**. Should the clarification result in changes to the essential elements of the bidding document, the Purchaser shall amend the bidding document following the procedure under ITB 8 and ITB 22.2.

8. Amendment of Bidding Document

8.1 At any time prior to the deadline for submission of Bids, the Purchaser may amend the bidding document by issuing addenda.

8.2 Any addendum issued shall be part of the bidding document and shall be communicated in writing to all who have obtained the bidding document from the Purchaser in accordance with ITB 6.3. The Purchaser shall also promptly publish the addendum on the Purchaser's web page in accordance with ITB 7.1.

8.3 To give prospective Bidders reasonable time in which to take an addendum into account in preparing their Bids, the Purchaser may, at its discretion, extend the deadline for the submission of Bids, pursuant to ITB 22.2.

C. Preparation of Bids

9. Cost of Bidding

9.1 The Bidder shall bear all costs associated with the preparation and submission of its Bid, and the Purchaser shall not be responsible or liable for those costs, regardless of the conduct or outcome of the Bidding process.

10. Language of Bid

10.1 The Bid, as well as all correspondence and documents relating to the Bid exchanged by the Bidder and the Purchaser, shall be written in the language specified **in the Bid Data Sheet.** Supporting documents and printed literature that are part of the Bid may be in another language provided they are accompanied by an accurate translation of the relevant passages into the language specified **in the Bid Data Sheet,** in which case, for purposes of interpretation of the Bid, such translation shall govern.

11. Documents Comprising the Bid

11.1 The Bid shall comprise the following:

(a) **Letter of Bid** prepared in accordance with ITB 12;

(b) **Price Schedules**: completed in accordance with ITB 12 and ITB 14;

(c) **Bid Security** or **Bid-Securing Declaration**, in accordance with ITB 19.1;

(d) **Alternative Bid**, if permissible, in accordance with ITB 13;

(e) **Authorization**: written confirmation authorizing the signatory of the Bid to commit the Bidder, in accordance with ITB 20.3;

(f) **Bidder's Qualifications**: documentary evidence in accordance with ITB 17 establishing the Bidder's qualifications to perform the Contract if its Bid is accepted;

(g) **Bidder's Eligibility**: documentary evidence in accordance with ITB 17 establishing the Bidder's eligibility to Bid;

(h) **Eligibility of Goods and Related Services**: documentary evidence in accordance with ITB 16, establishing the eligibility of the Goods and Related Services to be supplied by the Bidder;

(i) **Conformity**: documentary evidence in accordance with ITB 16, that the Goods and Related Services

conform to the bidding document; and

(j) any other document required **in the Bid Data Sheet.**

11.2 In addition to the requirements under ITB 11.1, Bids submitted by a JV shall include a copy of the Joint Venture Agreement entered into by all members. Alternatively, a letter of intent to execute a Joint Venture Agreement in the event of a successful Bid shall be signed by all members and submitted with the Bid, together with a copy of the proposed Agreement.

11.3 The Bidder shall furnish in the Letter of Bid information on commissions and gratuities, if any, paid or to be paid to agents or any other party relating to this Bid.

12. Letter of Bid and Price Schedules

12.1 The Letter of Bid and Price Schedules shall be prepared using the relevant forms furnished in Section IV, Bidding Forms. The forms must be completed without any alterations to the text, and no substitutes shall be accepted except as provided under ITB 20.3. All blank spaces shall be filled in with the information requested.

13. Alternative Bids

13.1 Unless otherwise specified **in the Bid Data Sheet,** alternative Bids shall not be considered.

14. Bid Prices and Discounts

14.1 The prices and discounts quoted by the Bidder in the Letter of Bid and in the Price Schedules shall conform to the requirements specified below.

14.2 All lots (contracts) and items must be listed and priced separately in the Price Schedules.

14.3 The price to be quoted in the Letter of Bid in accordance with ITB 12.1 shall be the total price of the Bid, excluding any discounts offered.

14.4 The Bidder shall quote any discounts and indicate the methodology for their application in the Letter of Bid, in accordance with ITB 12.1.

14.5 Prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account, unless otherwise specified **in the Bid Data Sheet.** A Bid submitted with an adjustable price quotation shall be treated as nonresponsive and shall be rejected, pursuant to ITB 29. However, if in accordance with the BDS, prices quoted by the Bidder shall be subject to adjustment during the performance of the Contract, a Bid submitted with a fixed price quotation shall not be rejected,

but the price adjustment shall be treated as zero.

14.6 If so specified in ITB 1.1, Bids are being invited for individual lots (contracts) or for any combination of lots (packages). Unless otherwise specified **in the Bid Data Sheet,** prices quoted shall correspond to 100 % of the items specified for each lot and to 100% of the quantities specified for each item of a lot. Bidders wishing to offer discounts for the award of more than one Contract shall specify in their Bid the price reductions applicable to each package, or alternatively, to individual Contracts within the package. Discounts shall be submitted in accordance with ITB 14.4 provided the Bids for all lots (contracts) are opened at the same time.

14.7 The terms EXW, CIP, and other similar terms shall be governed by the rules prescribed in the current edition of Incoterms, published by The International Chamber of Commerce, as specified **in the Bid Data Sheet.**

14.8 Prices shall be quoted as specified in each Price Schedule included in Section IV, Bidding Forms. The dis-aggregation of price components is required solely for the purpose of facilitating the comparison of Bids by the Purchaser. This shall not in any way limit the Purchaser's right to contract on any of the terms offered. In quoting prices, the Bidder shall be free to use transportation through carriers registered in any eligible country, in accordance with Section V, Eligible Countries. Similarly, the Bidder may obtain insurance services from any eligible country in accordance with Section V, Eligible Countries. Prices shall be entered in the following manner:

(a) for Goods manufactured in the Purchaser's Country:

(i) the price of the Goods quoted EXW (ex-works, ex-factory, ex warehouse, ex showroom, or off-the-shelf, as applicable), including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the Goods;

(ii) any Purchaser's Country sales tax and other taxes which will be payable on the Goods if the Contract is awarded to the Bidder; and

(iii) the price for inland transportation,

insurance, and other local services required to convey the Goods to their final destination (Project Site) **specified in the Bid Data Sheet**;

(b) for Goods manufactured outside the Purchaser's Country, to be imported:

(i) the price of the Goods, quoted CIP named place of destination, in the Purchaser's Country, as **specified in the BDS**; and

(ii) the price for inland transportation, insurance, and other local services required to convey the Goods from the named place of destination to their final destination (Project Site) **specified in the Bid Data Sheet**;

(c) for Goods manufactured outside the Purchaser's Country, already imported:

(i) the price of the Goods, including the original import value of the Goods; plus any mark-up (or rebate); plus any other related local cost, and custom duties and other import taxes already paid or to be paid on the Goods already imported;

(ii) the custom duties and other import taxes already paid (need to be supported with documentary evidence) or to be paid on the Goods already imported;

(iii) the price of the Goods, obtained as the difference between (i) and (ii) above;

(iv) any Purchaser's Country sales and other taxes which will be payable on the Goods if the Contract is awarded to the Bidder; and

(v) the price for inland transportation, insurance, and other local services required to convey the Goods to their final destination (Project Site) specified **in the Bid Data Sheet.**

(d) for Related Services, other than inland transportation and other services required to convey the Goods to

their final destination, whenever such Related Services are specified in the Schedule of Requirements:

(i) the price of each item comprising the Related Services (inclusive of any applicable taxes).

15. Currencies of Bid and Payment

15.1 The currency(ies) of the Bid and the currency(ies) of payments shall be **the same.** The Bidder shall quote in the currency of the Purchaser's Country the portion of the Bid price that corresponds to expenditures incurred in the currency of the Purchaser's Country, unless otherwise specified **in the Bid Data Sheet.**

15.2 The Bidder may express the Bid price in any currency. If the Bidder wishes to be paid in a combination of amounts in different currencies, it may quote its price accordingly but shall use no more than three foreign currencies in addition to the currency of the Purchaser's Country.

16. Documents Establishing the Eligibility and Conformity of the Goods and Related Services

16.1 To establish the eligibility of the Goods and Related Services in accordance with ITB 5, Bidders shall complete the country-of-origin declarations in the Price Schedule Forms, included in Section IV, Bidding Forms.

16.2 To establish the conformity of the Health Sector Goods and Related Services to the bidding document, the Bidder shall furnish as part of its Bid the documentary evidence that the Goods conform to the technical specifications and standards specified in Section VII, Schedule of Requirements.

16.3 The documentary evidence may be in the form of literature, drawings or data, and shall consist of:

(a) an item-by-item commentary on the provisions of Section VII, Schedule of Requirements demonstrating substantial responsiveness of the Goods and Services to the specifications, or a statement of deviations and exceptions to the provisions of the specifications; and

(b) any other procurement-specific documentation requirement as stated **in the Bid Data Sheet.**

16.4 Unless the **Bid Data Sheet** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in the Purchaser's Country. A Bidder who has already registered its Goods by the time of Bidding should submit a copy of the Registration Certificate with its Bid. Otherwise, the successful Bidder, by the time of Contract

signing, shall submit to the Purchaser either:

(a) a copy of the Registration Certificate of the Goods for use in the Purchaser's Country; or

(b) if such Registration Certificate has not yet been obtained, evidence establishing to the Purchaser's satisfaction that the Bidder has complied with all the documentary requirements for registration as specified **in the Bid Data Sheet.**

16.5 The Purchaser shall at all times cooperate with the successful Bidder to facilitate the registration process within the Purchaser's Country. The agency and contact person able to provide additional information about registration are identified **in the Bid Data Sheet.**

16.6 If the Goods of the successful Bidder have not been registered in the Purchaser's Country at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

16.7 Standards for workmanship, process, material, and equipment, as well as references to brand names or catalogue numbers specified by the Purchaser in the Schedule of Requirements, are intended to be descriptive only and not restrictive. The Bidder may offer other standards of quality, brand names, and/or catalogue numbers, provided that it demonstrates, to the Purchaser's satisfaction, that the substitutions ensure substantial equivalence or are superior to those specified in the Section VII, Schedule of Requirements.

17. Documents Establishing the Eligibility and Qualifications of the Bidder

17.1 To establish Bidder's eligibility in accordance with ITB 4, Bidders shall complete the Letter of Bid, included in Section IV, Bidding Forms.

17.2 The documentary evidence of the Bidder's qualifications to perform the Contract if its Bid is accepted shall establish to the Purchaser's satisfaction:

(a) that a Bidder that does not manufacture or produce the Health Sector Goods it offers to supply shall submit the Manufacturer's Authorization using the form included in Section IV, Bidding Forms to demonstrate that it has been duly authorized by the manufacturer or producer of the Goods to supply these Goods in the Purchaser's Country;

(b) that in case of a Bidder not doing business within the Purchaser's Country (or for other reasons will not itself carry out service obligations), the Bidder is or will be (if awarded the Contract) represented by a local service provider in the Purchaser's Country equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

(c) that the Bidder meets each of the qualification criterion specified in Section III, Evaluation and Qualification Criteria (see additional ITB for pharmaceuticals and vaccines).

18. Period of Validity of Bids

18.1 Bids shall remain valid until the date **specified in the BDS** or any extended date if amended by the Purchaser in accordance with ITP 8. A Bid that is not valid until the date **specified in the BDS**, or any extended date if amended by the Purchaser in accordance with ITP 8, shall be rejected by the Purchaser as nonresponsive.

18.2 In exceptional circumstances, prior to the expiry of the Bid validity, the Purchaser may request Bidders to extend the period of validity of their Bids. The request and the responses shall be made in writing. If a Bid Security is requested in accordance with ITB 19, it shall also be extended for a corresponding period. A Bidder may refuse the request without forfeiting its Bid Security. A Bidder granting the request shall not be required or permitted to modify its Bid, except as provided in ITB 18.3.

18.3 If the award is delayed by a period exceeding fifty-six (56) days beyond the expiry of the initial Bid validity period, the Contract price shall be determined as follows:

(a) in the case of **fixed price** contracts, the Contract price shall be the Bid price adjusted by the factor specified **in the BDS**;

(b) in the case of **adjustable price** contracts, no adjustment shall be made; or

(c) in any case, Bid evaluation shall be based on the Bid price without taking into consideration the applicable correction from those indicated above.

19. Bid Security

19.1 The Bidder shall furnish as part of its Bid, either a Bid-Securing Declaration or a Bid Security, as specified **in the BDS,** in original form and, in the case of a Bid Security, in

the amount and currency specified **in the BDS.**

19.2 A Bid-Securing Declaration shall use the form included in Section IV, Bidding Forms.

19.3 If a Bid Security is specified pursuant to ITB 19.1, the Bid Security shall be a demand guarantee in any of the following forms at the Bidder's option:

(a) an unconditional guarantee issued by a bank or non-bank financial institution (such as an insurance, bonding or surety company);

(b) an irrevocable letter of credit;

(c) a cashier's or certified check; or

(d) another security **specified in the BDS**,

from a reputable source, and an eligible country. If the unconditional guarantee is issued by a non-bank financial institution located outside the Purchaser's Country, the issuing non-bank financial institution shall have a correspondent financial institution located in the Purchaser's Country to make it enforceable unless the Purchaser has agreed in writing, prior to Bid submission, that a correspondent financial institution is not required. In the case of a bank guarantee, the Bid Security shall be submitted either using the Bid Security Form included in Section IV, Bidding Forms, or in another substantially similar format approved by the Purchaser prior to Bid submission. The Bid Security shall be valid for twenty-eight (28) days beyond the original date of expiry of the Bid validity, or beyond any extended date if requested under ITB 18.2.

19.4 If a Bid Security is specified pursuant to ITB 19.1, any Bid not accompanied by a substantially responsive Bid Security shall be rejected by the Purchaser as non-responsive.

19.5 If a Bid Security is specified pursuant to ITB 19.1, the Bid Security of unsuccessful Bidders shall be returned as promptly as possible upon the successful Bidder's signing the Contract and furnishing the Performance Security pursuant to ITB 46.

19.6 The Bid Security of the successful Bidder shall be returned as promptly as possible once the successful Bidder has signed the Contract and furnished the required Performance

Security.

19.7 The Bid Security may be forfeited:

(a) if a Bidder withdraws its Bid prior to the expiry date of Bid validity specified by the Bidder on the Letter of Bid or any extended date provided by the Bidder; or

(b) if the successful Bidder fails to:

(i) sign the Contract in accordance with ITB45; or

(ii) furnish a Performance Security in accordance with ITB 46.

19.8 The Bid Security or Bid- Securing Declaration of a JV must be in the name of the JV that submits the Bid. If the JV has not been legally constituted into a legally enforceable JV at the time of Bidding, the Bid Security or Bid-Securing Declaration shall be in the names of all future members as named in the letter of intent referred to in ITB 4.1 and ITB 11.2.

19.9 If a Bid Security is not required **in the BDS**, pursuant to ITB 19.1, and:

(a) if a Bidder withdraws its Bid during the period of Bid validity specified by the Bidder on the Letter of Bid, or any extended date provided by the Bidder; or

(b) if the successful Bidder fails to:

(i) sign the Contract in accordance with ITB 45; or

(ii) furnish a Performance Security in accordance with ITB 46;

the Borrower may, if provided for **in the BDS**, declare the Bidder ineligible to be awarded a contract by the Purchaser for a period of time as stated **in the BDS**.

20. Format and Signing of Bid

20.1 The Bidder shall prepare one original of the documents comprising the Bid as described in ITB 11 and clearly mark it "ORIGINAL." Alternative Bids, if permitted in accordance with ITB 13, shall be clearly marked "ALTERNATIVE." In addition, the Bidder shall submit copies of the Bid, in the number **specified in the BDS** and clearly mark them "COPY." In the event of any discrepancy between the original and the copies, the original shall prevail.

20.2 Bidders shall mark as "CONFIDENTIAL" information in their Bids which is confidential to their business. This may include proprietary information, trade secrets or commercial or financially sensitive information.

20.3 The original and all copies of the Bid shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Bidder. This authorization shall consist of a written confirmation **as specified in the BDS** and shall be attached to the Bid. The name and position held by each person signing the authorization must be typed or printed below the signature. All pages of the Bid where entries or amendments have been made shall be signed or initialed by the person signing the Bid.

20.4 In case the Bidder is a JV, the Bid shall be signed by an authorized representative of the JV on behalf of the JV, and so as to be legally binding on all the members as evidenced by a power of attorney signed by their legally authorized representatives.

20.5 Any inter-lineation, erasures, or overwriting shall be valid only if they are signed or initialed by the person signing the Bid.

D. Submission and Opening of Bids

21. Sealing and Marking of Bids

21.1 The Bidder shall deliver the Bid in a single, sealed envelope (one-envelope Bidding process). Within the single envelope the Bidder shall place the following separate, sealed envelopes:

(a) in an envelope marked "ORIGINAL", all documents comprising the Bid, as described in ITB 11; and

(b) in an envelope marked "COPIES", all required copies of the Bid; and,

(c) if alternative Bids are permitted in accordance with ITB 13, and if relevant:

(i) in an envelope marked "ORIGINAL – ALTERNATIVE BID", the alternative Bid; and

(ii) in the envelope marked "COPIES – ALTERNATIVE BID" all required copies of the alternative Bid.

21.2 The inner and outer envelopes shall:

(a) bear the name and address of the Bidder;

(b) be addressed to the Purchaser in accordance with ITB

22.1;

(c) bear the specific identification of this Bidding process indicated in ITB 1.1**;** and

(d) bear a warning not to open before the time and date for Bid opening.

21.3 If all envelopes are not sealed and marked as required, the Purchaser will assume no responsibility for the misplacement or premature opening of the Bid.

22. Deadline for Submission of Bids

22.1 Bids must be received by the Purchaser at the address and no later than the date and time specified **in the BDS. When so specified in the BDS**, Bidders shall have the option of submitting their Bids electronically. Bidders submitting Bids electronically shall follow the electronic Bid submission procedures **specified in the BDS**.

22.2 The Purchaser may, at its discretion, extend the deadline for the submission of Bids by amending the bidding document in accordance with ITB 8, in which case all rights and obligations of the Purchaser and Bidders previously subject to the deadline shall thereafter be subject to the deadline as extended.

23. Late Bids

23.1 The Purchaser shall not consider any Bid that arrives after the deadline for submission of Bids, in accordance with ITB 22. Any Bid received by the Purchaser after the deadline for submission of Bids shall be declared late, rejected, and returned unopened to the Bidder.

24. Withdrawal, Substitution, and Modification of Bids

24.1 A Bidder may withdraw, substitute, or modify its Bid after it has been submitted by sending a written notice, duly signed by an authorized representative, and shall include a copy of the authorization (the power of attorney) in accordance with ITB 20.3, (except that withdrawal notices do not require copies). The corresponding substitution or modification of the Bid must accompany the respective written notice. All notices must be:

(a) prepared and submitted in accordance with ITB 20 and 21 (except that withdrawal notices do not require copies), and in addition, the respective envelopes shall be clearly marked "WITHDRAWAL," "SUBSTITUTION," or "MODIFICATION;" and

(b) received by the Purchaser prior to the deadline prescribed for submission of Bids, in accordance with

ITB 22.1.

24.2 Bids requested to be withdrawn in accordance with ITB 24.1 shall be returned unopened to the Bidders.

24.3 No Bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of Bids and the expiration of the period of Bid validity specified by the Bidder on the Letter of Bid or any extension thereof.

25. Bid Opening

25.1 Except as in the cases specified in ITB 23 and ITB 24.2, the Purchaser shall publicly open and read out in accordance with this ITB all Bids received by the deadline at the date, time and place specified **in the BDS** in the presence of Bidders' designated representatives and anyone who choose to attend. All Bidders, or their representatives and any interested party may attend a public opening. Any specific electronic Bid opening procedures required if electronic Bidding is permitted in accordance with ITB 22.1, shall be as specified **in the BDS.**

25.2 First, envelopes marked "WITHDRAWAL" shall be opened and read out and the envelope with the corresponding Bid shall not be opened, but returned to the Bidder. If the withdrawal envelope does not contain a copy of the "power of attorney" confirming the signature as a person duly authorized to sign on behalf of the Bidder, the corresponding Bid will be opened. No Bid withdrawal shall be permitted unless the corresponding withdrawal notice contains a valid authorization to request the withdrawal and is read out at Bid opening.

25.3 Next, envelopes marked "SUBSTITUTION" shall be opened and read out and exchanged with the corresponding Bid being substituted, and the substituted Bid shall not be opened, but returned to the Bidder. No Bid substitution shall be permitted unless the corresponding substitution notice contains a valid authorization to request the substitution and is read out at Bid opening.

25.4 Next, envelopes marked "MODIFICATION" shall be opened and read out with the corresponding Bid. No Bid modification shall be permitted unless the corresponding modification notice contains a valid authorization to request the modification and is read out at Bid opening.

25.5 Next, all remaining envelopes shall be opened one at a time, reading out: the name of the Bidder and whether there is a

modification; the total Bid Prices, per item or lot (contract) if applicable, including any discounts and alternative Bids; the presence or absence of a Bid Security, if required; and any other details as the Purchaser may consider appropriate.

25.6 Only Bids, alternative Bids and discounts that are opened and read out at Bid opening shall be considered further for evaluation. The Letter of Bid and the Price Schedules are to be initialed by representatives of the Purchaser attending Bid opening in the manner specified **in the BDS.**

25.7 The Purchaser shall neither discuss the merits of any Bid nor reject any Bid (except for late Bids, in accordance with ITB 23.1).

25.8 The Purchaser shall prepare a record of the Bid opening that shall include, as a minimum:

(a) the name of the Bidder and whether there is a withdrawal, substitution, or modification;

(b) the Bid Price, per lot (contract) if applicable, including any discounts;

(c) any alternative Bids; and

(d) the presence or absence of a Bid Security or Bid Securing Declaration, if one was required.

25.9 The Bidders' representatives who are present shall be requested to sign the record. The omission of a Bidder's signature on the record shall not invalidate the contents and effect of the record. A copy of the record shall be distributed to all Bidders.

E. Evaluation and Comparison of Bids

26. Confidentiality

26.1 Information relating to the evaluation of Bids and recommendation of contract award, shall not be disclosed to Bidders or any other persons not officially concerned with the Bidding process until the Notification of Intention to Award the Contract is transmitted to all Bidders in accordance with ITB 43.

26.2 Any effort by a Bidder to influence the Purchaser in the evaluation or contract award decisions may result in the rejection of its Bid.

26.3 Notwithstanding ITB 26.2, from the time of Bid opening to the time of Contract Award, if any Bidder wishes to contact

the Purchaser on any matter related to the Bidding process, it should do so in writing.

27. Clarification of Bids

27.1 To assist in the examination, evaluation, comparison of the Bids, and qualification of the Bidders, the Purchaser may, at its discretion, ask any Bidder for a clarification of its Bid. Any clarification submitted by a Bidder in respect to its Bid and that is not in response to a request by the Purchaser shall not be considered. The Purchaser's request for clarification and the response shall be in writing. No change, including any voluntary increase or decrease, in the prices or substance of the Bid shall be sought, offered, or permitted, except to confirm the correction of arithmetic errors discovered by the Purchaser in the Evaluation of the Bids, in accordance with ITB 31.

27.2 If a Bidder does not provide clarifications of its Bid by the date and time set in the Purchaser's request for clarification, its Bid may be rejected.

28. Deviations, Reservations, and Omissions

28.1 During the evaluation of Bids, the following definitions apply:

(a) "Deviation" is a departure from the requirements specified in the bidding document;

(b) "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in the bidding document; and

(c) "Omission" is the failure to submit part or all of the information or documentation required in the bidding document.

29. Determination of Responsiveness

29.1 The Purchaser's determination of a Bid's responsiveness is to be based on the contents of the Bid itself, as defined in ITB 11.

29.2 A substantially responsive Bid is one that meets the requirements of the bidding document without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

(a) if accepted, would:

(i) affect in any substantial way the scope, quality, or performance of the Goods and Related Services specified in the Contract; or

(ii) limit in any substantial way, inconsistent with

the bidding document, the Purchaser's rights or the Bidder's obligations under the Contract; or

(b) if rectified, would unfairly affect the competitive position of other Bidders presenting substantially responsive Bids.

29.3 The Purchaser shall examine the technical aspects of the Bid submitted in accordance with ITB 16 and ITB 17, in particular, to confirm that all requirements of Section VII, Schedule of Requirements have been met without any material deviation or reservation, or omission.

29.4 If a Bid is not substantially responsive to the requirements of bidding document, it shall be rejected by the Purchaser and may not subsequently be made responsive by correction of the material deviation, reservation, or omission.

30. Nonconformities, Errors and Omissions

30.1 Provided that a Bid is substantially responsive, the Purchaser may waive any nonconformities in the Bid.

30.2 Provided that a Bid is substantially responsive, the Purchaser may request that the Bidder submit the necessary information or documentation, within a reasonable period of time, to rectify nonmaterial nonconformities or omissions in the Bid related to documentation requirements. Such omission shall not be related to any aspect of the price of the Bid. Failure of the Bidder to comply with the request may result in the rejection of its Bid.

30.3 Provided that a Bid is substantially responsive, the Purchaser shall rectify quantifiable nonmaterial nonconformities related to the Bid Price. To this effect, the Bid Price shall be adjusted, for comparison purposes only, to reflect the price of a missing or non-conforming item or component, by adding the average price of the item or component quoted by substantially responsive Bidders. If the price of the item or component cannot be derived from the price of other substantially responsive Bids, the Purchaser shall use its best estimate.

31. Correction of Arithmetical Errors

31.1 Provided that the Bid is substantially responsive, the Purchaser shall correct arithmetical errors on the following basis:

(a) if there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price shall prevail and the line item total shall be corrected, unless in the opinion of the Purchaser there is an obvious misplacement of the decimal point in the unit price, in

which case the line item total as quoted shall govern and the unit price shall be corrected;

(b) if there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and

(c) if there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to (a) and (b) above.

31.2 Bidders shall be requested to accept correction of arithmetical errors. Failure to accept the correction in accordance with ITB 31.1, shall result in the rejection of the Bid.

32. Conversion to Single Currency

32.1 For evaluation and comparison purposes, the currency(ies) of the Bid shall be converted in a single currency as specified **in the BDS.**

33. Margin of Preference

33.1 Unless otherwise specified **in the BDS,** a margin of preference shall not apply.

34. Evaluation of Bids

34.1 The Purchaser shall use the criteria and methodologies listed in this ITB and Section III, Evaluation and Qualification criteria. No other evaluation criteria or methodologies shall be permitted. By applying the criteria and methodologies, the Purchaser shall determine the Most Advantageous Bid. This is the Bid of the Bidder that meets the qualification criteria and whose Bid has been determined to be:

(a) substantially responsive to the bidding document; and

(b) the lowest evaluated cost.

34.2 To evaluate a Bid, the Purchaser shall consider the following:

(a) evaluation will be done for Items or Lots (contracts), as specified **in the BDS;** and the Bid Price as quoted in accordance with ITB 14;

(b) price adjustment for correction of arithmetic errors in accordance with ITB 31.1;

(c) price adjustment due to discounts offered in accordance with ITB 14.4;

(d) converting the amount resulting from applying (a) to

(c) above, if relevant, to a single currency in accordance with ITB 32;

(e) price adjustment due to quantifiable nonmaterial nonconformities in accordance with ITB 30.3; and

(f) the additional evaluation factors specified in Section III, Evaluation and Qualification Criteria.

34.3 The estimated effect of the price adjustment provisions of the Conditions of Contract, applied over the period of execution of the Contract, shall not be taken into account in Bid evaluation.

34.4 If this bidding document allows Bidders to quote separate prices for different lots (contracts), the methodology to determine the lowest evaluated cost of the lot (contract) combinations, including any discounts offered in the Letter of Bid, is specified in Section III, Evaluation and Qualification Criteria

34.5 The Purchaser's evaluation of a Bid will exclude and not take into account:

(a) in the case of Goods manufactured in the Purchaser's Country, sales and other similar taxes, which will be payable on the goods if a contract is awarded to the Bidder;

(b) in the case of Goods manufactured outside the Purchaser's Country, already imported or to be imported, customs duties and other import taxes levied on the imported Good, sales and other similar taxes, which will be payable on the Goods if the contract is awarded to the Bidder;

(c) any allowance for price adjustment during the period of execution of the contract, if provided in the Bid.

34.6 The Purchaser's evaluation of a Bid may require the consideration of other factors, in addition to the Bid Price quoted in accordance with ITB 14. These factors may be related to the characteristics, performance, and terms and conditions of purchase of the Goods and Related Services. The effect of the factors selected, if any, shall be expressed in monetary terms to facilitate comparison of Bids, unless otherwise specified **in the BDS** from amongst those set out in Section III, Evaluation and Qualification Criteria. The criteria and methodologies to be used shall be as specified in

ITB 34.2 (f).

35. Comparison of Bids

35.1 The Purchaser shall compare the evaluated costs of all substantially responsive Bids established in accordance with ITB 34.2 to determine the Bid that has the lowest evaluated cost. The comparison shall be on the basis of CIP (place of final destination) prices for imported goods and EXW prices, plus cost of inland transportation and insurance to place of destination, for goods manufactured within the Borrower's country, together with prices for any required installation, training, commissioning and other services. The evaluation of prices shall not take into account custom duties and other taxes levied on imported goods quoted CIP and sales and similar taxes levied in connection with the sale or delivery of goods.

36. Abnormally Low Bids

36.1 An Abnormally Low Bid is one where the Bid price, in combination with other constituent elements of the Bid, appears unreasonably low to the extent that the Bid price raises material concerns as to the capability of the Bidder to perform the Contract for the offered Bid price.

36.2 In the event of identification of a potentially Abnormally Low Bid, the Purchaser shall seek written clarification from the Bidder, including a detailed price analyses of its Bid price in relation to the subject matter of the contract, scope, delivery schedule, allocation of risks and responsibilities and any other requirements of the bidding document.

36.3 After evaluation of the price analyses, in the event that the Purchaser determines that the Bidder has failed to demonstrate its capability to perform the contract for the offered Bid price, the Purchaser shall reject the Bid.

37. Qualification of the Bidder

37.1 The Purchaser shall determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated cost and substantially responsive Bid is eligible and meets the qualifying criteria specified in BDS ITB 11.1 as applicable, and Section III, Evaluation and Qualification Criteria.

37.2 The determination shall be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB 17. The determination shall not take into consideration the qualifications of other firms such as the Bidder's subsidiaries, parent entities, affiliates, subcontractors or any

other firm(s) different from the Bidder.

37.3 Prior to Contract award, the Purchaser will verify that the successful Bidder (including each member of a JV) is not disqualified by the Bank due to noncompliance with contractual SEA/SH prevention and response obligations. The Purchaser will conduct the same verification for each subcontractor proposed by the successful Bidder. If any proposed subcontractor does not meet the requirement, the Purchaser will require the Bidder to propose a replacement subcontractor.

37.4 An affirmative determination shall be a prerequisite for award of the Contract to the Bidder. A negative determination shall result in disqualification of the Bid, in which event the Purchaser shall proceed to the Bidder who offers a substantially responsive Bid with the next lowest evaluated cost to make a similar determination of that Bidder's qualifications to perform satisfactorily.

38. Purchaser's Right to Accept Any Bid, and to Reject Any or All Bids

38.1 The Purchaser reserves the right to accept or reject any Bid, and to annul the Bidding process and reject all Bids at any time prior to Contract Award, without thereby incurring any liability to Bidders. In case of annulment, all Bids submitted and specifically, bid securities, shall be promptly returned to the Bidders.

39. Standstill Period

39.1 The Contract shall not be awarded earlier than the expiry of the Standstill Period. The Standstill Period shall be ten (10) Business Days unless extended in accordance with ITB 44. The Standstill Period commences the day after the date the Purchaser has transmitted to each Bidder the Notification of Intention to Award the Contract. Where only one Bid is submitted, or if this contract is in response to an emergency situation recognized by the Bank, the Standstill Period shall not apply.

40. Notification of Intention to Award

40.1 The Purchaser shall send to each Bidder the Notification of Intention to Award the Contract to the successful Bidder. The Notification of Intention to Award shall contain, at a minimum, the following information:

(a) the name and address of the Bidder submitting the successful Bid;

(b) the Contract price of the successful Bid;

(c) the names of all Bidders who submitted Bids, and their

Bid prices as readout, and as evaluated;

(d) a statement of the reason(s) the Bid (of the unsuccessful Bidder to whom the notification is addressed) was unsuccessful, unless the price information in c) above already reveals the reason;

(e) the expiry date of the Standstill Period; and

(f) instructions on how to request a debriefing and/or submit a complaint during the standstill period.

F. Award of Contract

41. Award Criteria

41.1 Subject to ITB 38, the Purchaser shall award the Contract to the successful Bidder. This is the Bidder whose Bid has been determined to be the Most Advantageous Bid. This is the Bid of the Bidder that meets the qualification criteria and whose Bid has been determined to be:

(a) substantially responsive to the bidding document, and

(b) the lowest evaluated cost.

42. Purchaser's Right to Vary Quantities at Time of Award

42.1 At the time the Contract is awarded, the Purchaser reserves the right to increase or decrease the quantity of Goods and Related Services originally specified in Section VII, Schedule of Requirements, provided this does not exceed the percentages specified **in the BDS**, and without any change in the unit prices or other terms and conditions of the Bid and the bidding document.

43. Notification of Award

43.1 Prior to the date of expiry of the Bid validity and upon expiry of the Standstill Period, specified in ITB 39.1 or any extension thereof, and upon satisfactorily addressing any complaint that has been filed within the Standstill Period, the Purchaser shall notify the successful Bidder, in writing, that its Bid has been accepted. The notification of award (hereinafter and in the Contract Forms called the "Letter of Acceptance") shall specify the sum that the Purchaser will pay the Supplier in consideration of the execution of the Contract (hereinafter and in the Conditions of Contract and Contract Forms called "the Contract Price").

43.2 Within ten (10) Business Days after the date of transmission of the Letter of Acceptance,, the Purchaser shall publish the Contract Award Notice which shall contain, at a minimum, the following information:

(a) name and address of the Purchaser;

(b) name and reference number of the contract being awarded, and the selection method used;

(c) names of all Bidders that submitted Bids, and their Bid prices as read out at Bid opening, and as evaluated;

(d) names of all Bidders whose Bids were rejected either as nonresponsive or as not meeting qualification criteria, or were not evaluated, with the reasons therefor;

(e) the name of the successful Bidder, the final total contract price, the contract duration and a summary of its scope; and

(f) successful Bidder's Beneficial Ownership Disclosure Form, if specified in BDS ITB 45.1.

43.3 The Contract Award Notice shall be published on the Purchaser's website with free access if available, or in at least one newspaper of national circulation in the Purchaser's Country, or in the official gazette. The Purchaser shall also publish the contract award notice in UNDB online.

43.4 Until a formal Contract is prepared and executed, the Letter of Acceptance shall constitute a binding Contract.

44. Debriefing by the Purchaser

44.1 On receipt of the Purchaser's Notification of Intention to Award referred to in ITB 40.1, an unsuccessful Bidder has three (3) Business Days to make a written request to the Purchaser for a debriefing. The Purchaser shall provide a debriefing to all unsuccessful Bidders whose request is received within this deadline.

44.2 Where a request for debriefing is received within the deadline, the Purchaser shall provide a debriefing within five (5) Business Days, unless the Purchaser decides, for justifiable reasons, to provide the debriefing outside this timeframe. In that case, the standstill period shall automatically be extended until five (5) Business Days after such debriefing is provided. If more than one debriefing is so delayed, the standstill period shall not end earlier than five (5) Business Days after the last debriefing takes place. The Purchaser shall promptly inform, by the quickest means available, all Bidders of the extended standstill period

44.3 Where a request for debriefing is received by the Purchaser

later than the three (3)-Business Day deadline, the Purchaser should provide the debriefing as soon as practicable, and normally no later than fifteen (15) Business Days from the date of publication of Public Notice of Award of contract. Requests for debriefing received outside the three (3)-day deadline shall not lead to extension of the standstill period.

44.4 Debriefings of unsuccessful Bidders may be done in writing or verbally. The Bidder shall bear their own costs of attending such a debriefing meeting.

45. Signing of Contract

45.1 The Purchaser shall send to the successful Bidder the Letter of Acceptance including the Contract Agreement, and, if specified in the BDS, a request to submit the Beneficial Ownership Disclosure Form providing additional information on its beneficial ownership. The Beneficial Ownership Disclosure Form, if so requested, shall be submitted within eight (8) Business Days of receiving this request.

45.2 The successful Bidder shall sign, date and return to the Purchaser, the Contract Agreement within twenty-eight (28) days of its receipt.

45.3 .Notwithstanding ITB 45.2 above, in case signing of the Contract Agreement is prevented by any export restrictions attributable to the Purchaser, to the country of the Purchaser, or to the use of the products/goods, systems or services to be supplied, where such export restrictions arise from trade regulations from a country supplying those products/goods, systems or services, the Bidder shall not be bound by its Bid, always provided however, that the Bidder can demonstrate to the satisfaction of the Purchaser and of the Bank that signing of the Contact Agreement has not been prevented by any lack of diligence on the part of the Bidder in completing any formalities, including applying for permits, authorizations and licenses necessary for the export of the products/goods, systems or services under the terms of the Contract.

46. Performance Security

46.1 Within twenty-eight (28) days of the receipt of Letter of Acceptance from the Purchaser, the successful Bidder, if required, shall furnish the Performance Security in accordance with the GCC 18, using for that purpose the Performance Security Form included in Section X, Contract Forms, or another Form acceptable to the Purchaser. If the Performance Security furnished by the successful Bidder is in the form of a bond, it shall be issued by a bonding or insurance company that has been determined by the successful Bidder to be acceptable to the Purchaser. A foreign institution providing

a bond shall have a correspondent financial institution located in the Purchaser's Country, unless the Purchaser has agreed in writing that a correspondent financial institution is not required.

46.2 Failure of the successful Bidder to submit the above-mentioned Performance Security or sign the Contract shall constitute sufficient grounds for the annulment of the award and forfeiture of the Bid Security. In that event the Purchaser may award the Contract to the Bidder with the next Most Advantageous Bid.

47. Procurement Related Complaint

47.1 The procedures for making a Procurement-related Complaint are as specified in the BDS.

Section II - Bid Data Sheet (BDS)

The following specific data for the goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions herein shall prevail over those in ITB.

Where an e-procurement system is used, modify the relevant parts of BDS to reflect the e-procurement process

ITB Reference	A. General
ITB 1.1	The reference number of the Request for Bids (RFB) is ***LK-SPC-370463-GO-RFB*** The Purchaser is: ***Ministry of Health, Sri Lanka*** The name of the RFB is: *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vials* The number and identification of lots (contracts) comprising this RFB is: **One**
ITB 1.2(a)	Deleted
ITB 2.1	The Borrower is: ***Ministry of Health*** Democratic Socialist Republic of Sri Lanka Loan or Financing Agreement amount: ***USD. 8,000,000.00*** The name of the Project is: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*
ITB 4.1	Maximum number of members in the Joint Venture (JV) shall be: Two
ITB 4.5	A list of debarred firms and individuals is available on the Bank's external website: http://www.worldbank.org/debarr.
	B. Contents of Bidding Document
ITB 7.1	For **Clarification of Bid purposes** only, the Purchaser's address is: Attention: Manager Imports (Pharma), Ministry of Health, Sri Lanka Address: "Mehewara Piyasa" 41, Kirula Road, Colombo 05, Sri Lanka. Floor/ Room number*: 16th Floor* City: ***Colombo 05***

	ZIP Code: 00500 Country: ***Sri Lanka*** Telephone: (00) 94- 11 - 2335374 Facsimile number: (00) 94 – 11 – 2582496 Electronic mail address: pharma.manager@spc.lk Requests for clarification should be received by the Purchaser no later than: ***14 Days prior to the deadline for bid submission.*** Web page: www.spc.lk
	C. Preparation of Bids
ITB 10.1	The language of the Bid is: ***English*** All correspondence exchange shall be in English language. Language for translation of supporting documents and printed literature is English.
ITB 11.1	Documentary evidence of the Bidder's qualifications to perform the Contract if its Bid is accepted: (i) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder: (a) is incorporated in the country of manufacture of the Goods; (b) has been licensed by the regulatory authority in the country of manufacture to supply the Goods; (c) has manufactured and marketed the specific goods covered by this bidding document, for at least three (3) years. (d) has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the goods or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC). (ii) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder does not manufacture or otherwise produce, (a) that the Bidder has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Purchaser's Country; and The Bidder shall also submit the following additional information:

	(a) a statement of installed manufacturing capacity; (b) copies of its audited financial statements for the past three fiscal years; (c) details of on-site quality control laboratory facilities and services and range of tests conducted; (d) list of major supply contracts conducted within the last five years.
ITB 11.1 (j)	The Bidder shall submit the following additional documents in its Bid: Bidders who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer, and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce pharmaceuticals or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling, and quality testing. The Bidder shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Goods offered.
ITB 13.1	Alternative Bids ***"shall not be"*** considered.
ITB 14.5	The prices quoted by the Bidder ***"shall not"*** be subject to adjustment during the performance of the Contract.
ITB 14.6	Prices quoted for each lot shall correspond **to *100*** percent of the quantity specified for each lot Prices quoted for each item of a lot shall correspond at least to ***100*** percent of the quantities specified for this item of a lot.
ITB 14.7	The Incoterms edition is: INCOTERMS 2020
ITB 14.8 (a) (iii), (b) (ii) and c(v)	Final Destination (Project Site): Medical Supplies Division, 357, Ven Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka
ITB 14.8 (b)(i)	Place of Destination: Foreign Bidders : Sea / Air port in Colombo Local Bidders : Medical Supplies Division, 357, Ven Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka
ITB 15.1	The Bidder **is** required to quote in the currency of the Purchaser's Country the portion of the Bid price that corresponds to expenditures incurred in that currency.

ITB 16.3 (b)	Documentation requirements for eligibility of Goods. In addition to the documents stated in ITB 16.1, 16.2, and 16.3 (a), the following documents should be included with the Bid: None
ITB 16.4	The Purchaser's Country ***does*** require registration of Goods with NMRA. However, Goods without NMRA registration also can be submitted subject to adhering to requirement stipulated in ITB 16.4 (b).
ITB 16.4 (b)	By the time of submitting the bid, the Bidder shall have complied with the following documentary requirements in order to obtain Waiver of Registration the Goods to be supplied under the Contract: • Certificate of Analysis (COA) of the relevant finished product • Certificate of Pharmaceuticals Product (COPP) • Stability data • Label of the product • Product Information Leaflet • Proforma Invoice **Obtaining Waiver of registration is not guaranteed however will be dependent upon successful submission and meeting of all required documentation as listed above. .**
ITB 16.5	For the purpose of obtaining additional information about the requirements for registration, Bidders may contact CEO / *Chief Pharmacist of NMRA* **Telephone No : +94 11 269 5173,** +94 112 303 072 **e-mail : ceo@nmra.lk** **www : mnra.gov.lk**
ITB 18.1	The Bid shall be valid until: 05 Mar 2024
ITB 18.3 (a)	*Not applicable*
ITB 19.1	A *Bid Security* ***"shall be"*** required A Bid-Securing Declaration ***"shall not be"*** required. If a Bid Security shall be required, the amount and currency of the Bid security shall be *LKR. 19,588,000.00 or equivalent value in USD according to the exchange rate on Bid issuing date*

ITB 19.3 (d)	Other types of acceptable securities: i. A bank guarantee or a bid bond issued by a commercially operating bank in Sri Lanka, approved by the Central Bank of Sri Lanka. ii. A bank based in another country but the security or guarantee "Confirmed" by a commercially operating bank in Sri Lanka. iii. A Letter of Credit issued by a foreign bank, but 'Confirmed' by a commercially operating bank in Sri Lanka. iv. Any other agency approved by the Treasury from time to time. Or v. A cash deposit
ITB 19.9	Not applicable
ITB 20.1	In addition to the original of the Bid, the number of copies is**: 01**
ITB 20.3	The written confirmation of authorization to sign on behalf of the Bidder shall consist of **Letter of Authorization issued to the authorized signatory or registered power of attorney in case of signatory is acting in the capacity of power of attorney holder**
D. Submission and Opening of Bids	
ITB 22.1	For **Bid submission purposes** only, the Purchaser's address is: Attention: The Chairman, Procurement Committee State Pharmaceutical Corporation of Sri Lanka, Street Address: No. 41, "Mehewara Piyasa", Kirula Road Floor/ Room number: *16th Floor* City: Colombo 05 ZIP/Postal Code: 00500 Country: Sri Lanka *Sealed bids may be despatched either by registered post to the address given above or deposited in the bid box kept for the purpose at the above address to receive on or before closing date and time. RFB number should be cleared marked on the left-hand corner of the outer envelope.* The deadline for Bid submission is:

	Date: 07 Sep 2023 Time: 10:00 Hours Bidders ***"shall not"*** have the option of submitting their Bids electronically. The electronic Bidding submission procedures shall be: ***Not Applicable***
ITB 25.1	The Bid opening shall take place at: State Pharmaceutical Corporation of Sri Lanka Street Address: No. 41, "Mehewara Piyasa", Kirula Road Floor/ Room number: *16th Floor* City: Colombo 05 Country: Sri Lanka Date : 07 Sep 2023 Time: 10:00 Hours
ITB 25.1	The electronic Bid opening procedures shall be: ***Not applicable***
ITB 25.6	The Letter of Bid and Price Schedules shall be initialed by Three (03) representatives of the Purchaser conducting Bid opening *via* Bid Opening Committee
E. Evaluation and Comparison of Bids	
ITB 32.1	The currency that shall be used for Bid evaluation and comparison purposes to convert (at the selling rate of Central Bank of Sri Lanka) all Bid prices expressed in various currencies into a single currency is Sri Lankan Rupees (LKR) The source of exchange rate shall be: ***Central Bank of Sri Lanka*** The date for the exchange rate shall be *: **27 Jul 2023***
ITB 33.1	A margin of domestic preference ***"shall"*** apply.
ITB 34.2(a)	Evaluation will be done on individual item basis Note: ***Bids will be evaluated for each item and the Contract will comprise the Item(s) awarded to the successful Bidder.***

ITB 34.6	The adjustments shall be determined using the following criteria, from amongst those set out in Section III, Evaluation and Qualification Criteria: **(a)** Deviation in Delivery schedule: No
F. Award of Contract	
ITB 42	The maximum percentage by which quantities may be increased is: ***15%***The maximum percentage by which quantities may be decreased is: ***15%***
ITB 45.1	The successful Bidder *shall* submit the Beneficial Ownership Disclosure Form.
ITB 47.1	The procedures for making a Procurement-related Complaint are detailed in the "Procurement Regulations for IPF Borrowers (Annex III)." If a Bidder wishes to make a Procurement-related Complaint, the Bidder should submit its complaint following these procedures, in writing (by the quickest means available, that is either by email or fax), to: **For the attention**: Chairman, Procurement Committee **Title/position**: Chairman **Purchaser**: *Ministry of Health, Sri Lanka* **Email address***: chairman@spc.lk* **Fax number**: +94 11 2055800 In summary, a Procurement-related Complaint may challenge any of the following: **1.** the terms of the Bidding Documents; and **2.** the Purchaser's decision to award the contract.

Bid Data Sheet (continued)

PHARMACEUTICALS

(Additional BDS for Pharmaceuticals)

ITB 11.1 (f)	Documentary evidence of the Bidder's qualifications to perform the Contract if its Bid is accepted: (i) (a) has a Good Distribution Practice (GDP) Certificate where appropriate. The Bidder will submit the following additional information: (b) list of pharmaceuticals being manufactured by the Bidder with product registration/license number and date. (c) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.
ITB 16.3 (b)	The pharmaceuticals offered should meet the specified pharmacopeial standards as stated in the Technical Specification. If the Goods offered are not included in one of the specified pharmacopoeias (e.g., the case of a new drug), the Bidder will provide testing protocols and alternative reference standards. BP, USP, IP or any other pharmacopeial standards acceptable to NMRA

Section III - Evaluation and Qualification Criteria

This Section contains the criteria that the Purchaser shall use to evaluate a Bid and qualify the Bidders. No other factors, methods or criteria shall be used other than specified in this bidding document.

Contents

1. Margin of Preference (ITB 33)

If the BDS so specifies, a margin of preference to goods manufactured in the Purchaser's Country for the purpose of Bid comparison shall be granted in accordance with the procedures outlined in subsequent paragraphs.

Bids will be classified in one of three groups, as follows:

(a) **Group A:** Bids offering goods manufactured in the Purchaser's Country, for which (i) labor, raw materials, and components from within the Purchaser's Country account for more than thirty (30) percent of the EXW price; and (ii) the production facility in which they will be manufactured or assembled has been engaged in manufacturing or assembling such goods at least since the date of Bid submission.

(b) **Group B:** All other Bids offering Goods manufactured in the Purchaser's Country.

(c) **Group C:** Bids offering Goods manufactured outside the Purchaser's Country that have been already imported or that will be imported.

To facilitate this classification by the Purchaser, the Bidder shall complete whichever version of the Price Schedule furnished in the bidding document is appropriate provided, however, that the completion of an incorrect version of the Price Schedule by the Bidder shall not result in rejection of its Bid, but merely in the Purchaser's reclassification of the Bid into its appropriate Bid group.

The Purchaser will first review the Bids to confirm the appropriateness of, and to modify as necessary, the Bid group classification to which Bidders assigned their Bids in preparing their Bid Forms and Price Schedules.

The Bids in each group will then be compared to determine the Bid with the lowest evaluated cost in that group. The lowest evaluated cost Bid from each group shall then be compared with each other and if as a result of this comparison a Bid from Group A or Group B is the lowest, it shall be selected for the award.

If as a result of the preceding comparison, the lowest evaluated cost is a Bid from Group C, all Bids from Group C shall be further compared with the Bid with the lowest evaluated cost from Group A after adding to the evaluated costs of goods offered in each Bid from Group C, for the purpose of this further comparison only, an amount equal to 15% (fifteen percent) of the respective CIP Bid price for goods to be imported and already imported goods. Both prices shall include unconditional discounts and be corrected for arithmetical errors. If the Bid from Group A is the lowest, it shall be selected for award. If not, the lowest evaluated Bid from Group C shall be selected.

Most Advantageous Bid

The Purchaser shall use the criteria and methodologies listed in this Section to determine the Most Advantageous Bid. The Most Advantageous Bid is the Bid of the Bidder that meets the qualification criteria and whose Bid has been determined to be:

(a) substantially responsive to the bidding document, and

(b) the lowest evaluated cost.

2. Evaluation (ITB 34)

2.1. Evaluation Criteria (ITB 34.6)

The Purchaser's evaluation of a Bid may take into account, in addition to the Bid Price quoted in accordance with ITB 14.8, one or more of the following factors as specified in ITB 34.2 (f) and in BDS referring to ITB 34.6**,** using the following criteria and methodologies.

(a) Delivery schedule (as per Incoterms specified in the BDS) **Not applicable**

The Goods specified in the List of Goods are required to be delivered within the acceptable time range (after the earliest and before the final date, both dates inclusive) specified in Section VII, Schedule of Requirements. No credit will be given to deliveries before the earliest date, and Bids offering delivery after the final date shall be treated as nonresponsive. Within this acceptable period, an adjustment of [insert the adjustment factor], will be added, for evaluation purposes only, to the Bid price of Bids offering deliveries later than the "Earliest Delivery Date" specified in Section VII, Schedule of Requirements.

(b) Deviation in payment schedule. **Not applicable**

(i) *Bidders shall state their Bid price for the payment schedule outlined in the SCC. Bids shall be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in Bid price they wish to offer for such alternative payment schedule. The Purchaser may consider the alternative payment schedule and the reduced Bid price offered by the Bidder selected on the basis of the base price for the payment schedule outlined in the SCC.*

(c) Specific additional criteria **Not applicable**

Other specific additional criteria to be considered in the evaluation, and the evaluation method shall be detailed in BDS 34.6]

[Other specific additional criteria to be considered in the evaluation, and the evaluation method shall be detailed in BDS 34.6]

*[If specific **sustainable procurement technical requirements** have been specified in Section VII- Specification, **either** state that (i) those requirements will be evaluated on a pass/fail (compliance basis) **or** otherwise (ii) in addition to evaluating those requirements on a pass/fail (compliance basis), if applicable, specify the monetary adjustments to be applied to Bid Prices for comparison purposes on account of Bids that exceed the specified minimum sustainable procurement technical requirements.]*

2.2. Multiple Contracts (ITB 34.4) NOT APPLICABLE

After considering all possible combination of lots, the Purchaser shall award multiple contracts to the Bidder that offers the lowest evaluated cost of the combination of Bids (one contract per Bid), and meets the qualification criteria in this Section III, Sub-Section ITB 37.1Qualification Requirements.

The Purchaser shall:

(a) evaluate only lots or contracts that include at least the percentages of items per lot and quantity per item as specified in ITB 14.6

Bid evaluation of such Bids will be carried out as per the following procedures. The average price (or highest price as specified in BDS 30.3)of an item quoted by substantially responsive Bidders will be added to the Bid price of those who did not quote for that item and the equivalent total cost of the Bid so determined will be used for Bid comparison, evaluation, and award

(b) take into account:

(i) the lowest-evaluated cost for each lot and

(ii) the price reduction per lot and the methodology for its application as offered by the Bidder in its Bid

2.3. Alternative Bids (ITB 13.1) NOT APPLICABLE

An alternative if permitted under ITB 13.1, will be evaluated as follows:

[insert one of the following]

"A Bidder may submit an alternative Bid only with a Bid for the base case. The Purchaser shall only consider the alternative Bids offered by the Bidder whose Bid for the base case was determined to be the Most Advantageous Bid."

or

"A Bidder may submit an alternative Bid with or without a Bid for the base case. The Purchaser shall consider Bids offered for alternatives as specified in the Technical Specifications of Section VII, Schedule of Requirements. All Bids received, for the base case, as well as alternative Bids meeting the specified requirements, shall be evaluated on their own merits in accordance with the same procedures, as specified in the ITB 34."

3. Qualification (ITB 37)

The Bidder shall demonstrate that it continues to meet the prequalification criteria. The Bidder shall use the relevant forms in Section IV in case there is any update to the information that it submitted for prequalification.

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
				Joint Venture (existing or intended)			
No.	Subject	Requirement	Single Entity	All Members Combined	Each Member	One Member	Submission Requirements
1. Eligibility							
1.1	**Nationality**	Nationality in accordance with ITB 4.4	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
1.2	**Conflict of Interest**	No conflicts of interest in accordance with ITB 4.2	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Bid Submission Letter
1.3	**Bank Eligibility**	Not having been declared ineligible by the Bank, as described in ITB 4.5 and 5.1	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Bid Submission Letter
1.4	**State-owned enterprise of the Borrower country**	Meet conditions of ITB 4.6	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
1.5	**United Nations resolution or Borrower's country law**	Not having been excluded as a result of prohibition in the Borrower's country laws or official regulations against commercial relations with the Bidder's country, or by an act of compliance with UN Security Council resolution, both in accordance with ITB 4.8 and Section V.	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
2. Historical Contract Non-Performance							
2.1	**History of Non-Performing Contracts**	Non-performance of a contract[1] did not occur as a result of Supplier's default since 1st	Must meet requirement	Must meet requirements	Must meet requirement[2]	N/A	Form PER-1

[1] Non performance, as decided by the Purchaser, shall include all contracts where (a) non performance was not challenged by the Supplier, including through referral to the dispute resolution mechanism under the respective contract, and (b) contracts that were so challenged but fully settled against the Supplier. Non performance shall not include contracts where Purchaser's decision was overruled by the dispute resolution mechanism. Non performance must be based on all information on fully settled disputes or litigation, i.e. dispute or litigation that has been resolved in accordance with the dispute resolution mechanism under the respective contract and where all appeal instances available to the Bidder have been exhausted.

[2] This requirement also applies to contracts executed by the Bidder as JV member.

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
				Joint Venture (existing or intended)			
No.	Subject	Requirement	Single Entity	All Members Combined	Each Member	One Member	Submission Requirements
		January 2018.					
2.2	**Suspension Based on Execution of Bid/Proposal Securing Declaration by the Purchaser**	Not under suspension based on execution of a Bid/Proposal Securing Declaration pursuant to ITB 4.7.	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Bid Submission Letter
2.3	**Pending Litigation**	Bidder's financial position and prospective long term profitability still sound according to criteria established in 3.1 below and assuming that all pending litigation will be resolved against the Bidder	Must meet requirement	N/A	Must meet requirement	N/A	Form PER-1
2.4	**Litigation History**	No consistent history of court/arbitral award decisions against the Bidder since 1st January *2018*	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Form PER-1
2.5	**Bank's SEA and/or SH Disqualification**	At the time of Contract Award, not subject to disqualification by the Bank for non-compliance with SEA/ SH obligations	Must meet requirement (including each subcontractor)	N/A	Must meet requirement (including each subcontractor proposed by the Applicant)	N/A	Bid Submission Letter, Form PER-2
3. Financial Situation and Performance							
3.1	**Financial Capabilities**	The audited balance sheets or, if not required by the laws of the Bidder's country, other financial statements acceptable to the Purchaser, for the last *3* years shall be submitted and must	Must meet requirement	N/A	Must meet requirement	N/A	

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
				Joint Venture (existing or intended)			
No.	Subject	Requirement	Single Entity	All Members Combined	Each Member	One Member	Submission Requirements
		demonstrate the current soundness of the Bidder's financial position and indicate its prospective long-term profitability.					
3.2	**Average Annual Turnover**	Average annual turnover (Average Annual Sales Revenue) from supply of Health Sector Goods of US$ *13,528,000.00– US Dollars thirteen million five hundred and twenty eight thousand)* calculated as total certified payments received for contracts in progress and/or completed during the last three years.	Must meet requirement	Must meet requirement	50% of the total	50% of the total	Form FIN – 3.2
3.3	**Current Commitments**	The Bidder shall also demonstrate, to the satisfaction of the Purchaser, that it has adequate sources of finance to meet the cash flow requirements on contracts currently in progress and for future contract commitments.					Form CON -1
4. Experience							
4.1	**General Experience**	Experience in supply of Health Sector Goods for at least the last three years	Must meet requirement	N/A	Must meet requirement	N/A	Form EXP –1
4.2 (a)	**Specific Experience**	(i) Documentary evidence of the Bidder's qualifications to perform the Contract in accordance with 4.2 (b)(i) below	Must meet requirement	Must meet requirement	N/A	Must meet requirement	

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
				Joint Venture (existing or intended)			
No.	Subject	Requirement	Single Entity	All Members Combined	Each Member	One Member	Submission Requirements
		(ii) Technical and Production Capability in accordance with 4.2(b)(ii) as below. (iii) Experience on Packaging, Distribution in accordance with 4.2(b)(iii) below.	Must meet requirement Must meet requirement	Must meet requirement Must meet requirement	N/A N/A	Must meet requirement Must meet requirement	
4.2 (b)	See below for details						

Specific Experience Requirements

The Specific Experience Requirements under 4.2 (b) (from the table above) are as follows:

4.2 (b)(i) Documentary evidence in accordance with BDS ITB 11.1

4.2(b)(ii) Technical and Production Capability

The Bidder shall provide evidence that it has the technical, and production capability necessary to perform the Contract:

(i) that it has successfully completed or substantially completed at least 3 - similar contracts for supply of the goods and within the last five years. Similar contracts are those of approximately the same size and that includes comparable products, e.g., capsules, tablets, vaccines.

The goods may have been supplied by the Bidder as a manufacturer or by its agent, with references being submitted to confirm satisfactory performance,

(ii) that it has achieved an annual average production rate of 3,000,000 PFS/vials during the last three years

4.2 (b)(iii) Experience on Packaging, Distribution and Transportation

The Bidder should provide proof of experience with and knowledge of modes of packing, distribution, and transportation of pharmaceuticals similar to those subject to Bidding under logistical and climatic conditions similar to the ones in the purchaser's country. It should provide names of countries to which the Bidder has supplied (including packaged, distributed, and transported) products worth at least the amount USD 2,706,000.00 within the past three years.

Section IV - Bidding Forms

Table of Forms

Letter of Bid

INSTRUCTIONS TO BIDDERS: DELETE THIS BOX ONCE YOU HAVE COMPLETED THE DOCUMENT

The Bidder must prepare this Letter of Bid on stationery with its letterhead clearly showing the Bidder's complete name and business address.

Note: All italicized text is to help Bidders in preparing this form.

Date of this Bid submission: [*insert date (as day, month and year) of Bid submission*]
Request for Bid No.: ***LK-SPC-370463-GO-RFB***
Alternative No.: [*insert identification No if this is a Bid for an alternative*]

To: **[*insert complete name of Purchaser*]**

(a) **No reservation:** We have examined and have no reservations to the bidding document, including Addenda issued in accordance with Instructions to Bidders (ITB 8);

(b) **Eligibility:** We meet the eligibility requirements and have no conflict of interest in accordance with ITB 4;

(c) We have not been suspended nor declared ineligible by the Purchaser based on execution of a Bid-Securing Declaration or Proposal-Securing Declaration in the Purchaser's Country in accordance with ITB 4.7;

(d) **Sexual Exploitation and Abuse (SEA) and/or Sexual Harassment (SH):** [*select the appropriate option from (i) to (iii) below and delete the others. In case of JV members and/or subcontractors, indicate the status of disqualification by the Bank of each JV member and/or subcontractor]*.

We, including any of our subcontractors:

(i) [have not been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations.]

(ii) [are subject to disqualification by the Bank for non-compliance with SEA/ SH obligations.]

(iii) [had been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations, and were removed from the disqualification list. An arbitral award on the disqualification case has been made in our favor.]

(e) **Conformity:** We offer to supply in conformity with the bidding document and in accordance with the Delivery Schedules specified in the Schedule of Requirements the following Goods: [*insert a brief description of the Goods and Related Services*];

(f) **Bid Price:** The total price of our Bid, excluding any discounts offered in item (f) below is: *[Insert one of the options below as appropriate]*

Option 1, in case of one lot: Total price is: [*insert the total price of the Bid in words and figures, indicating the various amounts and the respective currencies*];

Or

Option 2, in case of multiple lots: (a) Total price of each lot [*insert the total price of each lot in words and figures, indicating the various amounts and the respective currencies*]; and (b) Total price of all lots (sum of all lots) [*insert the total price of all lots in words and figures, indicating the various amounts and the respective currencies*];

(g) **Discounts:** The discounts offered and the methodology for their application are:

(i) The discounts offered are: [*Specify in detail each discount offered.*]

(ii) The exact method of calculations to determine the net price after application of discounts is shown below: [*Specify in detail the method that shall be used to apply the discounts*];

(h) **Bid Validity**: Our Bid shall be valid until *[insert day, month and year in accordance with ITP 18.1],* and it shall remain binding upon us and may be accepted at any time before the expiration of that period;

(i) **Performance Security**: If our Bid is accepted, we commit to obtain a Performance Security in accordance with the bidding document;

(j) **One Bid per Bidder**: We are not submitting any other Bid(s) as an individual Bidder, and we are not participating in any other Bid(s) as a Joint Venture partner or as a subcontractor, and meet the requirements of ITB 4.3, other than alternative Bids submitted in accordance with ITB 13;

(k) **Suspension and Debarment:** We, along with any of our subcontractors, suppliers, consultants, manufacturers, or service providers for any part of the contract, are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the World Bank Group or a debarment imposed by the World Bank Group in accordance with the Agreement for Mutual Enforcement of Debarment Decisions between the World Bank and other development banks. Further, we are not ineligible under the Purchaser's Country laws or official regulations or pursuant to a decision of the United Nations Security Council;

(l) **State-owned enterprise or institution:** [*select the appropriate option and delete the other*] [*We are not a state-owned enterprise or institution*] / [*We are a state-owned enterprise or institution but meet the requirements of ITB 4.6*];

(m) **Commissions, gratuities, fees:** We have paid, or will pay the following commissions, gratuities, or fees with respect to the Bidding process or execution of the Contract: [*insert complete name of each Recipient, its full address, the reason for which each commission or gratuity was paid and the amount and currency of each such commission or gratuity*]

Name of Recipient	Address	Reason	Amount

(If none has been paid or is to be paid, indicate "none.")

(n) **Binding Contract:** We understand that this Bid, together with your written acceptance thereof included in your Letter of Acceptance, shall constitute a binding contract between us, until a formal contract is prepared and executed;

(o) **Purchaser Not Bound to Accept:** We understand that you are not bound to accept the lowest evaluated cost Bid, the Most Advantageous Bid or any other Bid that you may receive; and

(p) **Fraud and Corruption:** We hereby certify that we have taken steps to ensure that no person acting for us or on our behalf engages in any type of Fraud and Corruption.

Name of the Bidder: *[*insert complete name of the Bidder*]

Name of the person duly authorized to sign the Bid on behalf of the Bidder: **[*insert complete name of person duly authorized to sign the Bid*]

Title of the person signing the Bid: [*insert complete title of the person signing the Bid*]

Signature of the person named above: [*insert signature of person whose name and capacity are shown above*]

Date signed [*insert date of signing*] **day of** [*insert month*], [*insert year*]

*: In the case of the Bid submitted by a Joint Venture specify the name of the Joint Venture as Bidder.

**: Person signing the Bid shall have the power of attorney given by the Bidder. The power of attorney shall be attached with the Bid Schedules.

Bidder Information Form

[The Bidder shall fill in this Form in accordance with the instructions indicated below. No alterations to its format shall be permitted and no substitutions shall be accepted.]

Date: *[insert date (as day, month and year) of Bid submission*]
RFB No.: ***[LK-SPC-370463-GO-RFB***]
Alternative No.: *[insert identification No if this is a Bid for an alternative]*

Page _____ of_ _____ pages

1. Bidder's Name *[insert Bidder's legal name]*
2. In case of JV, legal name of each member : *[insert legal name of each member in JV]*
3. Bidder's actual or intended country of registration: *[insert actual or intended country of registration]*
4. Bidder's year of registration: *[insert Bidder's year of registration]*
5. Bidder's Address in country of registration: *[insert Bidder's legal address in country of registration]*
6. Bidder's Authorized Representative Information Name: *[insert Authorized Representative's name]* Address: *[insert Authorized Representative's Address]* Telephone/Fax numbers: *[insert Authorized Representative's telephone/fax numbers]* Email Address: *[insert Authorized Representative's email address]*
7. Attached are copies of original documents of*[check the box(es) of the attached original documents]* ☐ Articles of Incorporation (or equivalent documents of constitution or association), and/or documents of registration of the legal entity named above, in accordance with ITB 4.4. ☐ In case of JV, letter of intent to form JV or JV agreement, in accordance with ITB 4.1. ☐ In case of state-owned enterprise or institution, in accordance with ITB 4.6 documents establishing:

- Legal and financial autonomy
- Operation under commercial law
- Establishing that the Bidder is not under the supervision of the Purchaser

8. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership. *[If required under BDS ITB 45.1, the successful Bidder shall provide additional information on beneficial ownership, using the Beneficial Ownership Disclosure Form.]*

Form ELI -1.1 (continued)

Bidder Information Form

Date: *[insert day, month, year*]
RFB No. and title: ***LK-SPC-370463-GO-RFB*** *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*
Page *[insert page number]* of *[insert total number]* pages

1. Bidder's name			
2. 2. Street Address:	Postal Code:	City:	Country:
3. P.O. Box and Mailing Address:			
4. Telephone Number:			
5. Fax Number:			
6. E-mail Address:			
7. Web Site:			
8. Contact Name:			
9. Contact Title:			
10. Type of Business:			
11. If Other, specify:			
12. Nature of Business:			
13. Year Established:			
14. Dates, Numbers, and Expiration Dates of Current Licenses and Permits:			
15. Current health authority registration information:			
16. Proof of product and facility registrations with purchaser's country regulatory authority and international agencies (e.g., WHO Certification Scheme, GMP)			
17. Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods: Date of last inspection:			

18. Quality Assurance Certification (Please include a copy of your latest certificate):	
19. Production capacity: *[insert peak and average production capacity over the last three years in units/day or units/month, etc.]*	
20. List of names and addresses of sources of raw material and what products they will be used in:	
21. List product recalls linked to defects during the last 36 months. Include reason and date of recall.	
22. Are technical documents available in: ***[Purchaser should insert language]*** Yes No	

Bidder's JV Members Information Form

[The Bidder shall fill in this Form in accordance with the instructions indicated below. The following table shall be filled in for the Bidder and for each member of a Joint Venture]].

Date: *[insert date (as day, month and year) of Bid submission*]
RFB No.: ***LK-SPC-370463-GO-RFB***
Alternative No.: *[insert identification No if this is a Bid for an alternative]*

Page _____ of_ _____ pages

1. Bidder's Name: *[insert Bidder's legal name]*
2. Bidder's JV Member's name: *[insert JV's Member legal name]*
3. Bidder's JV Member's country of registration: *[insert JV's Member country of registration]*
4. Bidder's JV Member's year of registration: *[insert JV's Member year of registration]*
5. Bidder's JV Member's legal address in country of registration: *[insert JV's Member legal address in country of registration]*
6. Bidder's JV Member's authorized representative information Name: *[insert name of JV's Member authorized representative]* Address: *[insert address of JV's Member authorized representative]* Telephone/Fax numbers: *[insert telephone/fax numbers of JV's Member authorized representative]* Email Address: *[insert email address of JV's Member authorized representative]*
7. Attached are copies of original documents of*[check the box(es) of the attached original documents]* ☐ Articles of Incorporation (or equivalent documents of constitution or association), and/or registration documents of the legal entity named above, in accordance with ITB4.4. ☐ In case of a state-owned enterprise or institution, documents establishing legal and financial autonomy, operation in accordance with commercial law, and not under the supervision of the Purchaser, in accordance with ITB4.6. 8. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership. *[If required under BDS ITB 45.1, the successful Bidder shall provide additional information on beneficial ownership for each JV member using the Beneficial Ownership Disclosure Form.]*

Form FIN – 3.1
Financial Situation and Performance

[The following table shall be filled in for the Bidder and for each member of a Joint Venture]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370463-GO-RFB*** *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*
Page *[insert page number]* of *[insert total number]* pages

1. Financial data

Type of Financial information in (currency)	**Historic information for previous** *[insert number] years, [insert in words]* **(amount in currency, currency, exchange rate, USD equivalent)**				
	Year 1	Year 2	Year 3		
Statement of Financial Position (Information from Balance Sheet)					
Total Assets (TA)					
Total Liabilities (TL)					
Total Equity/Net Worth (NW)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital (WC)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					
Cash Flow Information					

Cash Flow from Operating Activities					

3. Financial documents

The Bidder and its parties shall provide copies of financial statements for *[number]* years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

(a) reflect the financial situation of the Bidder or in case of JV member, and not an affiliated entity (such as parent company or group member).

(b) be independently audited or certified in accordance with local legislation.

(c) be complete, including all notes to the financial statements.

(d) correspond to accounting periods already completed and audited.

☐ Attached are copies of financial statements[3] for the *[number]* years required above; and complying with the requirements

[3] If the most recent set of financial statements is for a period earlier than 12 months from the date of bidding, the reason for this should be justified.

Form FIN - 3.2
Average Annual Turnover (Annual Sales Value)

[The following table shall be filled in for the Bidder and for each member of a Joint Venture]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370463-GO-RFB*** *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*
Page *[insert page number]* of *[insert total number]* pages

Annual turnover data			
Year	**Amount** **Currency**	**Exchange rate**	**USD equivalent**
[indicate calendar year]	*[insert amount and indicate currency]*		
		Average Annual Turnover *	

* Total USD equivalent for all years divided by the total number of years.

Form CON-1
Current Contract Commitments / Contracts in Progress Form

1. Name of Contract(s)
2. Purchaser Contact Information *[insert address, telephone, fax, e-mail address]*
3. Value of outstanding contracts *[current US$ equivalent]*
4. Estimated delivery date
5. Average monthly invoices over the last six months (US$/mon.)

Form- EXP-1
Experience

Contracts over *[insert amount]* during the last three years:				
Purchaser	Value	Year	Goods/Services Supplied	Country of Destination

Form- PER 1

Historical Contract Non-Performance, and Pending Litigation and Litigation History

[The following table shall be filled in for the Bidder and for each member of a Joint Venture]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370463-GO-RFB*** *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*
Page *[insert page number]* of *[insert total number]* pages

Non-Performed Contracts in accordance with Section III, Evaluation and Qualification Criteria *(In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document)*			
☐ Contract non-performance did not occur since 1st January *[insert year]* ☐ Contract(s) not performed since 1st January *[insert year]*			
Year	**Non-performed portion of contract**	**Contract Identification**	**Total Contract Amount (current value, currency, exchange rate and US$ equivalent)**
[insert year]	*[insert amount and percentage]*	Contract Identification: *[indicate complete contract name/ number, and any other identification]* Name of Purchaser: *[insert full name]* Address of Purchaser: *[insert street/city/country]* Reason(s) for nonperformance: *[indicate main reason(s)]*	*[insert amount]*
Pending Litigation, in accordance with Section III, Evaluation and Qualification Criteria *(In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document)*			
☐ No pending litigation ☐ Pending litigation as indicated below.			
Year of	**Amount in**	**Contract Identification**	**Total Contract**

dispute	dispute (currency)		Amount (currency), USD Equivalent (exchange rate)
[insert year]	*[insert amount]*	Contract Identification: [indicate complete contract name, number, and any other identification] Name of Purchaser: *[insert full name]* Address of Purchaser: *[insert street/city/country]* Matter in dispute: *[indicate main issues in dispute]* Party who initiated the dispute: *[indicate "Purchaser" or "Supplier"]* Status of dispute:	*[insert amount]*
Litigation History in accordance with Section III, Evaluation and Qualification Criteria *(In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document)*			
☐ No Litigation History ☐ Litigation History as indicated below:			
Year of award	**Outcome as percentage of Net Worth**	**Contract Identification**	**Total Contract Amount (currency), USD Equivalent (exchange rate)**
[insert year]	*[insert percentage]*	Contract Identification: [indicate complete contract name, number, and any other identification] Name of Purchaser: *[insert full name]* Address of Purchaser: *[insert street/city/country]* Matter in dispute: *[indicate main issues in dispute]* Party who initiated the dispute: *[indicate "Purchaser" or "Supplier"]* Reason(s) for Litigation and award decision *[indicate main reason(s)]*	*[insert amount]*

Form PER –2
Sexual Exploitation and Abuse (SEA) and/or Sexual Harassment Performance Declaration

[The following table shall be filled in by the Bidder, each member of a Joint Venture and each subcontractor proposed by the Bidder]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member's or Subcontractor's Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370463-GO-RFB*** *Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*
Page *[insert page number]* of *[insert total number]* pages

SEA and/or SH Declaration **in accordance with Section III, Qualification Criteria, and Requirements**
We: ☐ (a) have not been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations ☐ (b) are subject to disqualification by the Bank for non-compliance with SEA/ SH obligations ☐ (c) had been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations, and were removed from the disqualification list. An arbitral award on the disqualification case has been made in our favor.
[*If (c) above is applicable, attach evidence of an arbitral award reversing the findings on the issues underlying the disqualification.]*

Price Schedule Forms

*[The Bidder shall fill in these Price Schedule Forms in accordance with the instructions indicated. The list of line items in column 1 of the **Price Schedules** shall coincide with the List of Goods and Related Services specified by the Purchaser in the Schedule of Requirements.]*

Price Schedule: Goods Manufactured Outside the Purchaser's Country, to be Imported

(Group C Bids, goods to be imported)

Currencies in accordance with ITB 15

Date:_____
RFB No: LK-SPC-370463-GO-RFB

Alternative No: _____
Page N° _____ of _____

1	2	3	4	5	6	7			8	9	10	11	12	13	14
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices			Total unit price [a+b+c]	Total price per item [6 x 8]	Local agent's commission as a % of CIP price included in quoted price	Shipment weight and volume	Name of Manufacturer	Cnty. Of origin	Pharma-copoeial standard
						[a] CIP named place of destination (specify one)	[b] Inland transp., insurance & other local costs incidental to delivery if specified	[c] Other incidental costs as defined in the SCC							

Total Bid Price:
Currency:
In figures:
In words:

Name of Bidder *[insert complete name of Bidder]* Signature of Bidder *[signature of person signing the Bid]* Date *[Insert Date]*

In the capacity of: *[insert: **title or other appropriate designation**]*

Price Schedule: Goods Manufactured Outside the Purchaser's Country, already imported*

(Group C Bids, Goods already imported) Currencies in accordance with ITB 15	Date:_____ RFB No: LK-SPC-370463-GO-RFB Alternative No: _____ Page N° _____ of _____

1	2	3	4	5	6	7					8	9	10	11	12	13
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices					Total Unit price [c+d+e]	Total price per line item [6x8]	Sales and other taxes payable per item if Contract is awarded	Name of manufactu re-	Ctry. of origin	Pharma-copoeial standard
						[a] Unit price includin g Custom Duties and Import Taxes paid and payable	[b] Custom Duties and Import Taxes paid and payable per unit	[c]=a-b Unit Price net of custom duties and import taxes	[d] Inland transp., insurance & other local costs incidental to delivery	[e] Other incident-al costs as defined in the SCC						

Note: (i) Column 7[b] Custom Duties and Import Taxes paid should be supported by documentary evidence..	Total Bid Price: _____ Currency: _____ In figures: _____ In words: _____

Name of Bidder *[insert complete name of Bidder]* Signature of Bidder *[signature of person signing the Bid]* Date *[insert date]*

* *[For previously imported Goods, the quoted price shall be distinguishable from the original import value of these Goods declared to customs and shall include any rebate or mark-up of the local agent or representative and all local costs except import duties and taxes, which have been and/or have to be paid by the Purchaser. For clarity the Bidders are asked to quote the price including import duties, and additionally to provide the import duties and the price net of import duties which is the difference of those values.]*

Price Schedule: Goods Manufactured in the Purchaser's Country

Purchaser's Country _____						(Group A and B Bids) Currencies in accordance with ITB 15						Date:_____ RFB No: LK-SPC-370463-GO-RFB Alternative No: _____ Page N° _____ of _____		
1	2	3	4	5	6	7			8	9	10	11	12	13
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices			Total unit price [a+b+c]	Total price	Sales and other taxes payable if contract is awarded	Name of manufacturer	Pharma-copoeial standard	Local input in the cost as % of ex-factory price in column 7[a]
						[a] Ex-factory Ex-warehouse Ex-showroom Off the shelf	[b] Inland transp., insurance & other local costs incidental to delivery	[c] Other incident-al costs as defined in the SCC						
									Total Bid Price: _____ Currency: _____ In figures: _____ In words: _____					

Name of Bidder *[insert complete name of Bidder]* Signature of Bidder *[signature of person signing the Bid]* Date *[insert date]*

In the capacity of:*[insert: title or other appropriate designation]*

Form of Bid Security - (Bank guarantee)

[The bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]

[Guarantor letterhead or SWIFT identifier code]

Beneficiary: *[Purchaser to insert its name and address]*

RFB No.: *LK-SPC-370463-GO-RFB*

Alternative No.*: [Insert identification No if this is a Bid for an alternative]*

Date: *[Insert date of issue]*

BID GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that _____ *[insert name of the Bidder, which in the case of a joint venture shall be the name of the joint venture (whether legally constituted or prospective) or the names of all members thereof]* (hereinafter called "the Applicant") has submitted or will submit to the Beneficiary its Bid (hereinafter called "the Bid") for the execution of _____ under Request for Bids No. _____ ("the RFB").

Furthermore, we understand that, according to the Beneficiary's conditions, Bids must be supported by a Bid guarantee.

At the request of the Applicant, we, as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of _____ (_____) upon receipt by us of the Beneficiary's complying demand, supported by the Beneficiary's statement, whether in the demand itself or a separate signed document accompanying or identifying the demand, stating that either the Applicant:

(a) has withdrawn its Bid prior to the Bid validity expiry date set forth in the Applicant's Letter of Bid, or any extended date provided by the Applicant; or

(b) having been notified of the acceptance of its Bid by the Beneficiary prior to the expiry date of the Bid validity or any extension thereof provided by the Applicant has failed to: (i) sign the contract agreement, or (ii) furnish the performance security, in accordance with the Instructions to Bidders ("ITB") of the Beneficiary's bidding document.

This guarantee will expire: (a) if the Applicant is the successful Bidder, upon our receipt of copies of the contract agreement signed by the Applicant and the Performance Security issued to the Beneficiary in relation to such contract agreement; or (b) if the Applicant is not the successful Bidder, upon the earlier of (i) our receipt of a copy of the Beneficiary's notification to the Applicant of the results of the Bidding process; or (ii) twenty-eight days after the expiry date of the Bid validity.

Consequently, any demand for payment under this guarantee must be received by us at the office indicated above on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No. 758.

_____

[Signature(s)]

Note: All italicized text is for use in preparing this form and shall be deleted from the final product.

Form of Bid Security (Bid Bond)

[The Surety shall fill in this Bid Bond Form in accordance with the instructions indicated.]

BOND NO. _____

BY THIS BOND *[name of Bidder]* as Principal (hereinafter called "the Principal"), and *[name, legal title, and address of surety],* **authorized to transact business in** *[name of country of Purchaser],* as Surety (hereinafter called "the Surety"), are held and firmly bound unto *[name of Purchaser]* as Obligee (hereinafter called "the Purchaser") in the sum of *[amount of Bond]*[4] *[amount in words]*, for the payment of which sum, well and truly to be made, we, the said Principal and Surety, bind ourselves, our successors and assigns, jointly and severally, firmly by these presents.

WHEREAS the Principal has submitted or will submit a written Bid to the Purchaser dated the ___ day of _____, 20__, for the supply of *[name of Contract]* (hereinafter called the "Bid").

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION is such that if the Principal:

(a) withdraws its Bid prior to the Bid validity expiry date set forth in the Principal's Letter of Bid, or any extended date provided by the Principal; or

(b) having been notified of the acceptance of its Bid by the Purchaser prior to the expiry date of the Bid validity or any extension thereto provided by the Applicant has failed to: (i) execute the Contract agreement; or (ii) furnish the Performance Security, in accordance with the Instructions to Bidders ("ITB") of the Purchaser's bidding document.

then the Surety undertakes to immediately pay to the Purchaser up to the above amount upon receipt of the Purchaser's first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser shall state that the demand arises from the occurrence of any of the above events, specifying which event(s) has occurred.

The Surety hereby agrees that its obligation will remain in full force and effect up to and including the date 28 days after the date of expiry of the Bid validity set forth in the Principal's Letter of Bid or any extension thereto provided by the Principal.

IN TESTIMONY WHEREOF, the Principal and the Surety have caused these presents to be executed in their respective names this ____ day of _____ 20__.

Principal: _____ Surety: _____

Corporate Seal (where appropriate)

_____

_____	_____
(Signature)	*(Signature)*
(Printed name and title)	*(Printed name and title)*

Manufacturer's Authorization

*[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its Bid, if so indicated in the **BDS.**]*

Date: *[insert date (as day, month and year) of Bid submission]*
RFB No.: ***LK-SPC-370463-GO-RFB***
Alternative No.: *[insert identification No if this is a Bid for an alternative]*

To: *[insert complete name of Purchaser]*

WHEREAS

We *[insert complete name of Manufacturer],* who are official manufacturers of *[insert type of goods manufactured],* having factories at [insert full address of Manufacturer's factories], do hereby authorize *[insert complete name of Bidder]* to submit a Bid the purpose of which is to provide the following Goods, manufactured by us *[insert name and or brief description of the Goods],* and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 28 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

We confirm that we do not engage or employ forced labor or persons subject to trafficking or child labor, in accordance with Clause 14 of the General Conditions of Contract. We also confirm that we comply with applicable health and safety obligations in accordance with Clause 14 of the General Conditions of Contract.

Signed: *[insert signature(s) of authorized representative(s) of the Manufacturer]*

Name: *[insert complete name(s) of authorized representative(s) of the Manufacturer]*

Title: *[insert title]*

Dated on _____ day of _____, _____ *[insert date of signing]*

Specimen Certificate of a Pharmaceutical Product

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization *(general instructions and explanatory notes attached).*

No. of certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredients[2] and amount(s) per unit dose.[3]

_____

_____

_____

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no *(key in as appropriate)*

1.3 Is this product actually on the market in the exporting country? yes/no/unknown *(key in as appropriate)*

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.[6]

2A. 1 Number of product license[7] and date of issue:

_____

2A.2 Product-license holder (name and address):

_____

_____

_____

2A.3 Status of product-license holder:[8] a/b/c *(key in appropriate category as defined in note 8)*

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are: [9]

_____

_____

_____

2A.4 Is Summary Basis of Approval appended?[10] yes/no *(key in as appropriate)*

2A.5 Is the attached, officially approved product information complete and consonant with the license?[11] yes/no/not provided *(key in as appropriate)*

2A.6 Applicant for certificate, if different from license holder (name and address):[12]

2B. 1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c *(key in appropriate category as defined in note 8)*

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

_____

_____

_____

2B.3 Why is marketing authorization lacking?

not required/not requested/under consideration/refused *(key in as appropriate)*

2B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

yes/no/not applicable[14]*(key in as appropriate)*

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): _____

3.2 Has the manufacture of this type of dosage form been inspected?

yes/no *(key in as appropriate)*

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

yes/no/not applicable[16]*(key in as appropriate)*

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? [11]

yes/no *(key in as appropriate)*

If no, explain: _____

_____

Address of certifying authority: _____

Telephone number: _____ Fax number: _____

Name of authorized person:

_____

Signature:

_____

Stamp and date:

_____

General instructions

Please refer to the guidelines: https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1 This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2 Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

3 The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4 Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.

5 When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.

6 Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the license is provisional or if the product has not yet been approved.

[8] Specify whether the person responsible for placing the product on the market:
(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in none of the above.

[9] This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Noncompletion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

[10] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[11] This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

[12] In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

[13] Please indicate the reason that the applicant has provided for not requesting registration:
(a) The product has been developed exclusively for the treatment of conditions—particularly tropical diseases—not endemic in the country of export.
(b) The product has been reformulated with a view to improving its stability under tropical conditions.
(c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.
(d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
(e) Any other reason, please specify.

[14] Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

Section V - Eligible Countries

Eligibility for the Provision of Goods, Works and Non Consulting Services in Bank-Financed Procurement

In reference to ITB 4.8and 5.1, for the information of the Bidders, at the present time firms, goods and services from the following countries are excluded from this Bidding process:

Under ITB 4.8(a) and 5.1: **None**

Under ITB 4.8(b) and 5.1: **None**

Section VI - Fraud and Corruption

(Section VI shall not be modified)

1. Purpose

1.1 The Bank's Anti-Corruption Guidelines and this annex apply with respect to procurement under Bank Investment Project Financing operations.

2. Requirements

2.1 The Bank requires that Borrowers (including beneficiaries of Bank financing); bidders (applicants/proposers), consultants, contractors and suppliers; any sub-contractors, sub-consultants, service providers or suppliers; any agents (whether declared or not); and any of their personnel, observe the highest standard of ethics during the procurement process, selection and contract execution of Bank-financed contracts, and refrain from Fraud and Corruption.

2.2 To this end, the Bank:

a. Defines, for the purposes of this provision, the terms set forth below as follows:

i. "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

ii. "fraudulent practice" is any act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;

iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

v. "obstructive practice" is:

(a) deliberately destroying, falsifying, altering, or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive, or collusive practice; and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(b) acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under paragraph 2.2 e. below.

b. Rejects a proposal for award if the Bank determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub-consultants, sub-contractors, service providers, suppliers and/ or their employees, has, directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question;

c. In addition to the legal remedies set out in the relevant Legal Agreement, may take other appropriate actions, including declaring misprocurement, if the Bank determines at any time that representatives of the Borrower or of a recipient of any part of the proceeds of the loan engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices during the procurement process, selection and/or execution of the contract in question, without the Borrower having taken timely and appropriate action satisfactory to the Bank to address such practices when they occur, including by failing to inform the Bank in a timely manner at the time they knew of the practices;

d. Pursuant to the Bank's Anti- Corruption Guidelines and in accordance with the Bank's prevailing sanctions, policies and procedures, may sanction a firm or individual, either indefinitely or for a stated period of time, including by publicly declaring such firm or individual ineligible (i) to be awarded or otherwise benefit from a Bank-financed contract, financially or in any other manner;1 (ii) to be a nominated2 sub-contractor, consultant, manufacturer or supplier, or service provider of an otherwise eligible firm being awarded a Bank-financed contract; and (iii) to receive the proceeds of any loan made by the Bank or otherwise to participate further in the preparation or implementation of any Bank-financed project;

e. Requires that a clause be included in bidding/request for proposals documents and in contracts financed by a Bank loan, requiring (i) bidders (applicants/proposers), consultants, contractors, and suppliers, and their sub-contractors, sub-consultants, service providers, suppliers, agents personnel, permit the Bank to inspect[3] all

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1 For the avoidance of doubt, a sanctioned party's ineligibility to be awarded a contract shall include, without limitation, (i) applying for pre-qualification, expressing interest in a consultancy, and bidding, either directly or as a nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider, in respect of such contract, and (ii) entering into an addendum or amendment introducing a material modification to any existing contract.

2 A nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider (different names are used depending on the particular bidding document) is one which has been: (i) included by the bidder in its pre-qualification application or bid because it brings specific and critical experience and know-how that allow the bidder to meet the qualification requirements for the particular bid; or (ii) appointed by the Borrower.

3 Inspections in this context usually are investigative (i.e., forensic) in nature. They involve fact-finding activities undertaken by the Bank or persons appointed by the Bank to address specific matters related to investigations/audits, such as evaluating the veracity of an allegation of possible Fraud and Corruption, through the appropriate mechanisms. Such activity includes but is not limited to: accessing and examining a firm's or individual's financial records and information, and making copies thereof as relevant; accessing and examining any other documents, data and information (whether in hard copy or electronic format) deemed relevant for the investigation/audit, and making copies

accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have them audited by auditors appointed by the Bank.

thereof as relevant; interviewing staff and other relevant individuals; performing physical inspections and site visits; and obtaining third party verification of information.

PART 2 – Supply Requirements

Section VII - Schedule of Requirements

Contents

1. List of Goods and Delivery Schedule

Line Item N°	Description of Goods	Quantity	Physical unit	Final (Project Site) Destination as specified in BDS	Delivery (as per Incoterms) Date		
					Earliest Delivery Date	Latest Delivery Date	Bidder's offered Delivery date [*to be provided by the Bidder*]
00407201	*Enoxaparin Sodium Injection 6,000 IU in 0.6ml prefilled syringe/vial*	*1,000,000*	*Pre-filled syringes /Vials*	***Foreign bidders*** *: Sea/Air Colombo/ Sri Lanka* ***Import & Supply*** *: Medical Supplies Division, No 357, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10.*	*30 Nov.2023*	*15 Dec. 2023*	*[insert the number of days following the date of effectiveness the Contract]*

2. Technical Specifications

Technical Specifications Pharmaceuticals

PHARMACEUTICALS

1. Product and Package Specifications

Enoxaparin Sodium Injection, 6,000 IU in 0.6ml prefilled syringe / vial

Each 0.6ml prefilled syringe or vial to contain 6,000 IU of Enoxaparin Sodium salt of a low molecular weight Heparin obtained by depolymerization of Heparin for subcutaneous and intravenous injection.

Note:
1. The product to be stable for minimum of 24 months when stored under storage condition stipulated by the manufacturer.
2. Each vial or syringe should be labelled according to the point No 2 Labeling Instructions of Section VII – Schedule of Requirements

Pack Size : 1 PFS/vial in a pack

The product should be complied with British Pharmacopoeia/United States Pharmacopoeia/European Pharmacopoeia or any other pharmacopeial standard acceptable to NMRA

1. The consignments supplied in respect of an order concerned, shall exactly match with the product information (item descriptions, shelf life, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bidding document by the Bidder, which has been accepted by the procurement committee, and included in the Contract, issued by the Purchaser.

2. Maintaining the validity of the product registration / waiver of registration during the period of supply (delivery schedule) &/ import license / manufacture licensing at NMRA, is a requirement for the supply of pharmaceutical items. Hence all Suppliers shall produce relevant valid registration certificates/licenses or equivalent documentation acceptable to the NMRA, 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.

3. 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.

Shelf life & Warrantees

4. 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 75% of the product shelf life specified in the Contract or as certified in the product registration certificate or indicated in any other way by NMRA.

When the shelf life is not specified in the contract/item spec; the requested shelf life shall be considered as 24 months for Pharma. 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.

In the violation of bidding 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.

Storage Conditions & Temperature

5. 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.

6. 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.5 - Standards of quality control for supply of Section VII – Schedule of Requirements)**

Documents & Information

7. 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.
8. 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 security.

After releasing the Contract or establishing letter of credit, the latest logistical position of manufacturing & supply on the Contract, shall be updated biweekly through e-mails to Purchaser by the supplier. (follow instructions in the website www.msd.gov.lk)

Abbreviations *NMRA; National Medicines Regulatory Authority/Sri Lanka,* SPC; Ministry of Health, Sri Lanka*, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka*
L/C ; Letter of Credit.

2. Labeling Instructions

1. 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 MOH.

2. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No / Lot No, Name and address of manufacturer and "STATE LOGO" of Sri Lanka Government (Annexure 1) shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure (vial/ampoule, pre-filled syringe or bottle), 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 MOH and DOM & DOE shall consist of at least the year & month.

3. All outer most cartons (shipping packages) shall bear the MSD order list No, SPC Contract 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.

4. 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).

5. In respect of purchaser imported supplies, if the local agent does not follow suit as above, such extra expenses incurred

to purchaser shall be recovered from the supplier.

3.	**Case Identification**	Amalgamated in the labelling requirement above
4.	**Unique Identifiers**	Export packing should be in seaworthy strong cases or cartons to prevent damage in transit and should:- a. Indicate recommended storage temperature specially for goods which require cool/cold or freezer storage. b. Stenciled blue bands in the form of a cross on each face. c. Carry shipping marks – details provided by SPC with order. d. Be palletized and shrink wrapped if required by the bidding conditions. 5.4.5 Should carry Batch No./Exp. Date.
5.	**Standards of Quality Control for Supply**	1. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopeial Standards that are indicated in the item specifications or other Pharmacopeial Standards accepted in the product registration by the National Medicines Regulatory Authority. 2. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items, with information to users regarding the; storage conditions, shall be provided with the product, for acceptance of goods by Purchaser. 3. Any product deficient of or not at the specified quality standards, shall be rejected. 4. 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. (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. 06 - Product and Package Specifications)

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.

5. 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.

Consignments supplied to MOH 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. 4. **Standards of Quality Control for Supply**)

Annexure I

3. Inspections and Tests

The following inspections and tests shall be performed: *[insert list of inspections and tests]*

The supplier should submit pre-shipment sample test reports for each batch/lot supplied from a WHO accredited testing laboratory or NABL (National Accreditation Board for Testing and Calibration Laboratories) in India nominated by Purchaser for the parameters listed in the relevant pharmacopeia, if the supplier has not supplied the item previously or any quality issue reported on previous supplies.

PART 3 - Contract

Section VIII - General Conditions of Contract

Table of Clauses

Section VIII - General Conditions of Contract

1. Definitions

1.1. The following words and expressions shall have the meanings hereby assigned to them:

(a) "Bank" means the World Bank and refers to the International Bank for Reconstruction and Development (IBRD) or the International Development Association (IDA).

(b) "Contract" means the Contract Agreement entered into between the Purchaser and the Supplier, together with the Contract Documents referred to therein, including all attachments, appendices, and all documents incorporated by reference therein.

(c) "Contract Documents" means the documents listed in the Contract Agreement, including any amendments thereto.

(d) "Contract Price" means the price payable to the Supplier as specified in the Contract Agreement, subject to such additions and adjustments thereto or deductions therefrom, as may be made pursuant to the Contract.

(e) "Day" means calendar day.

(f) "Completion" means the fulfillment of the Related Services by the Supplier in accordance with the terms and conditions set forth in the Contract.

(g) "GCC" means the General Conditions of Contract.

(h) "Goods" means all of the pharmaceuticals including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms Supplier is required to supply to the Purchaser under the Contract.

(i) "Purchaser's Country" is the country specified **in the Special Conditions of Contract** (SCC).

(j) "Purchaser" means the entity purchasing the Goods and Related Services, as specified **in the SCC.**

(k) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser's Country in accordance with the Applicable Law.

(l) "Related Services" means the services incidental to the

supply of the goods, such as insurance, installation, training and initial maintenance and other such obligations of the Supplier under the Contract.

(m) "SCC" means the Special Conditions of Contract.

(n) "Supplier" means the person, private or government entity, or a combination of the above, whose Bid to perform the Contract has been accepted by the Purchaser and is named as such in the Contract Agreement.

(o) "The Project Site," where applicable, means the place named **in the SCC.**

2. Contract Documents

2.1 Subject to the order of precedence set forth in the Contract Agreement, all documents forming the Contract (and all parts thereof) are intended to be correlative, complementary, and mutually explanatory. The Contract Agreement shall be read as a whole.

3. Fraud and Corruption

3.1 The Bank requires compliance with the Bank's Anti-Corruption Guidelines and its prevailing sanctions policies and procedures as set forth in the WBG's Sanctions Framework, as set forth in Appendix 1 to the GCC.

3.2 The Purchaser requires the Supplier to disclose any commissions or fees that may have been paid or are to be paid to agents or any other party with respect to the Bidding process or execution of the Contract. The information disclosed must include at least the name and address of the agent or other party, the amount and currency, and the purpose of the commission, gratuity or fee.

4. Interpretation

4.1 If the context so requires it, singular means plural and vice versa.

4.2 Incoterms

(a) Unless inconsistent with any provision of the Contract**,** the meaning of any trade term and the rights and obligations of parties thereunder shall be as prescribed by Incoterms specified **in the SCC**.

(b) The terms EXW, CIP, FCA, CFR and other similar terms, when used, shall be governed by the rules prescribed in the current edition of Incoterms specified **in the SCC** and published by the International Chamber of Commerce in Paris, France.

4.3 Entire Agreement

The Contract constitutes the entire agreement between the Purchaser and the Supplier and supersedes all communications, negotiations and agreements (whether written or oral) of the parties with respect thereto made prior to the date of Contract.

4.4 Amendment

No amendment or other variation of the Contract shall be valid unless it is in writing, is dated, expressly refers to the Contract, and is signed by a duly authorized representative of each party thereto.

4.5 Nonwaiver

(a) Subject to GCC Sub-Clause 4.5(b) below, no relaxation, forbearance, delay, or indulgence by either party in enforcing any of the terms and conditions of the Contract or the granting of time by either party to the other shall prejudice, affect, or restrict the rights of that party under the Contract, neither shall any waiver by either party of any breach of Contract operate as waiver of any subsequent or continuing breach of Contract.

(b) Any waiver of a party's rights, powers, or remedies under the Contract must be in writing, dated, and signed by an authorized representative of the party granting such waiver, and must specify the right and the extent to which it is being waived.

4.6 Severability

If any provision or condition of the Contract is prohibited or rendered invalid or unenforceable, such prohibition, invalidity or unenforceability shall not affect the validity or enforceability of any other provisions and conditions of the Contract.

5. Language

5.1 The Contract as well as all correspondence and documents relating to the Contract exchanged by the Supplier and the Purchaser, shall be written in the language specified **in the SCC.** Supporting documents and printed literature that are part of the Contract may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified**,** in which case, for purposes of interpretation of the Contract, this translation shall govern.

5.2 The Supplier shall bear all costs of translation to the governing language and all risks of the accuracy of such translation, for

documents provided by the Supplier.

6. Joint Venture, Consortium or Association

6.1 If the Supplier is a joint venture, consortium, or association, all of the parties shall be jointly and severally liable to the Purchaser for the fulfillment of the provisions of the Contract and shall designate one party to act as a leader with authority to bind the joint venture, consortium, or association. The composition or the constitution of the joint venture, consortium, or association shall not be altered without the prior consent of the Purchaser.

7. Eligibility

7.1 The Supplier and its Subcontractors shall have the nationality of an eligible country. A Supplier or Subcontractor shall be deemed to have the nationality of a country if it is a citizen or constituted, incorporated, or registered, and operates in conformity with the provisions of the laws of that country.

7.2 All Goods and Related Services to be supplied under the Contract and financed by the Bank shall have their origin in Eligible Countries. For the purpose of this Clause, origin means the country where the goods have been grown, mined, cultivated, produced, manufactured, or processed; or through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

8. Notices

8.1 Any notice given by one party to the other pursuant to the Contract shall be in writing to the address specified **in the SCC.** The term "in writing" means communicated in written form with proof of receipt.

8.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

9. Governing Law

9.1 The Contract shall be governed by and interpreted in accordance with the laws of the Purchaser's Country, unless otherwise specified **in the SCC.**

9.2 Throughout the execution of the Contract, the Supplier shall comply with the import of goods and services prohibitions in the Purchaser's Country when

(a) as a matter of law or official regulations, the Borrower's country prohibits commercial relations with that country; or

(b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Borrower's Country prohibits any import of goods from that country or any payments to any

country, person, or entity in that country.

10 Settlement of Disputes

10.1 The Purchaser and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

10.2 If, after twenty-eight (28) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given. Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract. Arbitration proceedings shall be conducted in accordance with the rules of procedure specified **in the SCC.**

10.3 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and

(b) the Purchaser shall pay the Supplier any monies due the Supplier.

11. Inspections and Audit by the Bank

11.1 The Supplier shall keep, and shall make all reasonable efforts to cause its Subcontractors and subconsultants to keep, accurate and systematic accounts and records in respect of the Goods in such form and details as will clearly identify relevant time changes and costs.

11.2 Pursuant to paragraph 2.2 e. of Appendix 1 to the General Conditions the Supplier shall permit and shall cause its agents (where declared or not), subcontractors, subconsultants, service providers, suppliers, and personnel, to permit, the Bank and/or persons appointed by the Bank to inspect the site and/or the accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have such accounts, records and other documents audited by auditors appointed by the Bank. The Supplier's and its Subcontractors' and subconsultants' attention is drawn to Sub-Clause 3.1 (Fraud and Corruption) which provides, inter alia, that acts intended to materially impede the exercise of the Bank's

inspection and audit rights constitute a prohibited practice subject to contract termination (as well as to a determination of ineligibility pursuant to the Bank's prevailing sanctions procedures).

12. Scope of Supply

12.1 The Goods and Related Services to be supplied shall be as specified in the Schedule of Requirements.

13. Delivery and Documents

13.1 Subject to GCC Sub-Clause 33.1, the Delivery of the Goods and Completion of the Related Services shall be in accordance with the Delivery and Completion Schedule specified in the Schedule of Requirements. The details of shipping and other documents to be furnished by the Supplier are specified **in the SCC.**

14. Supplier's Responsibilities

14.1. The Supplier shall supply all the Goods and Related Services included in the Scope of Supply in accordance with GCC Clause 12, and the Delivery and Completion Schedule, as per GCC Clause 13.

14.2. The Supplier, including its Subcontractors, shall not employ or engage forced labor or persons subject to trafficking, as described in GCC Sub-Clauses 14.3 and 14.4.

14.3. Forced labor consists of any work or service, not voluntarily performed, that is exacted from an individual under threat of force or penalty, and includes any kind of involuntary or compulsory labor, such as contractured labor, bonded labor or similar labor-contracting arrangements.

14.4. Trafficking in persons is defined as the recruitment, transportation, transfer, harbouring or receipt of persons by means of the threat or use of force or other forms of coercion, abduction, fraud, deception, abuse of power, or of a position of vulnerability, or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purposes of exploitation.

14.5. The Supplier, including its Subcontractors, shall not employ or engage a child under the age of 14 unless the national law specifies a higher age (the minimum age).

14.6. The Supplier, including its Subcontractors, shall not employ or engage a child between the minimum age and the age of 18 in a manner that is likely to be hazardous, or to interfere with, the child's education, or to be harmful to the child's health or physical, mental, spiritual, moral, or social development.

14.7. Work considered hazardous for children is work that, by its nature or the circumstances in which it is carried out, is likely to

jeopardize the health, safety, or morals of children. Such work activities prohibited for children include work:

(a) with exposure to physical, psychological or sexual abuse;

(b) underground, underwater, working at heights or in confined spaces;

(c) with dangerous machinery, equipment or tools, or involving handling or transport of heavy loads;

(d) in unhealthy environments exposing children to hazardous substances, agents, or processes, or to temperatures, noise or vibration damaging to health; or

(e) under difficult conditions such as work for long hours, during the night or in confinement on the premises of the employer.

14.8. The Supplier shall comply, and shall require its Subcontractors if any to comply, with all applicable health and safety regulations, laws, guidelines, and any other requirement stated in the Technical Specifications.

15 Contract Price

15.1. Prices charged by the Supplier for the Goods supplied and the Related Services performed under the Contract shall not vary from the prices quoted by the Supplier in its Bid, with the exception of any price adjustments authorized **in the SCC.**

16. Terms of Payment

16.1 The Contract Price, including any Advance Payments, if applicable, shall be paid as specified **in the SCC.**

16.2 The Supplier's request for payment shall be made to the Purchaser in writing, accompanied by invoices describing, as appropriate, the Goods delivered and Related Services performed, and by the documents submitted pursuant to GCC Clause 13 and upon fulfillment of all other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or request for payment by the Supplier, and after the Purchaser has accepted it.

16.4 The currencies in which payments shall be made to the Supplier under this Contract shall be those in which the Bid price is expressed.

16.5 In the event that the Purchaser fails to pay the Supplier any payment by its due date or within the period set forth **in the SCC,** the Purchaser shall pay to the Supplier interest on the

amount of such delayed payment at the rate shown **in the SCC,** for the period of delay until payment has been made in full, whether before or after judgment or arbitrage award.

17. Taxes and Duties

17.1 For goods manufactured outside the Purchaser's Country, the Supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the Purchaser's Country.

17.2 For goods Manufactured within the Purchaser's Country, the Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser.

17.3 If any tax exemptions, reductions, allowances or privileges may be available to the Supplier in the Purchaser's Country, the Purchaser shall use its best efforts to enable the Supplier to benefit from any such tax savings to the maximum allowable extent.

18. Performance Security

18.1 If required as specified in the SCC, the Supplier shall, within twenty-eight (28) days of the notification of contract award, provide a Performance Security for the performance of the Contract in the amount specified **in the SCC.**

18.2 The proceeds of the Performance Security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

18.3 As specified in the SCC, the Performance Security, if required, shall be denominated in the currency(ies) of the Contract, or in a freely convertible currency acceptable to the Purchaser; and shall be in one of the format stipulated by the Purchaser **in the SCC,** or in another format acceptable to the Purchaser.

18.4 The Performance Security shall be discharged by the Purchaser and returned to the Supplier not later than twenty-eight (28) days following the date of Completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise **in the SCC.**

19. Certification of Goods in Accordance with Laws of the Purchaser's Country

19.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in the Purchaser's Country. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Purchaser's Country as specified **in the SCC**.

19.2 Unless otherwise specified **in the SCC,** the Contract shall become

effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's Country that the Goods have been registered for use in the Purchaser's Country.

19.3 If thirty (30) days, or such longer period specified **in the SCC,** elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 19.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's Performance Security shall be promptly returned.

20. Confidential Information

20.1 The Purchaser and the Supplier shall keep confidential and shall not, without the written consent of the other party hereto, divulge to any third party any documents, data, or other information furnished directly or indirectly by the other party hereto in connection with the Contract, whether such information has been furnished prior to, during or following completion or termination of the Contract. Notwithstanding the above, the Supplier may furnish to its Subcontractor such documents, data, and other information it receives from the Purchaser to the extent required for the Subcontractor to perform its work under the Contract, in which event the Supplier shall obtain from such Subcontractor an undertaking of confidentiality similar to that imposed on the Supplier under GCC Clause 20.

20.2 The Purchaser shall not use such documents, data, and other information received from the Supplier for any purposes unrelated to the contract. Similarly, the Supplier shall not use such documents, data, and other information received from the Purchaser for any purpose other than the performance of the Contract.

20.3 The obligation of a party under GCC Sub-Clauses 20.1 and 20.2 above, however, shall not apply to information that:

(a) the Purchaser or Supplier need to share with the Bank or other institutions participating in the financing of the Contract;

(b) now or hereafter enters the public domain through no fault of that party;

(c) can be proven to have been possessed by that party at the time of disclosure and which was not previously obtained, directly or indirectly, from the other party; or

(d) otherwise lawfully becomes available to that party from a

third party that has no obligation of confidentiality.

20.4 The above provisions of GCC Clause 20 shall not in any way modify any undertaking of confidentiality given by either of the parties hereto prior to the date of the Contract in respect of the Supply or any part thereof.

20.5 The provisions of GCC Clause 20 shall survive completion or termination, for whatever reason, of the Contract.

21. Subcontracting

21.1 The Supplier shall notify the Purchaser in writing of all subcontracts awarded under the Contract if not already specified in the Bid. Notification by the Supplier, for addition of any Subcontractor not named in the Contract, shall also include the Subcontractor's declaration in accordance with Appendix 2 to the GCC- Sexual exploitation and Abuse (SEA) and/or Sexual Harassment (SH) Performance Declaration. Such notification, in the original Bid or later shall not relieve the Supplier from any of its obligations, duties, responsibilities, or liability under the Contract.

21.2 Subcontracts shall comply with the provisions of GCC Clauses 3 and 7.

22. Specifications and Standards

22.1 The Goods supplied under this Contract shall conform to technical specifications and standards mentioned in Section VII, Schedule of Requirements and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

23. Packing and Documents

23.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. During transit, the packing shall be sufficient to withstand, without limitation, rough handling and exposure to extreme temperatures, salt and precipitation, and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.

23.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified **in the SCC,** and in any other instructions ordered by the Purchaser.

24. Insurance

24.1 Unless otherwise specified **in the SCC,** the Goods supplied under the Contract shall be fully insured—in a freely

convertible currency from an eligible country—against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery, in accordance with the applicable Incoterms or in the manner specified in the **SCC.**

25. Transportation and Incidental Services

25.1 Unless otherwise specified **in the SCC,** responsibility for arranging transportation of the Goods shall be in accordance with the specified Incoterms.

25.2 The Supplier may be required to provide any or all of the following services, including additional services, if any, specified **in SCC:**

(a) performance or supervision of on-site assembly and/or start-up of the supplied Goods;

(b) furnishing of tools required for assembly and/or maintenance of the supplied Goods;

(c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods;

(d) performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and

(e) training of the Purchaser's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.

25.3 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services

26. Inspections and Tests

26.1 The Supplier shall at its own expense and at no cost to the Purchaser carry out all such tests and/or inspections of the Goods and Related Services as are specified **in the SCC.**

26.2 The inspections and tests may be conducted on the premises of the Supplier or the manufacturer, at point of delivery, and/or at the Goods' final destination, or in another place in the Purchaser's Country as specified **in the SCC.** Subject to GCC Sub-Clause 26.3, if conducted on the premises of the Supplier or the manufacturer, all reasonable facilities and assistance, including access to production data, shall be furnished to the inspectors at no charge to the Purchaser.

26.3 The Purchaser or its designated representative shall be entitled to attend the tests and/or inspections referred to in GCC Sub-Clause 26.2, provided that the Purchaser bear all of its own costs and expenses incurred in connection with such attendance including, but not limited to, all traveling and board and lodging expenses.

26.4 Whenever the Supplier is ready to carry out any such test and inspection, it shall give a reasonable advance notice, including the place and time, to the Purchaser. The Supplier shall obtain from any relevant third party or manufacturer any necessary permission or consent to enable the Purchaser or its designated representative to attend the test and/or inspection.

(a) Said inspection and testing is for the Purchaser's account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

(b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

(c) Upon receipt of the Goods at place of final destination, the Purchaser's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

26.5 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 26.4 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party;

26.6 The Purchaser may require the Supplier to carry out any test

and/or inspection not required by the Contract but deemed necessary to verify that the characteristics and performance of the Goods comply with the technical specifications codes and standards under the Contract, provided that the Supplier's reasonable costs and expenses incurred in the carrying out of such test and/or inspection shall be added to the Contract Price. Further, if such test and/or inspection impedes the progress of manufacturing and/or the Supplier's performance of its other obligations under the Contract, due allowance will be made in respect of the Delivery Dates and Completion Dates and the other obligations so affected.

26.7 The Supplier shall provide the Purchaser with a report of the results of any such test and/or inspection.

26.8 The Purchaser may reject any Goods or any part thereof that fail to pass any test and/or inspection or do not conform to the specifications. The Supplier shall either rectify or replace such rejected Goods or parts thereof or make alterations necessary to meet the specifications at no cost to the Purchaser, and shall repeat the test and/or inspection, at no cost to the Purchaser, upon giving a notice pursuant to GCC Sub-Clause 26.4.

26.9 The Supplier agrees that neither the execution of a test and/or inspection of the Goods or any part thereof, nor the attendance by the Purchaser or its representative, nor the issue of any report pursuant to GCC Sub-Clause 26.7, shall release the Supplier from any warranties or other obligations under the Contract.

27. Liquidated Damages

27.1 Except as provided under GCC Clause 32, if the Supplier fails to deliver any or all of the Goods by the Date(s) of delivery or perform the Related Services within the period specified in the Contract, the Purchaser may without prejudice to all its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified **in the SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified **in the SCC.** Once the maximum is reached, the Purchaser may terminate the Contract pursuant to GCC Clause 35.

28. Warranty

28.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of

the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with a shelf life of two years or less, unless otherwise specified **in the SCC;** have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

28.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

28.3 In the event of a dispute by the Supplier, a counter-analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter-analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.

28.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 28.2 above, the Supplier fails to replace the defective Goods within the period specified **in the SCC,** the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

28.5 *Recalls.* In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the

Purchaser will, at the Supplier's expense, carry out the recall.

29. Patent Indemnity

29.1 The Supplier shall, subject to the Purchaser's compliance with GCC Sub-Clause 29.2, indemnify and hold harmless the Purchaser and its employees and officers from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Purchaser may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design, trademark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract by reason of the use of the Pharmaceuticals in the Purchaser's Country.

Such indemnity shall not cover any use of the Goods or any part thereof other than for the purpose indicated by or to be reasonably inferred from the Contract, neither any infringement resulting from the use of the Goods or any part thereof, or any products produced thereby in association or combination with any other equipment, plant, or materials not supplied by the Supplier, pursuant to the Contract.

29.2 If any proceedings are brought or any claim is made against the Purchaser arising out of the matters referred to in GCC Sub-Clause 29.1, the Purchaser shall promptly give the Supplier a notice thereof, and the Supplier may at its own expense and in the Purchaser's name conduct such proceedings or claim and any negotiations for the settlement of any such proceedings or claim.

29.3 If the Supplier fails to notify the Purchaser within twenty-eight (28) days after receipt of such notice that it intends to conduct any such proceedings or claim, then the Purchaser shall be free to conduct the same on its own behalf.

29.4 The Purchaser shall, at the Supplier's request, afford all available assistance to the Supplier in conducting such proceedings or claim, and shall be reimbursed by the Supplier for all reasonable expenses incurred in so doing.

29.5 The Purchaser shall indemnify and hold harmless the Supplier and its employees, officers, and Subcontractors from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Supplier may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design,

trademark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract arising out of or in connection with any design, data, drawing, specification, or other documents or materials provided or designed by or on behalf of the Purchaser.

30 Limitation of Liability

30.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 29,

(a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and

(b) (b)the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment, or to any obligation of the supplier to indemnify the Purchaser with respect to patent infringement.

31. Change in Laws and Regulations

31.1 Unless otherwise specified in the Contract, if after the date of 28 days prior to date of Bid submission, any law, regulation, ordinance, order or bylaw having the force of law is enacted, promulgated, abrogated, or changed in the place of the Purchaser's Country where the Site is located (which shall be deemed to include any change in interpretation or application by the competent authorities) that subsequently affects the Delivery Date and/or the Contract Price, then such Delivery Date and/or Contract Price shall be correspondingly increased or decreased, to the extent that the Supplier has thereby been affected in the performance of any of its obligations under the Contract. Notwithstanding the foregoing, such additional or reduced cost shall not be separately paid or credited if the same has already been accounted for in the price adjustment provisions where applicable, in accordance with GCC Clause 15.

32. Force Majeure

32.1 The Supplier shall not be liable for forfeiture of its Performance Security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

32.2 For purposes of this Clause, "Force Majeure" means an event

or situation beyond the control of the Supplier that is not foreseeable, is unavoidable, and its origin is not due to negligence or lack of care on the part of the Supplier. Such events may include, but not be limited to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

32.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

33. Change Orders and Contract Amendments

33.1 The Purchaser may at any time order the Supplier through notice in accordance GCC Clause 8, to make changes within the general scope of the Contract in any one or more of the following:

(a) drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and

(d) the Related Services to be provided by the Supplier.

33.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or in the Delivery/Completion Schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this Clause must be asserted within twenty-eight (28) days from the date of the Supplier's receipt of the Purchaser's change order.

33.3 Prices to be charged by the Supplier for any Related Services that might be needed but which were not included in the Contract shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

33.4 Subject to the above, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties. This includes, if specified **in**

the SCC, any variation to the contract resulting from a value engineering proposal agreed between the parties.

34. Extensions of Time

34.1 If at any time during performance of the Contract, the Supplier or its subcontractors should encounter conditions impeding timely delivery of the Goods or completion of Related Services pursuant to GCC Clause 13, the Supplier shall promptly notify the Purchaser in writing of the delay, its likely duration, and its cause. As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, in which case the extension shall be ratified by the parties by amendment of the Contract.

34.2 Except in case of Force Majeure, as provided under GCC Clause 32, a delay by the Supplier in the performance of its Delivery and Completion obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 27, unless an extension of time is agreed upon, pursuant to GCC Sub-Clause 34.1.

35. Termination

35.1 Termination for Default

(a) The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate the Contract in whole or in part:

(i) if the Supplier fails to deliver any or all of the Goods within the period specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 34;

(ii) if the Supplier fails to perform any other obligation under the Contract; or

(iii) if the Supplier, in the judgment of the Purchaser has engaged in Fraud and Corruption, as defined in paragraph 2.2 a of the Appendix 1 to the GCC, in competing for or in executing the Contract.

(b) In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 35.1(a), the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Related Services similar to those undelivered or not performed, and the Supplier shall be liable to the Purchaser for any additional costs for such similar Goods or Related Services. However, the Supplier shall continue

performance of the Contract to the extent not terminated.

35.2 Termination for Insolvency.

(a) The Purchaser may at any time terminate the Contract by giving notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In such event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser

35.3 Termination for Convenience.

(a) The Purchaser, by notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

(b) The Goods that are complete and ready for shipment within twenty-eight (28) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect:

(i) to have any portion completed and delivered at the Contract terms and prices; and/or

(ii) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Related Services and for materials and parts previously procured by the Supplier.

36. Assignment

36.1 Neither the Purchaser nor the Supplier shall assign, in whole or in part, their obligations under this Contract, except with prior written consent of the other party.

37. Export Restriction

37.1 Notwithstanding any obligation under the Contract to complete all export formalities, any export restrictions attributable to the Purchaser, to the country of the Purchaser, or to the use of the products/goods, systems or services to be supplied, which arise from trade regulations from a country supplying those products/goods, systems or services, and which substantially impede the Supplier from meeting its obligations under the Contract, shall release the Supplier from the obligation to provide deliveries or services, always provided, however, that

the Supplier can demonstrate to the satisfaction of the Purchaser and of the Bank that it has completed all formalities in a timely manner, including applying for permits, authorizations and licenses necessary for the export of the products/goods, systems or services under the terms of the Contract. Termination of the Contract on this basis shall be for the Purchaser's convenience pursuant to Sub-Clause 35.3.

APPENDIX 1 TO GENERAL CONDITIONS

Fraud and Corruption

(Text in this Appendix shall not be modified)

1. Purpose

1.1 The Bank's Anti-Corruption Guidelines and this annex apply with respect to procurement under Bank Investment Project Financing operations.

2. Requirements

2.1 The Bank requires that Borrowers (including beneficiaries of Bank financing); bidders (applicants/proposers), consultants, contractors and suppliers; any sub-contractors, sub-consultants, service providers or suppliers; any agents (whether declared or not); and any of their personnel, observe the highest standard of ethics during the procurement process, selection and contract execution of Bank-financed contracts, and refrain from Fraud and Corruption.

2.2 To this end, the Bank:

a. Defines, for the purposes of this provision, the terms set forth below as follows:

i. "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

ii. "fraudulent practice" is any act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;

iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

v. "obstructive practice" is:

(a) deliberately destroying, falsifying, altering, or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive, or collusive practice; and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(b) acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under paragraph 2.2 e. below.

b. Rejects a proposal for award if the Bank determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub-consultants, sub-contractors, service providers, suppliers and/ or their employees, has, directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question;

c. In addition to the legal remedies set out in the relevant Legal Agreement, may take other appropriate actions, including declaring misprocurement, if the Bank determines at any time that representatives of the Borrower or of a recipient of any part of the proceeds of the loan engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices during the procurement process, selection and/or execution of the contract in question, without the Borrower having taken timely and appropriate action satisfactory to the Bank to address such practices when they occur, including by failing to inform the Bank in a timely manner at the time they knew of the practices;

d. Pursuant to the Bank's Anti- Corruption Guidelines, and in accordance with the Bank's prevailing sanctions policies and procedures, may sanction a firm or individual, either indefinitely or for a stated period of time, including by publicly declaring such firm or individual ineligible (i) to be awarded or otherwise benefit from a Bank-financed contract, financially or in any other manner;[1] (ii) to be a nominated[2] sub-contractor, consultant, manufacturer or supplier, or service provider of an otherwise eligible firm being awarded a Bank-financed contract; and (iii) to receive the proceeds of any loan made by the Bank or otherwise to participate further in the preparation or implementation of any Bank-financed project;

e. Requires that a clause be included in bidding/request for proposals documents and in contracts financed by a Bank loan, requiring (i) bidders (applicants/proposers), consultants, contractors, and suppliers, and their sub-contractors, sub-consultants, service providers, suppliers, agents personnel, permit the Bank to inspect[3] all accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have them audited by auditors appointed by the Bank.

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[1] For the avoidance of doubt, a sanctioned party's ineligibility to be awarded a contract shall include, without limitation, (i) applying for pre-qualification, expressing interest in a consultancy, and bidding, either directly or as a nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider, in respect of such contract, and (ii) entering into an addendum or amendment introducing a material modification to any existing contract.

[2] A nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider (different names are used depending on the particular bidding document) is one which has been: (i) included by the bidder in its pre-qualification application or bid because it brings specific and critical experience and know-how that allow the bidder to meet the qualification requirements for the particular bid; or (ii) appointed by the Borrower.

[3] Inspections in this context usually are investigative (i.e., forensic) in nature. They involve fact-finding activities undertaken by the Bank or persons appointed by the Bank to address specific matters related to investigations/audits, such as evaluating the veracity of an allegation of possible Fraud and Corruption, through the appropriate mechanisms. Such activity includes but is not limited to: accessing and examining a firm's or individual's financial records and information, and making copies thereof as relevant; accessing and examining any other documents, data and information (whether in hard copy or electronic format) deemed relevant for the investigation/audit, and making copies thereof as relevant; interviewing staff and other relevant individuals; performing physical inspections and site visits; and obtaining third party verification of information.

APPENDIX 2
Sexual Exploitation and Abuse (SEA) and/or Sexual Harassment (SH) Performance Declaration for Subcontractors

[The following table shall be filled in by each subcontractor proposed by the Supplier, that was not named in the Contract]

Subcontractor's Name: *[insert full name]*
Date: *[insert day, month, year]*
Contract reference *[insert contract reference]*
Page *[insert page number]* of *[insert total number]* pages

SEA and/or SH Declaration
We: ☐ (a) have not been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations. ☐ (b) are subject to disqualification by the Bank for non-compliance with SEA/ SH obligations. ☐ (c) had been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations, and were removed from the disqualification list. An arbitral award on the disqualification case has been made in our favor.
[*If (c) above is applicable, attach evidence of an arbitral award reversing the findings on the issues underlying the disqualification.*]
Period of disqualification: From: _____ To: _____

Name of the Subcontractor_____

Name of the person duly authorized to sign on behalf of the Subcontractor_____

Title of the person signing on behalf of the Subcontractor_____

Signature of the person named above_____

Date signed _____ day of _____, _____

Countersignature of authorized representative of the Supplier:

Signature: _____

Date signed _____ day of _____, _____

Section IX - Special Conditions of Contract

The following Special Conditions of Contract (SCC) shall supplement and / or amend the General Conditions of Contract (GCC). Whenever there is a conflict, the provisions herein shall prevail over those in the GCC.

[The Purchaser shall select insert the appropriate wording using the samples below or other acceptable wording, and delete the text in italics]

GCC 1.1(i)	The Purchaser's Country is: Democratic Socialist Republic of *Sri Lanka*
GCC 1.1(j)	The Purchaser is: *Ministry of Health, Sri Lanka*
GCC 1.1 (o)	The Project Site(s)/Final Destination(s) is/are: *Medical Supplies Division,* 357, Ven Baddegama Wimalawansa Thero Mawatha, Colombo 010
GCC 1.1 (p)	The term **SEA/SH** where used in the Contract has the following meaning: • "**Sexual Exploitation and Abuse" "(SEA)"** means the following: **Sexual Exploitation** is defined as any actual or attempted abuse of position of vulnerability, differential power or trust, for sexual purposes, including, but not limited to, profiting monetarily, socially or politically from the sexual exploitation of another. **Sexual Abuse** is defined as the actual or threatened physical intrusion of a sexual nature, whether by force or under unequal or coercive conditions. • **"Sexual Harassment" "(SH)"** is defined as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature by contractor's personnel with other contractor's, or employer's personnel.
GCC 4.2 (a)	The meaning of the trade terms shall be as prescribed by Incoterms. If the meaning of any trade term and the rights and obligations of the parties thereunder shall not be as prescribed by Incoterms, they shall be as prescribed by: *[exceptional; refer to other internationally accepted trade terms]*
GCC 4.2 (b)	The version edition of Incoterms shall be *Incoterms 2020*
GCC 5.1	The language shall be: *English*

GCC 8.1	For **notices**, the Purchaser's address shall be: Attention: *The Chairman* *State Pharmaceuticals Corporation of Sri Lanka* Street Address: *"Mehewara Piyasa", Kirula Road, Colombo 05* Floor/ Room number*: 16th Floor* City: *Colombo* ZIP Code: *00500* Country: Sri Lanka Telephone: *+94 11 2338500* Facsimile number: *+94 11 2055800* Electronic mail address*: chairman@spc.lk*
GCC 9.1	The governing law shall be the law of: Democratic Socialist Republic of Sri Lanka
GCC 10.2	The rules of procedure for arbitration proceedings pursuant to GCC Clause 10.2 shall be as follows: ***(a) Contract with foreign Supplier:*** GCC 10.2 (a)—All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said Rules & shall be held in Singapore. ***(b) Contracts with Supplier national of the Purchaser's Country:*** In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's Country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's Country & shall be held in Singapore.
GCC 13.1	***For Goods supplied from abroad:*** Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. The Supplier shall fax and then send by

	courier the following documents to the Purchaser, with a copy to the insurance company: (i) three originals and two copies of the Supplier's invoice, showing Purchaser as *Ministry of Health, Sri Lanka of Sri Lanka;* the Contract number, loan number, Goods description, quantity, unit price, and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal; (ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as *Ministry of Health, Sri Lanka of Sri Lanka* and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements; (iii) four copies of the packing list identifying contents of each package; (iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied; (vi) one original of the Supplier's Certificate of Origin covering all items supplied; (vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required); (viii) any other procurement-specific documents required for delivery/payment purposes. ***For Goods from within the Purchaser's Country:*** Upon or before delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser: (i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, loan number; Goods' description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed

	with the company stamp/seal; (ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as *Ministry of Health, Sri Lanka of Sri Lanka* and delivery through to final destination as stated in the Contract; (iii) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (iv) four copies of the packing list identifying contents of each package; (v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied; (vi) one original of the Supplier's Certificate of Origin covering all items supplied; (vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required) (viii) other procurement-specific documents required for delivery/payment purposes. The above documents shall be received by the Purchaser before arrival of the Goods and, if not received, the Supplier will be responsible for any consequent expenses.
GCC 15.1	The prices charged for the Goods supplied and the related Services performed *"shall not"* be adjustable.
GCC 16.1	GCC 16.1—The method and conditions of payment to be made to the Supplier under this Contract shall be as follows: **Payment for Goods supplied from abroad:** Payment of foreign currency portion shall be made in USD in the following manner: (i) **On Shipment:** Seventy Five (75) percent of the Contract Price of the Goods shipped shall be paid through irrevocable confirmed letter of credit opened in favor of the Supplier in a bank in its country, upon submission of documents specified in GCC Clause 12.

	(ii) **On Acceptance:** Twenty five (25) percent of the Contract Price of Goods received shall be paid within sixty (60) days of receipt of the Goods upon submission of claim supported by the acceptance certificate issued by the Purchaser. Payment of local currency portion shall be made in LKR within sixty (60) days of presentation of claim supported by a certificate from the Purchaser declaring that the Goods have been delivered and that all other contracted Services have been performed. **Payment for Goods and Services supplied from within the Purchaser's Country:** Payment for Goods and Services supplied from within the Purchaser's Country shall be made in LKR, as follows: (i) **On Delivery:** Seventy five (75) percent of the Contract Price shall be paid on receipt of the Goods and upon submission of the documents specified in GCC Clause 13. (ii) **On Acceptance:** The remaining twenty five (25) percent of the Contract Price shall be paid to the Supplier within sixty (60) days after the date of the acceptance certificate for the respective delivery issued by the Purchaser.
GCC 16.5	The payment-delay period after which the Purchaser shall pay interest to the supplier shall be 60 days. The interest rate that shall be applied is *0.5 %*
GCC 18.1	A Performance Security *"shall" be required* *The amount of the Performance Security shall be:10% from contract value*
GCC 18.3	The Performance Security shall be in the form of : *Performance Bond* If required, the Performance security shall be denominated in 10% from the contract price by *USD for foreign suppliers LKR from local suppliers*
GCC 18.4	Discharge of the Performance Security shall take place: *30 days after final consignment.*
GCC19.1	The registration and other certification necessary to prove registration in Purchaser's Country is *NMRA Registration certificate, in the absence of NMRA registration Waiver of registration issued by NMRA may be considered.*

GCC19.2	The Effective Date of the Contract is *: **date of Contract signing** if EITHER: (i) the Goods have already been registered at the time of Contracting signing*
GCC19.3	***"NOT USED."***
GCC 23.2	The packing, marking and documentation within and outside the packages shall be: 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
GCC 24.1	The insurance coverage shall be as specified in the Incoterms.
GCC 25.1	Responsibility for transportation of the Goods shall be as specified in the Incoterms. If not in accordance with Incoterms, responsibility for transportations shall be as follows: *Not applicable*
GCC 25.2	Incidental services to be provided are: *Not applicable*
GCC 26.1	The inspections and tests shall be: Immediately after delivery at MSD, the consignments shall be subject to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory
GCC 26.2	The Inspections and tests shall be conducted at: *NMQAL (National Medicines Quality Assurance Laboratory)*
GCC 27.1	The liquidated damage shall be: 3.5% per week
GCC 27.1	The maximum amount of liquidated damages shall be: *10%*
GCC 28.1	[*Insert any alternative warranty requirements or indicate: not applicable*

GCC 28.4	The period for replacement shall be: *N/A*
GCC 33.4	~~*[Value engineering may be included if it has been specified here and agreed by the Bank]*~~ Value Engineering: *NOT APPLICABLE*

Special Conditions of Contract

PHARMACEUTICALS

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in bidding document for the procurement of pharmaceuticals.	
GCC 13.1	***For Goods supplied from abroad**:* (ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied. (x) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods. (xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

Attachment: Price Adjustment Formula – Not Applicable

If in accordance with GCC 15.1, prices shall be adjustable, the following method shall be used to calculate the price adjustment:

15.1 Prices payable to the Supplier, as stated in the Contract, shall be subject to adjustment during performance of the Contract to reflect changes in the cost of labor and material components in accordance with the formula:

$$P_1 = P_0 \left[a + \frac{bL_1}{L_0} + \frac{cM_1}{M_0}\right] - P_0$$

$$a+b+c = 1$$

in which:

P_1	=	adjustment amount payable to the Supplier.
P_0	=	Contract Price (base price).
a	=	fixed element representing profits and overheads included in the Contract Price and generally in the range of five (5) to fifteen (15) percent.
b	=	estimated percentage of labor component in the Contract Price.
c	=	estimated percentage of material component in the Contract Price.
L_0, L_1	=	*labor indices applicable to the appropriate industry in the country of origin on the base date and date for adjustment, respectively.
M_0, M_1	=	*material indices for the major raw material on the base date and date for adjustment, respectively, in the country of origin.

The Bidder shall indicate the source of the indices, and the source of exchange rate (if applicable) and the base date indices in its Bid.

The coefficients a, b, and c as specified by the Purchaser are as follows:

a = *[insert value of coefficient]*
b= *[insert value of coefficient]*
c= *[insert value of coefficient]*

Base date = thirty (30) days prior to the deadline for submission of the Bids.

Date of adjustment = *[insert number of weeks]* weeks prior to date of shipment (representing the mid-point of the period of manufacture).

The above price adjustment formula shall be invoked by either party subject to the following further conditions:

(a) No price adjustment shall be allowed beyond the original delivery dates. As a rule, no price adjustment shall be allowed for periods of delay for which the

Supplier is entirely responsible. The Purchaser will, however, be entitled to any decrease in the prices of the Goods and Services subject to adjustment.

(b) If the currency in which the Contract Price P_0 is expressed is different from the currency of origin of the labor and material indices, a correction factor will be applied to avoid incorrect adjustments of the Contract Price. The correction factor shall be: Z_0 / Z_1, where,

Z_0 = the number of units of currency of the origin of the indices which equal to one unit of the currency of the Contract Price P_0 on the Base date, and

Z_1 = the number of units of currency of the origin of the indices which equal to one unit of the currency of the Contract Price P_0 on the Date of Adjustment.

(c) No price adjustment shall be payable on the portion of the Contract Price paid to the Supplier as advance payment.

Section X - Contract Forms

Table of Forms

Notification of Intention to Award

[*This Notification of Intention to Award shall be sent to each Bidder that submitted a Bid.*]

[*Send this Notification to the Bidder's Authorized Representative named in the Bidder Information Form*]
For the attention of Bidder's Authorized Representative
Name: *[insert Authorized Representative's name]*
Address: *[insert Authorized Representative's Address]*
Telephone/Fax numbers: *[insert Authorized Representative's telephone/fax numbers]*
Email Address: *[insert Authorized Representative's email address]*

[IMPORTANT: insert the date that this Notification is transmitted to Bidders. The Notification must be sent to all Bidders simultaneously. This means on the same date and as close to the same time as possible.]
DATE OF TRANSMISSION: This Notification is sent by: [*email/fax*] on [*date*] (local time)

Notification of Intention to Award

Purchaser: *[insert the name of the Purchaser]*
Project: *[insert name of project]*
Contract title: *[insert the name of the contract]*
Country: *[insert country where RFB is issued]*
Loan No. /Credit No. / Grant No.: *[insert reference number for loan/credit/grant]*
RFB No: *[insert RFB reference number from Procurement Plan]*

This Notification of Intention to Award (Notification) notifies you of our decision to award the above contract. The transmission of this Notification begins the Standstill Period. During the Standstill Period you may:

a) request a debriefing in relation to the evaluation of your Bid, and/or

b) submit a Procurement-related Complaint in relation to the decision to award the contract.

1. The successful Bidder

Name:	[*insert name of successful Bidder*]
Address:	[*insert address of the successful Bidder*]
Contract price:	[*insert contract price of the successful Bid*]

2. Other Bidders ***[INSTRUCTIONS: insert names of all Bidders that submitted a Bid. If the Bid's price was evaluated include the evaluated price as well as the Bid price as read out.]***

Name of Bidder	Bid price	Evaluated Bid price (if applicable)
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]

3. Reason/s why your Bid was unsuccessful

[INSTRUCTIONS: State the reason/s why <u>this</u> Bidder's Bid was unsuccessful. Do NOT include: (a) a point by point comparison with another Bidder's Bid or (b) information that is marked confidential by the Bidder in its Bid.]

4. How to request a debriefing

DEADLINE: The deadline to request a debriefing expires at midnight on [*insert date*] (local time).

You may request a debriefing in relation to the results of the evaluation of your Bid. If you decide to request a debriefing your written request must be made within three (3) Business Days of receipt of this Notification of Intention to Award.

Provide the contract name, reference number, name of the Bidder, contact details; and address the request for debriefing as follows:

Attention: [*insert full name of person, if applicable*]

Title/position: [*insert title/position*]

Agency: [*insert name of Purchaser*]

Email address: [*insert email address*]

Fax number: [*insert fax number*] ***delete if not used***

If your request for a debriefing is received within the 3 Business Days deadline, we will provide the debriefing within five (5) Business Days of receipt of your request. If we are unable to provide the debriefing within this period, the Standstill Period shall be extended by five (5) Business Days after the date that the debriefing is provided. If this happens, we will notify you and confirm the date that the extended Standstill Period will end.

The debriefing may be in writing, by phone, video conference call or in person. We shall promptly advise you in writing how the debriefing will take place and confirm the date and

time.

If the deadline to request a debriefing has expired, you may still request a debriefing. In this case, we will provide the debriefing as soon as practicable, and normally no later than fifteen (15) Business Days from the date of publication of the Contract Award Notice.

5. How to make a complaint

Period: Procurement-related Complaint challenging the decision to award shall be submitted by midnight, [*insert date*] (local time).

Provide the contract name, reference number, name of the Bidder, contact details; and address the Procurement-related Complaint as follows:

Attention: [*insert full name of person, if applicable*]

Title/position: [*insert title/position*]

Agency: [*insert name of Purchaser*]

Email address: [*insert email address*]

Fax number: [*insert fax number*] ***delete if not used***

At this point in the procurement process, you may submit a Procurement-related Complaint challenging the decision to award the contract. You do not need to have requested, or received, a debriefing before making this complaint. Your complaint must be submitted within the Standstill Period and received by us before the Standstill Period ends.

Further information:

For more information see the Procurement Regulations for IPF Borrowers (Procurement Regulations)[https://policies.worldbank.org/sites/ppf3/PPFDocuments/Forms/DispPage.aspx?docid=4005] (Annex III). You should read these provisions before preparing and submitting your complaint. In addition, the World Bank's Guidance "How to make a Procurement-related Complaint" [http://www.worldbank.org/en/projects-operations/products-and-services/brief/procurement-new-framework#framework] provides a useful explanation of the process, as well as a sample letter of complaint.

In summary, there are four essential requirements:

1. You must be an 'interested party'. In this case, that means a Bidder who submitted a Bid in this bidding process, and is the recipient of a Notification of Intention to Award.
2. The complaint can only challenge the decision to award the contract.
3. You must submit the complaint within the period stated above.
4. You must include, in your complaint, all of the information required by the Procurement Regulations (as described in Annex III).

6. Standstill Period

DEADLINE: The Standstill Period is due to end at midnight on [*insert date*] (local

time).

The Standstill Period lasts ten (10) Business Days after the date of transmission of this Notification of Intention to Award.

The Standstill Period may be extended as stated in Section 4 above.

If you have any questions regarding this Notification please do not hesitate to contact us.

On behalf of the Purchaser:

Signature: _____

Name: _____

Title/position: _____

Telephone: _____

Email: _____

Beneficial Ownership Disclosure Form

INSTRUCTIONS TO BIDDERS: DELETE THIS BOX ONCE YOU HAVE COMPLETED THE FORM

This Beneficial Ownership Disclosure Form ("Form") is to be completed by the successful Bidder. In case of joint venture, the Bidder must submit a separate Form for each member. The beneficial ownership information to be submitted in this Form shall be current as of the date of its submission.

For the purposes of this Form, a Beneficial Owner of a Bidder is any natural person who ultimately owns or controls the Bidder by meeting one or more of the following conditions:

- *directly or indirectly holding 25% or more of the shares*
- *directly or indirectly holding 25% or more of the voting rights*
- *directly or indirectly having the right to appoint a majority of the board of directors or equivalent governing body of the Bidder*

RFB No.: [*insert number of RFB process*]
Request for Bid No.: [*insert identification*]

To: **[*insert complete name of Purchaser*]**

In response to your request in the Letter of Acceptance *dated [insert date of letter of Acceptance]* to furnish additional information on beneficial ownership: *[select one option as applicable and delete the options that are not applicable]*

(i) we hereby provide the following beneficial ownership information.

Details of beneficial ownership

Identity of Beneficial Owner	Directly or indirectly holding 25% or more of the shares (Yes / No)	Directly or indirectly holding 25 % or more of the Voting Rights (Yes / No)	Directly or indirectly having the right to appoint a majority of the board of the directors or an equivalent governing body of the Bidder (Yes / No)
[include full name (last, middle, first), nationality, country			

of residence]			

OR

(ii) *We declare that there is no Beneficial Owner meeting one or more of the following conditions:*

- directly or indirectly holding 25% or more of the shares
- directly or indirectly holding 25% or more of the voting rights
- directly or indirectly having the right to appoint a majority of the board of directors or equivalent governing body of the Bidder

OR

(iii) We declare that we are unable to identify any Beneficial Owner meeting one or more of the following conditions. [If this option is selected, the Bidder shall provide explanation on why it is unable to identify any Beneficial Owner]

- directly or indirectly holding 25% or more of the shares
- directly or indirectly holding 25% or more of the voting rights
- directly or indirectly having the right to appoint a majority of the board of directors or equivalent governing body of the Bidder]"

Name of the Bidder: *[*insert complete name of the Bidder*]_____

Name of the person duly authorized to sign the Bid on behalf of the Bidder: **[*insert complete name of person duly authorized to sign the Bid*]_____

Title of the person signing the Bid: [*insert complete title of the person signing the Bid*]_____

Signature of the person named above: [*insert signature of person whose name and capacity are shown above*]_____

Date signed [*insert date of signing*] **day of** [*insert month*], [*insert year*]_____

* In the case of the Bid submitted by a Joint Venture specify the name of the Joint Venture as Bidder. In the event that the Bidder is a joint venture, each reference to "Bidder" in the Beneficial Ownership Disclosure Form (including this Introduction thereto) shall be read to refer to the joint venture member.

** Person signing the Bid shall have the power of attorney given by the Bidder. The power of attorney shall be attached with the Bid Schedules.

Letter of Acceptance

[letterhead paper of the Purchaser]

[date]

To: *[name and address of the Supplier]*

Subject: ***Notification of Award Contract No.*** . . . . . .

This is to notify you that your Bid dated . . . . ***[insert date] . .*** . . for execution of the . . . . ***.[insert name of the contract and identification number, as given in the SCC]***. . . . . for the Accepted Contract Amount of . . . . . ***.[insert amount in numbers and words and name of currency]***, as corrected and modified in accordance with the Instructions to Bidders is hereby accepted by our Agency.

You are requested to furnish (i) the Performance Security within 28 days in accordance with the Conditions of Contract, using for that purpose one of the Performance Security Form*s* and (ii) the additional information on beneficial ownership in accordance with BDS ITB 45.1 within eight (8) Business days using the Beneficial Ownership Disclosure Form, included in Section X, - Contract Forms, of the Bidding Document.

Authorized Signature: _____
Name and Title of Signatory: _____
Name of Agency: _____

Attachment: Contract Agreement

Contract Agreement

[The successful Bidder shall fill in this form in accordance with the instructions indicated]

THIS AGREEMENT made

the *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*.

BETWEEN

(1) *[insert complete name of Purchaser]*, a *[insert description of type of legal entity, for example, an agency of the Ministry of .... of the Government of { insert name of Country of Purchaser }, or corporation incorporated under the laws of { insert name of Country of Purchaser }]* and having its principal place of business at *[insert address of Purchaser]* (hereinafter called "the Purchaser"), of the one part, and

(2) *[insert name of Supplier]*, a corporation incorporated under the laws of *[insert: country of Supplier]* and having its principal place of business at *[insert: address of Supplier]* (hereinafter called "the Supplier"), of the other part:

WHEREAS the Purchaser invited Bids for certain Goods and ancillary services, viz., *[insert brief description of Goods and Services]* and has accepted a Bid by the Supplier for the supply of those Goods and Services

The Purchaser and the Supplier agree as follows:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Contract documents referred to.

2. The following documents shall be deemed to form and be read and construed as part of this Agreement. This Agreement shall prevail over all other contract documents.

   (a) the Letter of Acceptance

   (b) the Letter of Bid

   (c) the Addenda Nos._____ (if any)

   (d) Special Conditions of Contract

   (e) General Conditions of Contract

   (f) the Specification (including Schedule of Requirements and Technical Specifications)

   (g) the completed Schedules (including Price Schedules)

   (h) any other document listed in GCC as forming part of the Contract

3. In consideration of the payments to be made by the Purchaser to the Supplier as specified in this Agreement, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with the laws of *[insert the name of the Contract governing law country]* on the day, month and year indicated above.

For and on behalf of the Purchaser

Signed: *[insert signature]*
in the capacity of *[insert title or other appropriate designation]*
in the presence of *[insert identification of official witness]*

For and on behalf of the Supplier

Signed: *[insert signature of authorized representative(s) of the Supplier]*
in the capacity of *[insert title or other appropriate designation]*
in the presence of *[insert identification of official witness]*

Performance Security

Bank Guarantee

[The bank, as requested by the successful Bidder, shall fill in this form in accordance with the instructions indicated]

[Guarantor letterhead or SWIFT identifier code]

Beneficiary: *[insert name and Address of Purchaser]*

Date: _ *[Insert date of issue]*

PERFORMANCE GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that _ *[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (hereinafter called "the Applicant") has entered into Contract No. *[insert reference number of the contract]* dated *[insert date]* with the Beneficiary, for the supply of _ *[insert name of contract and brief description of Health Goods and related Services]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Applicant, we as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of *[insert amount in figures]* ()*[insert amount in words]*,[1] such sum being payable in the types and proportions of currencies in which the Contract Price is payable, upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating that the Applicant is in breach of its obligation(s) under the Contract, without the Beneficiary needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire, no later than the …. Day of ……, 2… [2], and any demand for payment under it must be received by us at this office indicated above on or before that date.

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[1] *The Guarantor shall insert an amount representing the percentage of the Accepted Contract Amount specified in the Letter of Acceptance, and denominated either in the currency(ies) of the Contract or a freely convertible currency acceptable to the Beneficiary.*

[2] *Insert the date twenty-eight days after the expected completion date as described in GC Clause 18.4. The Purchaser should note that in the event of an extension of this date for completion of the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee,*

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No. 758, except that the supporting statement under Article 15(a) is hereby excluded.

_____

[signature(s)]

Note: All italicized text (including footnotes) is for use in preparing this form and shall be deleted from the final product.

the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Beneficiary's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

Advance Payment Security

[Guarantor letterhead or SWIFT identifier code]

Beneficiary: *[Insert name and Address of Purchaser]*

Date: *[Insert date of issue]*

ADVANCE PAYMENT GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that *[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (hereinafter called "the Applicant") has entered into Contract No. *[insert reference number of the contract]* dated *[insert date]* with the Beneficiary, for the execution of *[insert name of contract and brief description of Health Goods and related Services]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance payment in the sum *[insert amount in figures]* () *[insert amount in words]* is to be made against an advance payment guarantee.

At the request of the Applicant, we as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of *[insert amount in figures]* () *[insert amount in words]*[1] upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating either that the Applicant:

(a) has used the advance payment for purposes other than toward delivery of Goods; or

(b) has failed to repay the advance payment in accordance with the Contract conditions, specifying the amount which the Applicant has failed to repay.

A demand under this guarantee may be presented as from the presentation to the Guarantor of a certificate from the Beneficiary's bank stating that the advance payment referred to above has

[1] *The Guarantor shall insert an amount representing the amount of the advance payment and denominated either in the currency(ies) of the advance payment as specified in the Contract, or in a freely convertible currency acceptable to the Purchaser.*

been credited to the Applicant on its account number *[insert number]* at *[insert name and address of Applicant's bank]*.

The maximum amount of this guarantee shall be progressively reduced by the amount of the advance payment repaid by the Applicant as specified in copies of interim statements or payment certificates which shall be presented to us. This guarantee shall expire, at the latest, upon our receipt of a copy of the interim payment certificate indicating that ninety (90) percent of the Accepted Contract Amount, has been certified for payment, or on the *[insert day]* day of *[insert month]*, 2 *[insert year]*, whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No.758, except that the supporting statement under Article 15(a) is hereby excluded.

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_____

[signature(s)]

Note: All italicized text (including footnotes) is for use in preparing this form and shall be deleted from the final product.

Amendment to the advertisement dated 18/07/2023

With reference to the paper advertisement dated 18/07/2023, published on "Daily News" please note that the last date of bid submission on point no 6 should be corrected as 29th August 2023. The corrected advertisement as follows;

Request for Bids
Health Goods

Purchaser: *Ministry of Health, Sri Lanka*

Project: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*

Contract title: *Human Albumin Solution 20% in 50ml bottle*

Country: *Sri Lanka*

Loan No. /Credit No. / Grant No.: *IBRD-9296*

RFB No: ***LK-SPC-370471-GO-RFB***

Issued on: 18th *Jul 2023*

1. The ***Government of Sri Lanka / Ministry of Health*** *has received* financing from the World Bank toward the cost of the *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*], and intends to apply part of the proceeds toward payments under the contract for *Human Albumin Solution 20% in 50ml bottle* "For this contract, the Borrower shall process the payments using the Direct Payment disbursement method, as defined in the World Bank's Disbursement Guidelines for Investment Project Financing, except for those payments, which the contract provides to be made through letter of credit."

2. The ***Ministry of Health, Sri Lanka*** now invites sealed Bids from eligible Bidders for *supply of 215,000 bottles of Human Albumin Solution 20% in 50ml bottle*

3. Bidding will be conducted through international competitive procurement using a Request for Bids (RFB)as specified in the World Bank's "Procurement Regulations for IPF Borrowers" November 2020 ("Procurement Regulations"), and is open to all eligible Bidders as defined in the Procurement Regulations.

4. Interested eligible Bidders may obtain further information from *Mr. Saman Munasinghe, Manager Imports (DHS- Pharma) of Ministry of Health, Sri Lanka (pharma.manager@spc.lk)* and inspect the bidding document during office hours ***[8.00 to 15.00** hours]* at the address given below. *The Bidding Document is published on the website www.spc.lk for reference only.*

5. The bidding document in **English** may be purchased by interested Bidders upon the submission of a written application to the address below and upon payment of a nonrefundable fee of [*LKR. 100,000.00 + Taxes*]. The method of payment will be ***cash***. The document will be handed over to the representative. If no local representative for the interested Bidder the bidding document could be downloaded from the State Pharmaceuticals Corporation of Sri lanka (SPC) web site after submitting proof documents for the payment.

6. Bids must be delivered to the address below on or before 29 August 2023. Electronic Bidding ***will not*** be permitted. Late Bids will be rejected. Bids will be publicly opened in the presence of the Bidders' designated representatives and anyone who chooses to attend at the address below on 10:00 Hour, 29th August 2023.

7. All Bids must be accompanied by a *"Bid Security"* of *LKR. 19,736,000.00 or equivalent value in USD according to the exchange rate on Bid issuing date.*

8. Attention is drawn to the Procurement Regulations requiring the Borrower to disclose information on the successful bidder's beneficial ownership, as part of the Contract Award Notice, using the Beneficial Ownership Disclosure Form as included in the bidding document.

9. The address referred to above is:

Ministry of Health, Sri Lanka of Sri Lanka
Mr. Sarath Liyanage, Chairman
State Pharmaceuticals Corporation of Sri Lanka.
16th Floor, No. 41, "Mehewara Piyasa", Kirula Road, Colombo 05, Sri Lanka
Tel. : +94 11 2338500
Fax : +94 11 2055800
Email :chairman@spc.lk
Web : www.spc.lk

GENERAL MANAGER
STATE PHARMACEUTICALS CORPORATION OF SRI LANKA
"MEHEWARA PIYASA" 26TH FLOOR,
NO. 41, KIRULA ROAD, COLOMBO 05.

STANDARD PROCUREMENT DOCUMENT

Request for Bids
Health Sector Goods
(Pharmaceuticals)

Standard Procurement Document

Summary

Specific Procurement Notice

Specific Procurement Notice - Request for Bids (RFB)

The template attached is the Specific Procurement Notice for Request for Bids method, one-envelope Bidding process. This is the template to be used by the Borrower.

Bidding Document: Request for Bids – Health Sector Goods

PART 1 – BIDDING PROCEDURES

Section I - Instructions to Bidders (ITB)

This Section provides information to help Bidders prepare their Bids. Information is also provided on the submission, opening, and evaluation of Bids and on the award of Contracts. **Section I contains provisions that are to be used without modification.**

Section II - Bid Data Sheet (BDS)

This Section includes provisions that are specific to each procurement and that supplement Section I, Instructions to Bidders.

Section III - Evaluation and Qualification Criteria

This Section specifies the criteria to determine the Most Advantageous Bid.

Section IV - Bidding Forms

This Section includes the forms for the Bid submission, Price Schedules, Bid Security, and the Manufacturer's Authorization and Certificate of a Pharmaceutical Product to be completed and submitted by the Bidder as part of its Bid.

Section V - Eligible Countries

This Section contains information regarding eligible countries.

Section VI - Fraud and Corruption

This Section includes the fraud and corruption provisions which apply to this Bidding process.

PART 2 – SUPPLY REQUIREMENTS

Section VII - Schedule of Requirements

This Section includes the List of Goods and Related Services, the Delivery and Completion Schedules, the Technical Specifications and the Drawings that describe the Goods and Related Services to be procured.

PART 3 – CONDITIONS OF CONTRACT AND CONTRACT FORMS

Section VIII - General Conditions of Contract

This Section includes the general clauses to be applied in all contracts. **The text of the clauses in this Section shall not be modified.**

Section IX - Special Conditions of Contract

This Section contains the Special Conditions of Contract (SCC). The contents of this Section modify or supplement, but not over-write, the General Conditions and shall be prepared by the Purchaser.

Section X - Contract Forms

This Section contains the Letter of Acceptance, Contract Agreement and other relevant forms.

Request for Bids
Health Goods

Purchaser: *Ministry of Health, Sri Lanka*

Project: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*

Contract title: *Human Albumin Solution 20% in 50ml bottle*

Country: *Sri Lanka*

Loan No. /Credit No. / Grant No.: *IBRD-9296*

RFB No: ***LK-SPC-370471-GO-RFB***

Issued on: 18th *Jul 2023*

1. The ***Government of Sri Lanka / Ministry of Health*** *has received* financing from the World Bank toward the cost of the *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*], and intends to apply part of the proceeds toward payments under the contract for *Human Albumin Solution 20% in 50ml bottle* "For this contract, the Borrower shall process the payments using the Direct Payment disbursement method, as defined in the World Bank's Disbursement Guidelines for Investment Project Financing, except for those payments, which the contract provides to be made through letter of credit."

2. The ***Ministry of Health, Sri Lanka*** now invites sealed Bids from eligible Bidders for *supply of 215,000 bottles of Human Albumin Solution 20% in 50ml bottle*

3. Bidding will be conducted through international competitive procurement using a Request for Bids (RFB)as specified in the World Bank's "Procurement Regulations for IPF Borrowers" November 2020 ("Procurement Regulations"), and is open to all eligible Bidders as defined in the Procurement Regulations.

4. Interested eligible Bidders may obtain further information from *Mr. Saman Munasinghe, Manager Imports (DHS- Pharma) of Ministry of Health, Sri Lanka (pharma.manager@spc.lk)* and inspect the bidding document during office hours ***[8.00 to 15.00*** *hours]* at the address given below. *The Bidding Document is published on the website www.spc.lk for reference only.*

5. The bidding document in **English** may be purchased by interested Bidders upon the submission of a written application to the address below and upon payment of a nonrefundable fee of [*LKR. 100,000.00 + Taxes*]. The method of payment will be ***cash***. The document will be handed over to the representative. If no local representative for the interested Bidder the bidding document could be downloaded from the State Pharmaceuticals Corporation of Sri lanka (SPC) web site after submitting proof documents for the payment.

6. Bids must be delivered to the address below on or before 29 August 2023. Electronic Bidding ***will not*** be permitted. Late Bids will be rejected. Bids will be publicly opened

in the presence of the Bidders' designated representatives and anyone who chooses to attend at the address below on 10:00 Hour, 29th August 2023.

7. All Bids must be accompanied by a *"Bid Security"* of *LKR. 19,736,000.00 or equivalent value in USD according to the exchange rate on Bid issuing date.*

8. Attention is drawn to the Procurement Regulations requiring the Borrower to disclose information on the successful bidder's beneficial ownership, as part of the Contract Award Notice, using the Beneficial Ownership Disclosure Form as included in the bidding document.

9. The address referred to above is:

Ministry of Health, Sri Lanka of Sri Lanka
Mr. Sarath Liyanage, Chairman
16th Floor, No. 41, "Mehewara Piyasa", Kirula Road, Colombo 05, Sri Lanka
Tel. : +94 11 2338500
Fax : +94 11 2055800
Email :chairman@spc.lk
Web : www.spc.lk

Request for Bids
Health Sector Goods

Procurement of:
Human Albumin Solution 20% in 50ml bottles

Purchaser: *Ministry of Health, Sri Lanka*

Project: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*

Contract title: *Human Albumin Solution 20% in 50ml bottles*

Country: *Sri Lanka*

Loan No. /Credit No. / Grant No.: *IBRD-9296*

RFB No: ***LK-SPC-370471-GO-RFB***

Issued on: 18 Jul *2023*

Table of Contents

PART 1 – Bidding Procedures

Section I - Instructions to Bidders

Contents

Section I - Instructions to Bidders

A General

1. Scope of Bid

1.1 In connection with the Specific Procurement Notice - Request for Bids (RFB), specified **in the Bid Data Sheet (BDS),** the Purchaser, **as specified in the Bid Data Sheet,** issues this bidding document for the supply of Goods (pharmaceuticals, vaccines, contraceptives, or nutritional supplements) and Related Services incidental thereto as specified in Section VII, Schedule of Requirements. The name, identification and number of lots (contracts) of this RFB are specified **in the Bid Data Sheet.**

1.2 Throughout this bidding document:

(a) the term "in writing" means communicated in written form (e.g. by mail, e-mail, fax, including if specified **in the Bid Data Sheet**, distributed or received through the electronic-procurement system used by the Purchaser) with proof of receipt;

(b) if the context so requires, "singular" means "plural" and vice versa; and

(c) "Day" means calendar day, unless otherwise specified as "Business Day." A Business Day is any day that is an official working day of the Borrower. It excludes the Borrower's official public holidays.

2. Source of Funds

2.1 The Borrower or Recipient (hereinafter called "Borrower") specified **in the Bid Data Sheet** has applied for or received financing (hereinafter called "funds") from the International Bank for Reconstruction and Development or the International Development Association (hereinafter called "the Bank") in an amount specified **in Bid Data Sheet,** toward the project named **in Bid Data Sheet.** The Borrower intends to apply a portion of the funds to eligible payments under the contract for which this bidding document is issued.

2.2 Payment by the Bank will be made only at the request of the Borrower and upon approval by the Bank in accordance with the terms and conditions of the Loan (or other financing) Agreement. The Loan (or other financing) Agreement prohibits a withdrawal from the Loan (or other financing) account for the purpose of any payment to persons or entities, or for any import of goods, equipment, plant or materials if such payment or import, to the knowledge of the

Bank, is prohibited by decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. No party other than the Borrower shall derive any rights from the Loan (or other financing) Agreement or have any claim to the proceeds of the Loan (or other financing).

3. Fraud and Corruption

3.1 The Bank requires compliance with the Bank's Anti-Corruption Guidelines and its prevailing sanctions policies and procedures as set forth in the WBG's Sanctions Framework, as set forth in Section VI.

3.2 In further pursuance of this policy, Bidders shall permit and shall cause their agents (where declared or not), subcontractors, subconsultants, service providers, suppliers, and personnel, to permit the Bank to inspect all accounts, records and other documents relating to any initial selection process, prequalification process, bid submission, proposal submission, and contract performance (in the case of award), and to have them audited by auditors appointed by the Bank.

4. Eligible Bidders

4.1 A Bidder may be a firm that is a private entity, a state-owned enterprise or institution subject to ITB 4.6 or any combination of such entities in the form of a joint venture (JV) under an existing agreement or with the intent to enter into such an agreement supported by a letter of intent. In the case of a joint venture, all members shall be jointly and severally liable for the execution of the entire Contract in accordance with the Contract terms. The JV shall nominate a Representative who shall have the authority to conduct all business for and on behalf of any and all the members of the JV during the Bidding process and, in the event the JV is awarded the Contract, during contract execution. Unless specified **in the Bid Data Sheet**, there is no limit on the number of members in a JV.

4.2 A Bidder shall not have a conflict of interest. Any Bidder found to have a conflict of interest shall be disqualified. A Bidder may be considered to have a conflict of interest for the purpose of this Bidding process, if the Bidder:

(a) directly or indirectly controls, is controlled by or is under common control with another Bidder; or

(b) receives or has received any direct or indirect subsidy from another Bidder; or

(c) has the same legal representative as another Bidder; or

(d) has a relationship with another Bidder, directly or

through common third parties, that puts it in a position to influence the Bid of another Bidder, or influence the decisions of the Purchaser regarding this Bidding process; or

(e) or any of its affiliates participated as a consultant in the preparation of the design or technical specifications of the goods that are the subject of the Bid; or

(f) or any of its affiliates has been hired (or is proposed to be hired) by the Purchaser or Borrower for the Contract implementation; or

(g) would be providing goods, works, or non-consulting services resulting from or directly related to consulting services for the preparation or implementation of the project specified in the BDS ITB 2.1 that it provided or were provided by any affiliate that directly or indirectly controls, is controlled by, or is under common control with that firm; or

(h) has a close business or family relationship with a professional staff of the Borrower (or of the project implementing agency, or of a recipient of a part of the loan) who: (i) are directly or indirectly involved in the preparation of the bidding document or specifications of the Contract, and/or the Bid evaluation process of such Contract; or (ii) would be involved in the implementation or supervision of such contract unless the conflict stemming from such relationship has been resolved in a manner acceptable to the Bank throughout the Bidding process and execution of the Contract.

4.3 A firm that is a Bidder (either individually or as a JV member) shall not participate in more than one Bid, except for permitted alternative Bids. This includes participation as a subcontractor. Such participation shall result in the disqualification of all Bids in which the firm is involved. A firm that is not a Bidder or a JV member, may participate as a subcontractor in more than one Bid.

4.4 A Bidder may have the nationality of any country, subject to the restrictions pursuant to ITB 4.8. A Bidder shall be deemed to have the nationality of a country if the Bidder is constituted, incorporated or registered in and operates in conformity with the provisions of the laws of that country, as evidenced by its

articles of incorporation (or equivalent documents of constitution or association) and its registration documents, as the case may be. This criterion also shall apply to the determination of the nationality of proposed subcontractors or subconsultants for any part of the Contract including related Services.

4.5 A Bidder that has been sanctioned by the Bank, pursuant to the Bank's Anti-Corruption Guidelines, and in accordance with its prevailing sanctions policies and procedures as set forth in the WBG's Sanctions Framework as described in Section VI paragraph 2.2 d., shall be ineligible to be prequalified for, initially selected for, bid for, propose for, or be awarded a Bank-financed contract or benefit from a Bank-financed contract, financially or otherwise, during such period of time as the Bank shall have determined. The list of debarred firms and individuals is available at the electronic address specified in the BDS.

4.6 Bidders that are state-owned enterprises or institutions in the Purchaser's Country may be eligible to compete and be awarded a Contract(s) only if they can establish, in a manner acceptable to the Bank, that they (i) are legally and financially autonomous (ii) operate under commercial law, and (iii) are not under supervision of the Purchaser.

4.7 A Bidder shall not be under suspension from Bidding by the Purchaser as the result of the operation of a Bid–Securing Declaration or Proposal-Securing Declaration.

4.8 Firms and individuals may be ineligible if so indicated in Section V and (a) as a matter of law or official regulations, the Borrower's country prohibits commercial relations with that country, provided that the Bank is satisfied that such exclusion does not preclude effective competition for the supply of goods or the contracting of works or services required; or (b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Borrower's country prohibits any import of goods or contracting of works or services from that country, or any payments to any country, person, or entity in that country.

4.9 A Bidder shall provide such documentary evidence of eligibility satisfactory to the Purchaser, as the Purchaser shall reasonably request.

4.10 A firm that is under a sanction of debarment by the Borrower from being awarded a contract is eligible to participate in this

procurement, unless the Bank, at the Borrower's request, is satisfied that the debarment; (a) relates to fraud or corruption, and (b) followed a judicial or administrative proceeding that afforded the firm adequate due process.

5. Eligible Goods and Related Services

5.1 All the Goods and Related Services to be supplied under the Contract and financed by the Bank may have their origin in any country in accordance with Section V, Eligible Countries.

5.2 For purposes of this ITB, the term "goods" includes any goods that are the subject of this Request for Bids, and "Related Services" includes services such as transportation, insurance, commissioning and training.

5.3 The term "origin" means the country where the goods have been mined, grown, cultivated, produced, manufactured or processed; or, through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

B. Contents of Bidding Document

6. Sections of Bidding Document

6.1 The bidding document consists of Parts 1, 2, and 3, which includes all the sections indicated below, and should be read in conjunction with any Addenda issued in accordance with ITB 8.

PART 1 Bidding Procedures

- Section I - Instructions to Bidders (ITB)
- Section II - Bidding Data Sheet (BDS)
- Section III - Evaluation and Qualification Criteria
- Section IV -Bidding Forms
- Section V - Eligible Countries
- Section VI -Fraud and Corruption

PART 2 Supply Requirements

- Section VII - Schedule of Requirements

PART 3 Contract

- Section VIII - General Conditions of Contract
- Section IX - Special Conditions of Contract
- Section X - Contract Forms

6.2 The Specific Procurement Notice - Request for Bids (RFB) issued by the Purchaser is not part of this bidding document.

6.3 Unless obtained directly from the Purchaser, the Purchaser is not responsible for the completeness of the document, responses to requests for clarification, or Addenda to the bidding document in accordance with ITB 8. In case of any contradiction, documents obtained directly from the Purchaser shall prevail.

6.4 The Bidder is expected to examine all instructions, forms, terms, and specifications in the bidding document and to furnish with its Bid all information or documentation as is required by the bidding document.

7. Clarification of Bidding Document

7.1 A Bidder requiring any clarification of the bidding document shall contact the Purchaser in writing at the Purchaser's address specified **in the Bid Data Sheet**. The Purchaser will respond in writing to any request for clarification, provided that such request is received prior to the deadline for submission of Bids within a period specified **in the Bid Data Sheet.** The Purchaser shall forward copies of its response to all Bidders who have acquired the bidding document in accordance with ITB 6.3, including a description of the inquiry but without identifying its source. If so specified **in the Bid Data Sheet**, the Purchaser shall also promptly publish its response at the web page identified **in the Bid Data Sheet**. Should the clarification result in changes to the essential elements of the bidding document, the Purchaser shall amend the bidding document following the procedure under ITB 8 and ITB 22.2.

8. Amendment of Bidding Document

8.1 At any time prior to the deadline for submission of Bids, the Purchaser may amend the bidding document by issuing addenda.

8.2 Any addendum issued shall be part of the bidding document and shall be communicated in writing to all who have obtained the bidding document from the Purchaser in accordance with ITB 6.3. The Purchaser shall also promptly publish the addendum on the Purchaser's web page in accordance with ITB 7.1.

8.3 To give prospective Bidders reasonable time in which to take an addendum into account in preparing their Bids, the Purchaser may, at its discretion, extend the deadline for the submission of Bids, pursuant to ITB 22.2.

C. Preparation of Bids

9. Cost of Bidding

9.1 The Bidder shall bear all costs associated with the preparation and submission of its Bid, and the Purchaser shall not be responsible or liable for those costs, regardless of the conduct or outcome of the Bidding process.

10. Language of Bid

10.1 The Bid, as well as all correspondence and documents relating to the Bid exchanged by the Bidder and the Purchaser, shall be written in the language specified **in the Bid Data Sheet.** Supporting documents and printed literature that are part of the Bid may be in another language provided they are accompanied by an accurate translation of the relevant passages into the language specified **in the Bid Data Sheet,** in which case, for purposes of interpretation of the Bid, such translation shall govern.

11. Documents Comprising the Bid

11.1 The Bid shall comprise the following:

(a) **Letter of Bid** prepared in accordance with ITB 12;

(b) **Price Schedules**: completed in accordance with ITB 12 and ITB 14;

(c) **Bid Security** or **Bid-Securing Declaration**, in accordance with ITB 19.1;

(d) **Alternative Bid**, if permissible, in accordance with ITB 13;

(e) **Authorization**: written confirmation authorizing the signatory of the Bid to commit the Bidder, in accordance with ITB 20.3;

(f) **Bidder's Qualifications**: documentary evidence in accordance with ITB 17 establishing the Bidder's qualifications to perform the Contract if its Bid is accepted;

(g) **Bidder's Eligibility**: documentary evidence in accordance with ITB 17 establishing the Bidder's eligibility to Bid;

(h) **Eligibility of Goods and Related Services**: documentary evidence in accordance with ITB 16, establishing the eligibility of the Goods and Related Services to be supplied by the Bidder;

(i) **Conformity**: documentary evidence in accordance with ITB 16, that the Goods and Related Services

conform to the bidding document; and

(j) any other document required **in the Bid Data Sheet.**

11.2 In addition to the requirements under ITB 11.1, Bids submitted by a JV shall include a copy of the Joint Venture Agreement entered into by all members. Alternatively, a letter of intent to execute a Joint Venture Agreement in the event of a successful Bid shall be signed by all members and submitted with the Bid, together with a copy of the proposed Agreement.

11.3 The Bidder shall furnish in the Letter of Bid information on commissions and gratuities, if any, paid or to be paid to agents or any other party relating to this Bid.

12. Letter of Bid and Price Schedules

12.1 The Letter of Bid and Price Schedules shall be prepared using the relevant forms furnished in Section IV, Bidding Forms. The forms must be completed without any alterations to the text, and no substitutes shall be accepted except as provided under ITB 20.3. All blank spaces shall be filled in with the information requested.

13. Alternative Bids

13.1 Unless otherwise specified **in the Bid Data Sheet,** alternative Bids shall not be considered.

14. Bid Prices and Discounts

14.1 The prices and discounts quoted by the Bidder in the Letter of Bid and in the Price Schedules shall conform to the requirements specified below.

14.2 All lots (contracts) and items must be listed and priced separately in the Price Schedules.

14.3 The price to be quoted in the Letter of Bid in accordance with ITB 12.1 shall be the total price of the Bid, excluding any discounts offered.

14.4 The Bidder shall quote any discounts and indicate the methodology for their application in the Letter of Bid, in accordance with ITB 12.1.

14.5 Prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account, unless otherwise specified **in the Bid Data Sheet.** A Bid submitted with an adjustable price quotation shall be treated as nonresponsive and shall be rejected, pursuant to ITB 29. However, if in accordance with the BDS, prices quoted by the Bidder shall be subject to adjustment during the performance of the Contract, a Bid submitted with a fixed price quotation shall not be rejected,

but the price adjustment shall be treated as zero.

14.6 If so specified in ITB 1.1, Bids are being invited for individual lots (contracts) or for any combination of lots (packages). Unless otherwise specified **in the Bid Data Sheet,** prices quoted shall correspond to 100 % of the items specified for each lot and to 100% of the quantities specified for each item of a lot. Bidders wishing to offer discounts for the award of more than one Contract shall specify in their Bid the price reductions applicable to each package, or alternatively, to individual Contracts within the package. Discounts shall be submitted in accordance with ITB 14.4 provided the Bids for all lots (contracts) are opened at the same time.

14.7 The terms EXW, CIP, and other similar terms shall be governed by the rules prescribed in the current edition of Incoterms, published by The International Chamber of Commerce, as specified **in the Bid Data Sheet.**

14.8 Prices shall be quoted as specified in each Price Schedule included in Section IV, Bidding Forms. The dis-aggregation of price components is required solely for the purpose of facilitating the comparison of Bids by the Purchaser. This shall not in any way limit the Purchaser's right to contract on any of the terms offered. In quoting prices, the Bidder shall be free to use transportation through carriers registered in any eligible country, in accordance with Section V, Eligible Countries. Similarly, the Bidder may obtain insurance services from any eligible country in accordance with Section V, Eligible Countries. Prices shall be entered in the following manner:

(a) for Goods manufactured in the Purchaser's Country:

(i) the price of the Goods quoted EXW (ex-works, ex-factory, ex warehouse, ex showroom, or off-the-shelf, as applicable), including all customs duties and sales and other taxes already paid or payable on the components and raw material used in the manufacture or assembly of the Goods;

(ii) any Purchaser's Country sales tax and other taxes which will be payable on the Goods if the Contract is awarded to the Bidder; and

(iii) the price for inland transportation,

insurance, and other local services required to convey the Goods to their final destination (Project Site) **specified in the Bid Data Sheet**;

(b) for Goods manufactured outside the Purchaser's Country, to be imported:

(i) the price of the Goods, quoted CIP named place of destination, in the Purchaser's Country, as **specified in the BDS**; and

(ii) the price for inland transportation, insurance, and other local services required to convey the Goods from the named place of destination to their final destination (Project Site) **specified in the Bid Data Sheet**;

(c) for Goods manufactured outside the Purchaser's Country, already imported:

(i) the price of the Goods, including the original import value of the Goods; plus any mark-up (or rebate); plus any other related local cost, and custom duties and other import taxes already paid or to be paid on the Goods already imported;

(ii) the custom duties and other import taxes already paid (need to be supported with documentary evidence) or to be paid on the Goods already imported;

(iii) the price of the Goods, obtained as the difference between (i) and (ii) above;

(iv) any Purchaser's Country sales and other taxes which will be payable on the Goods if the Contract is awarded to the Bidder; and

(v) the price for inland transportation, insurance, and other local services required to convey the Goods to their final destination (Project Site) specified **in the Bid Data Sheet.**

(d) for Related Services, other than inland transportation and other services required to convey the Goods to

their final destination, whenever such Related Services are specified in the Schedule of Requirements:

(i) the price of each item comprising the Related Services (inclusive of any applicable taxes).

15. Currencies of Bid and Payment

15.1 The currency(ies) of the Bid and the currency(ies) of payments shall be the same. The Bidder shall quote in the currency of the Purchaser's Country the portion of the Bid price that corresponds to expenditures incurred in the currency of the Purchaser's Country, unless otherwise specified **in the Bid Data Sheet.**

15.2 The Bidder may express the Bid price in any currency. If the Bidder wishes to be paid in a combination of amounts in different currencies, it may quote its price accordingly but shall use no more than three foreign currencies in addition to the currency of the Purchaser's Country.

16. Documents Establishing the Eligibility and Conformity of the Goods and Related Services

16.1 To establish the eligibility of the Goods and Related Services in accordance with ITB 5, Bidders shall complete the country-of-origin declarations in the Price Schedule Forms, included in Section IV, Bidding Forms.

16.2 To establish the conformity of the Health Sector Goods and Related Services to the bidding document, the Bidder shall furnish as part of its Bid the documentary evidence that the Goods conform to the technical specifications and standards specified in Section VII, Schedule of Requirements.

16.3 The documentary evidence may be in the form of literature, drawings or data, and shall consist of:

(a) an item-by-item commentary on the provisions of Section VII, Schedule of Requirements demonstrating substantial responsiveness of the Goods and Services to the specifications, or a statement of deviations and exceptions to the provisions of the specifications; and

(b) any other procurement-specific documentation requirement as stated **in the Bid Data Sheet.**

16.4 Unless the **Bid Data Sheet** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in the Purchaser's Country. A Bidder who has already registered its Goods by the time of Bidding should submit a copy of the Registration Certificate with its Bid. Otherwise, the successful Bidder, by the time of Contract

signing, shall submit to the Purchaser either:

(a) a copy of the Registration Certificate of the Goods for use in the Purchaser's Country; or

(b) if such Registration Certificate has not yet been obtained, evidence establishing to the Purchaser's satisfaction that the Bidder has complied with all the documentary requirements for registration as specified **in the Bid Data Sheet.**

16.5 The Purchaser shall at all times cooperate with the successful Bidder to facilitate the registration process within the Purchaser's Country. The agency and contact person able to provide additional information about registration are identified **in the Bid Data Sheet.**

16.6 If the Goods of the successful Bidder have not been registered in the Purchaser's Country at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

16.7 Standards for workmanship, process, material, and equipment, as well as references to brand names or catalogue numbers specified by the Purchaser in the Schedule of Requirements, are intended to be descriptive only and not restrictive. The Bidder may offer other standards of quality, brand names, and/or catalogue numbers, provided that it demonstrates, to the Purchaser's satisfaction, that the substitutions ensure substantial equivalence or are superior to those specified in the Section VII, Schedule of Requirements.

17. Documents Establishing the Eligibility and Qualifications of the Bidder

17.1 To establish Bidder's eligibility in accordance with ITB 4, Bidders shall complete the Letter of Bid, included in Section IV, Bidding Forms.

17.2 The documentary evidence of the Bidder's qualifications to perform the Contract if its Bid is accepted shall establish to the Purchaser's satisfaction:

(a) that a Bidder that does not manufacture or produce the Health Sector Goods it offers to supply shall submit the Manufacturer's Authorization using the form included in Section IV, Bidding Forms to demonstrate that it has been duly authorized by the manufacturer or producer of the Goods to supply these Goods in the Purchaser's Country;

(b) that in case of a Bidder not doing business within the Purchaser's Country (or for other reasons will not itself carry out service obligations), the Bidder is or will be (if awarded the Contract) represented by a local service provider in the Purchaser's Country equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

(c) that the Bidder meets each of the qualification criterion specified in Section III, Evaluation and Qualification Criteria (see additional ITB for pharmaceuticals and vaccines).

18. Period of Validity of Bids

18.1 Bids shall remain valid until the date **specified in the BDS** or any extended date if amended by the Purchaser in accordance with ITP 8. A Bid that is not valid until the date **specified in the BDS**, or any extended date if amended by the Purchaser in accordance with ITP 8, shall be rejected by the Purchaser as nonresponsive.

18.2 In exceptional circumstances, prior to the expiry of the Bid validity, the Purchaser may request Bidders to extend the period of validity of their Bids. The request and the responses shall be made in writing. If a Bid Security is requested in accordance with ITB 19, it shall also be extended for a corresponding period. A Bidder may refuse the request without forfeiting its Bid Security. A Bidder granting the request shall not be required or permitted to modify its Bid, except as provided in ITB 18.3.

18.3 If the award is delayed by a period exceeding fifty-six (56) days beyond the expiry of the initial Bid validity period, the Contract price shall be determined as follows:

(a) in the case of **fixed price** contracts, the Contract price shall be the Bid price adjusted by the factor specified **in the BDS**;

(b) in the case of **adjustable price** contracts, no adjustment shall be made; or

(c) in any case, Bid evaluation shall be based on the Bid price without taking into consideration the applicable correction from those indicated above.

19. Bid Security

19.1 The Bidder shall furnish as part of its Bid, either a Bid-Securing Declaration or a Bid Security, as specified **in the BDS,** in original form and, in the case of a Bid Security, in

the amount and currency specified **in the BDS.**

19.2 A Bid-Securing Declaration shall use the form included in Section IV, Bidding Forms.

19.3 If a Bid Security is specified pursuant to ITB 19.1, the Bid Security shall be a demand guarantee in any of the following forms at the Bidder's option:

(a) an unconditional guarantee issued by a bank or non-bank financial institution (such as an insurance, bonding or surety company);

(b) an irrevocable letter of credit;

(c) a cashier's or certified check; or

(d) another security **specified in the BDS**,

from a reputable source, and an eligible country. If the unconditional guarantee is issued by a non-bank financial institution located outside the Purchaser's Country, the issuing non-bank financial institution shall have a correspondent financial institution located in the Purchaser's Country to make it enforceable unless the Purchaser has agreed in writing, prior to Bid submission, that a correspondent financial institution is not required. In the case of a bank guarantee, the Bid Security shall be submitted either using the Bid Security Form included in Section IV, Bidding Forms, or in another substantially similar format approved by the Purchaser prior to Bid submission. The Bid Security shall be valid for twenty-eight (28) days beyond the original date of expiry of the Bid validity, or beyond any extended date if requested under ITB 18.2.

19.4 If a Bid Security is specified pursuant to ITB 19.1, any Bid not accompanied by a substantially responsive Bid Security shall be rejected by the Purchaser as non-responsive.

19.5 If a Bid Security is specified pursuant to ITB 19.1, the Bid Security of unsuccessful Bidders shall be returned as promptly as possible upon the successful Bidder's signing the Contract and furnishing the Performance Security pursuant to ITB 46.

19.6 The Bid Security of the successful Bidder shall be returned as promptly as possible once the successful Bidder has signed the Contract and furnished the required Performance

Security.

19.7 The Bid Security may be forfeited:

(a) if a Bidder withdraws its Bid prior to the expiry date of Bid validity specified by the Bidder on the Letter of Bid or any extended date provided by the Bidder; or

(b) if the successful Bidder fails to:

(i) sign the Contract in accordance with ITB45; or

(ii) furnish a Performance Security in accordance with ITB 46.

19.8 The Bid Security or Bid- Securing Declaration of a JV must be in the name of the JV that submits the Bid. If the JV has not been legally constituted into a legally enforceable JV at the time of Bidding, the Bid Security or Bid-Securing Declaration shall be in the names of all future members as named in the letter of intent referred to in ITB 4.1 and ITB 11.2.

19.9 If a Bid Security is not required **in the BDS**, pursuant to ITB 19.1, and:

(a) if a Bidder withdraws its Bid during the period of Bid validity specified by the Bidder on the Letter of Bid, or any extended date provided by the Bidder; or

(b) if the successful Bidder fails to:

(i) sign the Contract in accordance with ITB 45; or

(ii) furnish a Performance Security in accordance with ITB 46;

the Borrower may, if provided for **in the BDS**, declare the Bidder ineligible to be awarded a contract by the Purchaser for a period of time as stated **in the BDS**.

20. Format and Signing of Bid

20.1 The Bidder shall prepare one original of the documents comprising the Bid as described in ITB 11 and clearly mark it "ORIGINAL." Alternative Bids, if permitted in accordance with ITB 13, shall be clearly marked "ALTERNATIVE." In addition, the Bidder shall submit copies of the Bid, in the number specified **in the BDS** and clearly mark them "COPY." In the event of any discrepancy between the original and the copies, the original shall prevail.

20.2 Bidders shall mark as "CONFIDENTIAL" information in their Bids which is confidential to their business. This may include proprietary information, trade secrets or commercial or financially sensitive information.

20.3 The original and all copies of the Bid shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Bidder. This authorization shall consist of a written confirmation as specified **in the BDS** and shall be attached to the Bid. The name and position held by each person signing the authorization must be typed or printed below the signature. All pages of the Bid where entries or amendments have been made shall be signed or initialed by the person signing the Bid.

20.4 In case the Bidder is a JV, the Bid shall be signed by an authorized representative of the JV on behalf of the JV, and so as to be legally binding on all the members as evidenced by a power of attorney signed by their legally authorized representatives.

20.5 Any inter-lineation, erasures, or overwriting shall be valid only if they are signed or initialed by the person signing the Bid.

D. Submission and Opening of Bids

21. Sealing and Marking of Bids

21.1 The Bidder shall deliver the Bid in a single, sealed envelope (one-envelope Bidding process). Within the single envelope the Bidder shall place the following separate, sealed envelopes:

(a) in an envelope marked "ORIGINAL", all documents comprising the Bid, as described in ITB 11; and

(b) in an envelope marked "COPIES", all required copies of the Bid; and,

(c) if alternative Bids are permitted in accordance with ITB 13, and if relevant:

(i) in an envelope marked "ORIGINAL – ALTERNATIVE BID", the alternative Bid; and

(ii) in the envelope marked "COPIES – ALTERNATIVE BID" all required copies of the alternative Bid.

21.2 The inner and outer envelopes shall:

(a) bear the name and address of the Bidder;

(b) be addressed to the Purchaser in accordance with ITB

22.1;

(c) bear the specific identification of this Bidding process indicated in ITB 1.1**;** and

(d) bear a warning not to open before the time and date for Bid opening.

21.3 If all envelopes are not sealed and marked as required, the Purchaser will assume no responsibility for the misplacement or premature opening of the Bid.

22. Deadline for Submission of Bids

22.1 Bids must be received by the Purchaser at the address and no later than the date and time specified **in the BDS.** When so specified **in the BDS**, Bidders shall have the option of submitting their Bids electronically. Bidders submitting Bids electronically shall follow the electronic Bid submission procedures specified **in the BDS**.

22.2 The Purchaser may, at its discretion, extend the deadline for the submission of Bids by amending the bidding document in accordance with ITB 8, in which case all rights and obligations of the Purchaser and Bidders previously subject to the deadline shall thereafter be subject to the deadline as extended.

23. Late Bids

23.1 The Purchaser shall not consider any Bid that arrives after the deadline for submission of Bids, in accordance with ITB 22. Any Bid received by the Purchaser after the deadline for submission of Bids shall be declared late, rejected, and returned unopened to the Bidder.

24. Withdrawal, Substitution, and Modification of Bids

24.1 A Bidder may withdraw, substitute, or modify its Bid after it has been submitted by sending a written notice, duly signed by an authorized representative, and shall include a copy of the authorization (the power of attorney) in accordance with ITB 20.3, (except that withdrawal notices do not require copies). The corresponding substitution or modification of the Bid must accompany the respective written notice. All notices must be:

(a) prepared and submitted in accordance with ITB 20 and 21 (except that withdrawal notices do not require copies), and in addition, the respective envelopes shall be clearly marked "WITHDRAWAL," "SUBSTITUTION," or "MODIFICATION;" and

(b) received by the Purchaser prior to the deadline prescribed for submission of Bids, in accordance with

ITB 22.1.

24.2 Bids requested to be withdrawn in accordance with ITB 24.1 shall be returned unopened to the Bidders.

24.3 No Bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of Bids and the expiration of the period of Bid validity specified by the Bidder on the Letter of Bid or any extension thereof.

25. Bid Opening

25.1 Except as in the cases specified in ITB 23 and ITB 24.2, the Purchaser shall publicly open and read out in accordance with this ITB all Bids received by the deadline at the date, time and place specified **in the BDS** in the presence of Bidders' designated representatives and anyone who choose to attend. All Bidders, or their representatives and any interested party may attend a public opening. Any specific electronic Bid opening procedures required if electronic Bidding is permitted in accordance with ITB 22.1, shall be as specified **in the BDS.**

25.2 First, envelopes marked "WITHDRAWAL" shall be opened and read out and the envelope with the corresponding Bid shall not be opened, but returned to the Bidder. If the withdrawal envelope does not contain a copy of the "power of attorney" confirming the signature as a person duly authorized to sign on behalf of the Bidder, the corresponding Bid will be opened. No Bid withdrawal shall be permitted unless the corresponding withdrawal notice contains a valid authorization to request the withdrawal and is read out at Bid opening.

25.3 Next, envelopes marked "SUBSTITUTION" shall be opened and read out and exchanged with the corresponding Bid being substituted, and the substituted Bid shall not be opened, but returned to the Bidder. No Bid substitution shall be permitted unless the corresponding substitution notice contains a valid authorization to request the substitution and is read out at Bid opening.

25.4 Next, envelopes marked "MODIFICATION" shall be opened and read out with the corresponding Bid. No Bid modification shall be permitted unless the corresponding modification notice contains a valid authorization to request the modification and is read out at Bid opening.

25.5 Next, all remaining envelopes shall be opened one at a time, reading out: the name of the Bidder and whether there is a

modification; the total Bid Prices, per item or lot (contract) if applicable, including any discounts and alternative Bids; the presence or absence of a Bid Security, if required; and any other details as the Purchaser may consider appropriate.

25.6 Only Bids, alternative Bids and discounts that are opened and read out at Bid opening shall be considered further for evaluation. The Letter of Bid and the Price Schedules are to be initialed by representatives of the Purchaser attending Bid opening in the manner specified **in the BDS.**

25.7 The Purchaser shall neither discuss the merits of any Bid nor reject any Bid (except for late Bids, in accordance with ITB 23.1).

25.8 The Purchaser shall prepare a record of the Bid opening that shall include, as a minimum:

(a) the name of the Bidder and whether there is a withdrawal, substitution, or modification;

(b) the Bid Price, per lot (contract) if applicable, including any discounts;

(c) any alternative Bids; and

(d) the presence or absence of a Bid Security or Bid Securing Declaration, if one was required.

25.9 The Bidders' representatives who are present shall be requested to sign the record. The omission of a Bidder's signature on the record shall not invalidate the contents and effect of the record. A copy of the record shall be distributed to all Bidders.

E. Evaluation and Comparison of Bids

26. Confidentiality

26.1 Information relating to the evaluation of Bids and recommendation of contract award, shall not be disclosed to Bidders or any other persons not officially concerned with the Bidding process until the Notification of Intention to Award the Contract is transmitted to all Bidders in accordance with ITB 43.

26.2 Any effort by a Bidder to influence the Purchaser in the evaluation or contract award decisions may result in the rejection of its Bid.

26.3 Notwithstanding ITB 26.2, from the time of Bid opening to the time of Contract Award, if any Bidder wishes to contact

the Purchaser on any matter related to the Bidding process, it should do so in writing.

27. Clarification of Bids

27.1 To assist in the examination, evaluation, comparison of the Bids, and qualification of the Bidders, the Purchaser may, at its discretion, ask any Bidder for a clarification of its Bid. Any clarification submitted by a Bidder in respect to its Bid and that is not in response to a request by the Purchaser shall not be considered. The Purchaser's request for clarification and the response shall be in writing. No change, including any voluntary increase or decrease, in the prices or substance of the Bid shall be sought, offered, or permitted, except to confirm the correction of arithmetic errors discovered by the Purchaser in the Evaluation of the Bids, in accordance with ITB 31.

27.2 If a Bidder does not provide clarifications of its Bid by the date and time set in the Purchaser's request for clarification, its Bid may be rejected.

28. Deviations, Reservations, and Omissions

28.1 During the evaluation of Bids, the following definitions apply:

(a) "Deviation" is a departure from the requirements specified in the bidding document;

(b) "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in the bidding document; and

(c) "Omission" is the failure to submit part or all of the information or documentation required in the bidding document.

29. Determination of Responsiveness

29.1 The Purchaser's determination of a Bid's responsiveness is to be based on the contents of the Bid itself, as defined in ITB 11.

29.2 A substantially responsive Bid is one that meets the requirements of the bidding document without material deviation, reservation, or omission. A material deviation, reservation, or omission is one that:

(a) if accepted, would:

(i) affect in any substantial way the scope, quality, or performance of the Goods and Related Services specified in the Contract; or

(ii) limit in any substantial way, inconsistent with

the bidding document, the Purchaser's rights or the Bidder's obligations under the Contract; or

(b) if rectified, would unfairly affect the competitive position of other Bidders presenting substantially responsive Bids.

29.3 The Purchaser shall examine the technical aspects of the Bid submitted in accordance with ITB 16 and ITB 17, in particular, to confirm that all requirements of Section VII, Schedule of Requirements have been met without any material deviation or reservation, or omission.

29.4 If a Bid is not substantially responsive to the requirements of bidding document, it shall be rejected by the Purchaser and may not subsequently be made responsive by correction of the material deviation, reservation, or omission.

30. Nonconformities, Errors and Omissions

30.1 Provided that a Bid is substantially responsive, the Purchaser may waive any nonconformities in the Bid.

30.2 Provided that a Bid is substantially responsive, the Purchaser may request that the Bidder submit the necessary information or documentation, within a reasonable period of time, to rectify nonmaterial nonconformities or omissions in the Bid related to documentation requirements. Such omission shall not be related to any aspect of the price of the Bid. Failure of the Bidder to comply with the request may result in the rejection of its Bid.

30.3 Provided that a Bid is substantially responsive, the Purchaser shall rectify quantifiable nonmaterial nonconformities related to the Bid Price. To this effect, the Bid Price shall be adjusted, for comparison purposes only, to reflect the price of a missing or non-conforming item or component, by adding the average price of the item or component quoted by substantially responsive Bidders. If the price of the item or component cannot be derived from the price of other substantially responsive Bids, the Purchaser shall use its best estimate.

31. Correction of Arithmetical Errors

31.1 Provided that the Bid is substantially responsive, the Purchaser shall correct arithmetical errors on the following basis:

(a) if there is a discrepancy between the unit price and the line item total that is obtained by multiplying the unit price by the quantity, the unit price shall prevail and the line item total shall be corrected, unless in the opinion of the Purchaser there is an obvious misplacement of the decimal point in the unit price, in

which case the line item total as quoted shall govern and the unit price shall be corrected;

(b) if there is an error in a total corresponding to the addition or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected; and

(c) if there is a discrepancy between words and figures, the amount in words shall prevail, unless the amount expressed in words is related to an arithmetic error, in which case the amount in figures shall prevail subject to (a) and (b) above.

31.2 Bidders shall be requested to accept correction of arithmetical errors. Failure to accept the correction in accordance with ITB 31.1, shall result in the rejection of the Bid.

32. Conversion to Single Currency

32.1 For evaluation and comparison purposes, the currency(ies) of the Bid shall be converted in a single currency as specified **in the BDS.**

33. Margin of Preference

33.1 Unless otherwise specified **in the BDS,** a margin of preference shall not apply.

34. Evaluation of Bids

34.1 The Purchaser shall use the criteria and methodologies listed in this ITB and Section III, Evaluation and Qualification criteria. No other evaluation criteria or methodologies shall be permitted. By applying the criteria and methodologies, the Purchaser shall determine the Most Advantageous Bid. This is the Bid of the Bidder that meets the qualification criteria and whose Bid has been determined to be:

(a) substantially responsive to the bidding document; and

(b) the lowest evaluated cost.

34.2 To evaluate a Bid, the Purchaser shall consider the following:

(a) evaluation will be done for Items or Lots (contracts), as specified **in the BDS;** and the Bid Price as quoted in accordance with ITB 14;

(b) price adjustment for correction of arithmetic errors in accordance with ITB 31.1;

(c) price adjustment due to discounts offered in accordance with ITB 14.4;

(d) converting the amount resulting from applying (a) to

(c) above, if relevant, to a single currency in accordance with ITB 32;

(e) price adjustment due to quantifiable nonmaterial nonconformities in accordance with ITB 30.3; and

(f) the additional evaluation factors specified in Section III, Evaluation and Qualification Criteria.

34.3 The estimated effect of the price adjustment provisions of the Conditions of Contract, applied over the period of execution of the Contract, shall not be taken into account in Bid evaluation.

34.4 If this bidding document allows Bidders to quote separate prices for different lots (contracts), the methodology to determine the lowest evaluated cost of the lot (contract) combinations, including any discounts offered in the Letter of Bid, is specified in Section III, Evaluation and Qualification Criteria

34.5 The Purchaser's evaluation of a Bid will exclude and not take into account:

(a) in the case of Goods manufactured in the Purchaser's Country, sales and other similar taxes, which will be payable on the goods if a contract is awarded to the Bidder;

(b) in the case of Goods manufactured outside the Purchaser's Country, already imported or to be imported, customs duties and other import taxes levied on the imported Good, sales and other similar taxes, which will be payable on the Goods if the contract is awarded to the Bidder;

(c) any allowance for price adjustment during the period of execution of the contract, if provided in the Bid.

34.6 The Purchaser's evaluation of a Bid may require the consideration of other factors, in addition to the Bid Price quoted in accordance with ITB 14. These factors may be related to the characteristics, performance, and terms and conditions of purchase of the Goods and Related Services. The effect of the factors selected, if any, shall be expressed in monetary terms to facilitate comparison of Bids, unless otherwise specified **in the BDS** from amongst those set out in Section III, Evaluation and Qualification Criteria. The criteria and methodologies to be used shall be as specified in

ITB 34.2 (f).

35. Comparison of Bids

35.1 The Purchaser shall compare the evaluated costs of all substantially responsive Bids established in accordance with ITB 34.2 to determine the Bid that has the lowest evaluated cost. The comparison shall be on the basis of CIP (place of final destination) prices for imported goods and EXW prices, plus cost of inland transportation and insurance to place of destination, for goods manufactured within the Borrower's country, together with prices for any required installation, training, commissioning and other services. The evaluation of prices shall not take into account custom duties and other taxes levied on imported goods quoted CIP and sales and similar taxes levied in connection with the sale or delivery of goods.

36. Abnormally Low Bids

36.1 An Abnormally Low Bid is one where the Bid price, in combination with other constituent elements of the Bid, appears unreasonably low to the extent that the Bid price raises material concerns as to the capability of the Bidder to perform the Contract for the offered Bid price.

36.2 In the event of identification of a potentially Abnormally Low Bid, the Purchaser shall seek written clarification from the Bidder, including a detailed price analyses of its Bid price in relation to the subject matter of the contract, scope, delivery schedule, allocation of risks and responsibilities and any other requirements of the bidding document.

36.3 After evaluation of the price analyses, in the event that the Purchaser determines that the Bidder has failed to demonstrate its capability to perform the contract for the offered Bid price, the Purchaser shall reject the Bid.

37. Qualification of the Bidder

37.1 The Purchaser shall determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated cost and substantially responsive Bid is eligible and meets the qualifying criteria specified in BDS ITB 11.1 as applicable, and Section III, Evaluation and Qualification Criteria.

37.2 The determination shall be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB 17. The determination shall not take into consideration the qualifications of other firms such as the Bidder's subsidiaries, parent entities, affiliates, subcontractors or any

other firm(s) different from the Bidder.

37.3 Prior to Contract award, the Purchaser will verify that the successful Bidder (including each member of a JV) is not disqualified by the Bank due to noncompliance with contractual SEA/SH prevention and response obligations. The Purchaser will conduct the same verification for each subcontractor proposed by the successful Bidder. If any proposed subcontractor does not meet the requirement, the Purchaser will require the Bidder to propose a replacement subcontractor.

37.4 An affirmative determination shall be a prerequisite for award of the Contract to the Bidder. A negative determination shall result in disqualification of the Bid, in which event the Purchaser shall proceed to the Bidder who offers a substantially responsive Bid with the next lowest evaluated cost to make a similar determination of that Bidder's qualifications to perform satisfactorily.

38. Purchaser's Right to Accept Any Bid, and to Reject Any or All Bids

38.1 The Purchaser reserves the right to accept or reject any Bid, and to annul the Bidding process and reject all Bids at any time prior to Contract Award, without thereby incurring any liability to Bidders. In case of annulment, all Bids submitted and specifically, bid securities, shall be promptly returned to the Bidders.

39. Standstill Period

39.1 The Contract shall not be awarded earlier than the expiry of the Standstill Period. The Standstill Period shall be ten (10) Business Days unless extended in accordance with ITB 44. The Standstill Period commences the day after the date the Purchaser has transmitted to each Bidder the Notification of Intention to Award the Contract. Where only one Bid is submitted, or if this contract is in response to an emergency situation recognized by the Bank, the Standstill Period shall not apply.

40. Notification of Intention to Award

40.1 The Purchaser shall send to each Bidder the Notification of Intention to Award the Contract to the successful Bidder. The Notification of Intention to Award shall contain, at a minimum, the following information:

(a) the name and address of the Bidder submitting the successful Bid;

(b) the Contract price of the successful Bid;

(c) the names of all Bidders who submitted Bids, and their

Bid prices as readout, and as evaluated;

(d) a statement of the reason(s) the Bid (of the unsuccessful Bidder to whom the notification is addressed) was unsuccessful, unless the price information in c) above already reveals the reason;

(e) the expiry date of the Standstill Period; and

(f) instructions on how to request a debriefing and/or submit a complaint during the standstill period.

F. Award of Contract

41. Award Criteria

41.1 Subject to ITB 38, the Purchaser shall award the Contract to the successful Bidder. This is the Bidder whose Bid has been determined to be the Most Advantageous Bid. This is the Bid of the Bidder that meets the qualification criteria and whose Bid has been determined to be:

(a) substantially responsive to the bidding document, and

(b) the lowest evaluated cost.

42. Purchaser's Right to Vary Quantities at Time of Award

42.1 At the time the Contract is awarded, the Purchaser reserves the right to increase or decrease the quantity of Goods and Related Services originally specified in Section VII, Schedule of Requirements, provided this does not exceed the percentages specified **in the BDS**, and without any change in the unit prices or other terms and conditions of the Bid and the bidding document.

43. Notification of Award

43.1 Prior to the date of expiry of the Bid validity and upon expiry of the Standstill Period, specified in ITB 39.1 or any extension thereof, and upon satisfactorily addressing any complaint that has been filed within the Standstill Period, the Purchaser shall notify the successful Bidder, in writing, that its Bid has been accepted. The notification of award (hereinafter and in the Contract Forms called the "Letter of Acceptance") shall specify the sum that the Purchaser will pay the Supplier in consideration of the execution of the Contract (hereinafter and in the Conditions of Contract and Contract Forms called "the Contract Price").

43.2 Within ten (10) Business Days after the date of transmission of the Letter of Acceptance,, the Purchaser shall publish the Contract Award Notice which shall contain, at a minimum, the following information:

(a) name and address of the Purchaser;

(b) name and reference number of the contract being awarded, and the selection method used;

(c) names of all Bidders that submitted Bids, and their Bid prices as read out at Bid opening, and as evaluated;

(d) names of all Bidders whose Bids were rejected either as nonresponsive or as not meeting qualification criteria, or were not evaluated, with the reasons therefor;

(e) the name of the successful Bidder, the final total contract price, the contract duration and a summary of its scope; and

(f) successful Bidder's Beneficial Ownership Disclosure Form, if specified in BDS ITB 45.1.

43.3 The Contract Award Notice shall be published on the Purchaser's website with free access if available, or in at least one newspaper of national circulation in the Purchaser's Country, or in the official gazette. The Purchaser shall also publish the contract award notice in UNDB online.

43.4 Until a formal Contract is prepared and executed, the Letter of Acceptance shall constitute a binding Contract.

44. Debriefing by the Purchaser

44.1 On receipt of the Purchaser's Notification of Intention to Award referred to in ITB 40.1, an unsuccessful Bidder has three (3) Business Days to make a written request to the Purchaser for a debriefing. The Purchaser shall provide a debriefing to all unsuccessful Bidders whose request is received within this deadline.

44.2 Where a request for debriefing is received within the deadline, the Purchaser shall provide a debriefing within five (5) Business Days, unless the Purchaser decides, for justifiable reasons, to provide the debriefing outside this timeframe. In that case, the standstill period shall automatically be extended until five (5) Business Days after such debriefing is provided. If more than one debriefing is so delayed, the standstill period shall not end earlier than five (5) Business Days after the last debriefing takes place. The Purchaser shall promptly inform, by the quickest means available, all Bidders of the extended standstill period

44.3 Where a request for debriefing is received by the Purchaser

later than the three (3)-Business Day deadline, the Purchaser should provide the debriefing as soon as practicable, and normally no later than fifteen (15) Business Days from the date of publication of Public Notice of Award of contract. Requests for debriefing received outside the three (3)-day deadline shall not lead to extension of the standstill period.

44.4 Debriefings of unsuccessful Bidders may be done in writing or verbally. The Bidder shall bear their own costs of attending such a debriefing meeting.

45. Signing of Contract

45.1 The Purchaser shall send to the successful Bidder the Letter of Acceptance including the Contract Agreement, and, if specified in the BDS, a request to submit the Beneficial Ownership Disclosure Form providing additional information on its beneficial ownership. The Beneficial Ownership Disclosure Form, if so requested, shall be submitted within eight (8) Business Days of receiving this request.

45.2 The successful Bidder shall sign, date and return to the Purchaser, the Contract Agreement within twenty-eight (28) days of its receipt.

45.3 .Notwithstanding ITB 45.2 above, in case signing of the Contract Agreement is prevented by any export restrictions attributable to the Purchaser, to the country of the Purchaser, or to the use of the products/goods, systems or services to be supplied, where such export restrictions arise from trade regulations from a country supplying those products/goods, systems or services, the Bidder shall not be bound by its Bid, always provided however, that the Bidder can demonstrate to the satisfaction of the Purchaser and of the Bank that signing of the Contact Agreement has not been prevented by any lack of diligence on the part of the Bidder in completing any formalities, including applying for permits, authorizations and licenses necessary for the export of the products/goods, systems or services under the terms of the Contract.

46. Performance Security

46.1 Within twenty-eight (28) days of the receipt of Letter of Acceptance from the Purchaser, the successful Bidder, if required, shall furnish the Performance Security in accordance with the GCC 18, using for that purpose the Performance Security Form included in Section X, Contract Forms, or another Form acceptable to the Purchaser. If the Performance Security furnished by the successful Bidder is in the form of a bond, it shall be issued by a bonding or insurance company that has been determined by the successful Bidder to be acceptable to the Purchaser. A foreign institution providing

a bond shall have a correspondent financial institution located in the Purchaser's Country, unless the Purchaser has agreed in writing that a correspondent financial institution is not required.

46.2 Failure of the successful Bidder to submit the above-mentioned Performance Security or sign the Contract shall constitute sufficient grounds for the annulment of the award and forfeiture of the Bid Security. In that event the Purchaser may award the Contract to the Bidder with the next Most Advantageous Bid.

47. Procurement Related Complaint

47.1 The procedures for making a Procurement-related Complaint are as specified in the BDS.

Section II - Bid Data Sheet (BDS)

The following specific data for the goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions herein shall prevail over those in ITB.

Where an e-procurement system is used, modify the relevant parts of BDS to reflect the e-procurement process

ITB Reference	A. General
ITB 1.1	The reference number of the Request for Bids (RFB) is ***LK-SPC-370471-GO-RFB*** The Purchaser is: ***Ministry of Health, Sri Lanka*** The name of the RFB is: *Human Albumin Solution 20% in 50ml bottles* The number and identification of lots (contracts) comprising this RFB is: **One**
ITB 1.2(a)	Deleted
ITB 2.1	The Borrower is: ***Ministry of Health*** Democratic Socialist Republic of Sri Lanka Loan or Financing Agreement amount: ***USD. 8,000,000.00*** The name of the Project is: *Sri Lanka Covid -19 Emergency Response & Health Systems Preparedness Project (P 173867)*
ITB 4.1	Maximum number of members in the Joint Venture (JV) shall be: Two
ITB 4.5	A list of debarred firms and individuals is available on the Bank's external website: http://www.worldbank.org/debarr.
	B. Contents of Bidding Document
ITB 7.1	For **Clarification of Bid purposes** only, the Purchaser's address is: Attention: Manager Imports (Pharma), Ministry of Health, Sri Lanka Address: "Mehewara Piyasa" 41, Kirula Road, Colombo 05, Sri Lanka. Floor/ Room number*: 16th Floor* City: ***Colombo 05*** ZIP Code: 00500

	Country: ***Sri Lanka*** Telephone: (00) 94- 11 - 2335374 Facsimile number: (00) 94 – 11 – 2582496 Electronic mail address: pharma.manager@spc.lk Requests for clarification should be received by the Purchaser no later than: ***14 Days prior to the deadline for bid submission.*** Web page: www.spc.lk
	C. Preparation of Bids
ITB 10.1	The language of the Bid is: ***English*** All correspondence exchange shall be in English language. Language for translation of supporting documents and printed literature is English.
ITB 11.1	Documentary evidence of the Bidder's qualifications to perform the Contract if its Bid is accepted: (i) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder: (a) is incorporated in the country of manufacture of the Goods; (b) has been licensed by the regulatory authority in the country of manufacture to supply the Goods; (c) has manufactured and marketed the specific goods covered by this bidding document, for at least three (3) years. (d) has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the goods or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC). (ii) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder does not manufacture or otherwise produce, (a) that the Bidder has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Purchaser's Country; and The Bidder shall also submit the following additional information: (a) a statement of installed manufacturing capacity;

	(b) copies of its audited financial statements for the past three fiscal years; (c) details of on-site quality control laboratory facilities and services and range of tests conducted; (d) list of major supply contracts conducted within the last five years.
ITB 11.1 (j)	The Bidder shall submit the following additional documents in its Bid: Bidders who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer, and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce pharmaceuticals or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling, and quality testing. The Bidder shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Goods offered.
ITB 13.1	Alternative Bids ***"shall not be"*** considered.
ITB 14.5	The prices quoted by the Bidder ***"shall not"*** be subject to adjustment during the performance of the Contract.
ITB 14.6	Prices quoted for each lot shall correspond **to *100*** percent of the quantity specified for each lot Prices quoted for each item of a lot shall correspond at least to ***100*** percent of the quantities specified for this item of a lot.
ITB 14.7	The Incoterms edition is: INCOTERMS 2020
ITB 14.8 (a) (iii), (b) (ii) and c(v)	Final Destination (Project Site): Medical Supplies Division, 357, Ven Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka
ITB 14.8 (b)(i)	Place of Destination: Foreign Bidders : Sea / Air port in Colombo Local Bidders : Medical Supplies Division, 357, Ven Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka
ITB 15.1	The Bidder **is** required to quote in the currency of the Purchaser's Country the portion of the Bid price that corresponds to expenditures incurred in that currency.

ITB 16.3 (b)	Documentation requirements for eligibility of Goods. In addition to the documents stated in ITB 16.1, 16.2, and 16.3 (a), the following documents should be included with the Bid: None
ITB 16.4	The Purchaser's Country ***does*** require registration of Goods with NMRA. However, Goods without NMRA registration also can be submitted subject to adhering to requirement stipulated in ITB 16.4 (b).
ITB 16.4 (b)	By the time of submitting the bid, the Bidder shall have complied with the following documentary requirements in order to obtain Waiver of Registration the Goods to be supplied under the Contract: • Certificate of Analysis (COA) of the relevant finished product • Certificate of Pharmaceuticals Product (COPP) • Stability data • Label of the product • Product Information Leaflet • Proforma Invoice **Obtaining Waiver of registration is not guaranteed however will be dependent upon successful submission and meeting of all required documentation as listed above. .**
ITB 16.5	For the purpose of obtaining additional information about the requirements for registration, Bidders may contact CEO / *Chief Pharmacist of NMRA* **Telophone No : +94 11 269 5173,** +94 112 303 072 **e-mail : ceo@nmra.lk** **www : mnra.gov.lk**
ITB 18.1	The Bid shall be valid until: 25 Feb 2024
ITB 18.3 (a)	*Not applicable*
ITB 19.1	A *Bid Security* ***"shall be"*** required A Bid-Securing Declaration ***"shall not be"*** required. If a Bid Security shall be required, the amount and currency of the Bid security shall be *LKR. 19,736,000.00 or equivalent value in USD according to the exchange rate on Bid issuing date*

ITB 19.3 (d)	Other types of acceptable securities: i. A bank guarantee or a bid bond issued by a commercially operating bank in Sri Lanka, approved by the Central Bank of Sri Lanka. ii. A bank based in another country but the security or guarantee "Confirmed" by a commercially operating bank in Sri Lanka. iii. A Letter of Credit issued by a foreign bank, but 'Confirmed' by a commercially operating bank in Sri Lanka. iv. Any other agency approved by the Treasury from time to time. Or v. A cash deposit
ITB 19.9	Not applicable
ITB 20.1	In addition to the original of the Bid, the number of copies is**: 01**
ITB 20.3	The written confirmation of authorization to sign on behalf of the Bidder shall consist of **Letter of Authorization issued to the authorized signatory or registered power of attorney in case of signatory is acting in the capacity of power of attorney holder**
D. Submission and Opening of Bids	
ITB 22.1	For **Bid submission purposes** only, the Purchaser's address is: Attention: The Chairman, Procurement Committee State Pharmaceutical Corporation of Sri Lanka, Street Address: No. 41, "Mehewara Piyasa", Kirula Road Floor/ Room number: *16th Floor* City: Colombo 05 ZIP/Postal Code: 00500 Country: Sri Lanka *Sealed bids may be despatched either by registered post to the address given above or deposited in the bid box kept for the purpose at the above address to receive on or before closing date and time. RFB number should be cleared marked on the left-hand corner of the outer envelope.* The deadline for Bid submission is:

	Date: 29 August 2023 Time: 10:00 Hours Bidders ***"shall not"*** have the option of submitting their Bids electronically. The electronic Bidding submission procedures shall be: ***Not Applicable***
ITB 25.1	The Bid opening shall take place at: State Pharmaceutical Corporation of Sri Lanka Street Address: No. 41, "Mehewara Piyasa", Kirula Road Floor/ Room number: *16th Floor* City: Colombo 05 Country: Sri Lanka Date : 29th August 2023 Time: 10:00 Hours
ITB 25.1	The electronic Bid opening procedures shall be: ***Not applicable***
ITB 25.6	The Letter of Bid and Price Schedules shall be initialed by Three (03) representatives of the Purchaser conducting Bid opening *via* Bid Opening Committee
E. Evaluation and Comparison of Bids	
ITB 32.1	The currency that shall be used for Bid evaluation and comparison purposes to convert (at the selling rate of Central Bank of Sri Lanka) all Bid prices expressed in various currencies into a single currency is Sri Lankan Rupees (LKR) The source of exchange rate shall be: ***Central Bank of Sri Lanka*** The date for the exchange rate shall be *:* ***18th July 2023***
ITB 33.1	A margin of domestic preference ***"shall "*** apply.
ITB 34.2(a)	Evaluation will be done on individual item basis Note: ***Bids will be evaluated for each item and the Contract will comprise the Item(s) awarded to the successful Bidder.***

ITB 34.6	The adjustments shall be determined using the following criteria, from amongst those set out in Section III, Evaluation and Qualification Criteria: **(a)** Deviation in Delivery schedule: No
F. Award of Contract	
ITB 42	The maximum percentage by which quantities may be increased is: ***15%***The maximum percentage by which quantities may be decreased is: ***15%***
ITB 45.1	The successful Bidder *shall* submit the Beneficial Ownership Disclosure Form.
ITB 47.1	The procedures for making a Procurement-related Complaint are detailed in the "Procurement Regulations for IPF Borrowers (Annex III)." If a Bidder wishes to make a Procurement-related Complaint, the Bidder should submit its complaint following these procedures, in writing (by the quickest means available, that is either by email or fax), to: **For the attention**: Chairman, Procurement Committee **Title/position**: Chairman **Purchaser**: *Ministry of Health, Sri Lanka* **Email address***: chairman@spc.lk* **Fax number**: In summary, a Procurement-related Complaint may challenge any of the following: **1.** the terms of the Bidding Documents; and **2.** the Purchaser's decision to award the contract.

Bid Data Sheet (continued)

PHARMACEUTICALS

(Additional BDS for Pharmaceuticals)

ITB 11.1 (f)	Documentary evidence of the Bidder's qualifications to perform the Contract if its Bid is accepted: (i) (a) has a Good Distribution Practice (GDP) Certificate where appropriate. The Bidder will submit the following additional information: (b) list of pharmaceuticals being manufactured by the Bidder with product registration/license number and date. (c) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.
ITB 16.3 (b)	The pharmaceuticals offered should meet the specified pharmacopeial standards as stated in the Technical Specification. If the Goods offered are not included in one of the specified pharmacopoeias (e.g., the case of a new drug), the Bidder will provide testing protocols and alternative reference standards. BP, USP, IP or any other pharmacopeial standards acceptable to NMRA

Section III - Evaluation and Qualification Criteria

This Section contains the criteria that the Purchaser shall use to evaluate a Bid and qualify the Bidders. No other factors, methods or criteria shall be used other than specified in this bidding document.

Contents

1. Margin of Preference (ITB 33)

If the BDS so specifies, a margin of preference to goods manufactured in the Purchaser's Country for the purpose of Bid comparison shall be granted in accordance with the procedures outlined in subsequent paragraphs.

Bids will be classified in one of three groups, as follows*:*

(a) **Group A:** Bids offering goods manufactured in the Purchaser's Country, for which (i) labor, raw materials, and components from within the Purchaser's Country account for more than thirty (30) percent of the EXW price; and (ii) the production facility in which they will be manufactured or assembled has been engaged in manufacturing or assembling such goods at least since the date of Bid submission.

(b) **Group B:** All other Bids offering Goods manufactured in the Purchaser's Country.

(c) **Group C:** Bids offering Goods manufactured outside the Purchaser's Country that have been already imported or that will be imported.

To facilitate this classification by the Purchaser, the Bidder shall complete whichever version of the Price Schedule furnished in the bidding document is appropriate provided, however, that the completion of an incorrect version of the Price Schedule by the Bidder shall not result in rejection of its Bid, but merely in the Purchaser's reclassification of the Bid into its appropriate Bid group.

The Purchaser will first review the Bids to confirm the appropriateness of, and to modify as necessary, the Bid group classification to which Bidders assigned their Bids in preparing their Bid Forms and Price Schedules.

The Bids in each group will then be compared to determine the Bid with the lowest evaluated cost in that group. The lowest evaluated cost Bid from each group shall then be compared with each other and if as a result of this comparison a Bid from Group A or Group B is the lowest, it shall be selected for the award.

If as a result of the preceding comparison, the lowest evaluated cost is a Bid from Group C, all Bids from Group C shall be further compared with the Bid with the lowest evaluated cost from Group A after adding to the evaluated costs of goods offered in each Bid from Group C, for the purpose of this further comparison only, an amount equal to 15% (fifteen percent) of the respective CIP Bid price for goods to be imported and already imported goods. Both prices shall include unconditional discounts and be corrected for arithmetical errors. If the Bid from Group A is the lowest, it shall be selected for award. If not, the lowest evaluated Bid from Group C shall be selected.

Most Advantageous Bid

The Purchaser shall use the criteria and methodologies listed in this Section to determine the Most Advantageous Bid. The Most Advantageous Bid is the Bid of the Bidder that meets the qualification criteria and whose Bid has been determined to be:

(a) substantially responsive to the bidding document, and

(b) the lowest evaluated cost.

2. Evaluation (ITB 34)

2.1. Evaluation Criteria (ITB 34.6)

The Purchaser's evaluation of a Bid may take into account, in addition to the Bid Price quoted in accordance with ITB 14.8, one or more of the following factors as specified in ITB 34.2 (f) and in BDS referring to ITB 34.6**,** using the following criteria and methodologies.

(a) Delivery schedule (as per Incoterms specified in the BDS) **Not applicable**

The Goods specified in the List of Goods are required to be delivered within the acceptable time range (after the earliest and before the final date, both dates inclusive) specified in Section VII, Schedule of Requirements. No credit will be given to deliveries before the earliest date, and Bids offering delivery after the final date shall be treated as nonresponsive. Within this acceptable period, an adjustment of [insert the adjustment factor], will be added, for evaluation purposes only, to the Bid price of Bids offering deliveries later than the "Earliest Delivery Date" specified in Section VII, Schedule of Requirements.

(b) Deviation in payment schedule. **Not applicable**

(i) *Bidders shall state their Bid price for the payment schedule outlined in the SCC. Bids shall be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in Bid price they wish to offer for such alternative payment schedule. The Purchaser may consider the alternative payment schedule and the reduced Bid price offered by the Bidder selected on the basis of the base price for the payment schedule outlined in the SCC.*

(c) Specific additional criteria **Not applicable**

Other specific additional criteria to be considered in the evaluation, and the evaluation method shall be detailed in BDS 34.6]

[Other specific additional criteria to be considered in the evaluation, and the evaluation method shall be detailed in BDS 34.6]

*[If specific **sustainable procurement technical requirements** have been specified in Section VII- Specification, **either** state that (i) those requirements will be evaluated on a pass/fail (compliance basis) **or** otherwise (ii) in addition to evaluating those requirements on a pass/fail (compliance basis), if applicable, specify the monetary adjustments to be applied to Bid Prices for comparison purposes on account of Bids that exceed the specified minimum sustainable procurement technical requirements.]*

2.2. Multiple Contracts (ITB 34.4) NOT APPLICABLE

After considering all possible combination of lots, the Purchaser shall award multiple contracts to the Bidder that offers the lowest evaluated cost of the combination of Bids (one contract per Bid), and meets the qualification criteria in this Section III, Sub-Section ITB 37.1Qualification Requirements.

The Purchaser shall:

(a) evaluate only lots or contracts that include at least the percentages of items per lot and quantity per item as specified in ITB 14.6

Bid evaluation of such Bids will be carried out as per the following procedures. The average price (or highest price as specified in BDS 30.3)of an item quoted by substantially responsive Bidders will be added to the Bid price of those who did not quote for that item and the equivalent total cost of the Bid so determined will be used for Bid comparison, evaluation, and award

(b) take into account:

(i) the lowest-evaluated cost for each lot and

(ii) the price reduction per lot and the methodology for its application as offered by the Bidder in its Bid

2.3. Alternative Bids (ITB 13.1) NOT APPLICABLE

An alternative if permitted under ITB 13.1, will be evaluated as follows:

[insert one of the following]

"A Bidder may submit an alternative Bid only with a Bid for the base case. The Purchaser shall only consider the alternative Bids offered by the Bidder whose Bid for the base case was determined to be the Most Advantageous Bid."

or

"A Bidder may submit an alternative Bid with or without a Bid for the base case. The Purchaser shall consider Bids offered for alternatives as specified in the Technical Specifications of Section VII, Schedule of Requirements. All Bids received, for the base case, as well as alternative Bids meeting the specified requirements, shall be evaluated on their own merits in accordance with the same procedures, as specified in the ITB 34."

3. Qualification (ITB 37)

The Bidder shall demonstrate that it continues to meet the prequalification criteria. The Bidder shall use the relevant forms in Section IV in case there is any update to the information that it submitted for prequalification.

~~**NOT APPPLICABLE**~~

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
				Joint Venture (existing or intended)			
No.	Subject	Requirement	Single Entity	All Members Combined	Each Member	One Member	Submission Requirements
1. Eligibility							
1.1	**Nationality**	Nationality in accordance with ITB 4.4	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
1.2	**Conflict of Interest**	No conflicts of interest in accordance with ITB 4.2	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Bid Submission Letter
1.3	**Bank Eligibility**	Not having been declared ineligible by the Bank, as described in ITB 4.5 and 5.1	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Bid Submission Letter
1.4	**State-owned enterprise of the Borrower country**	Meet conditions of ITB 4.6	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
1.5	**United Nations resolution or Borrower's country law**	Not having been excluded as a result of prohibition in the Borrower's country laws or official regulations against commercial relations with the Bidder's country, or by an act of compliance with UN Security Council resolution, both in accordance with ITB 4.8 and Section V.	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
2. Historical Contract Non-Performance							
2.1	**History of Non-Performing**	Non-performance of a contract[1] did not occur as a result of	Must meet requirement	Must meet requirements	Must meet requirement[2]	N/A	Form PER-1

[1] Non performance, as decided by the Purchaser, shall include all contracts where (a) non performance was not challenged by the Supplier, including through referral to the dispute resolution mechanism under the respective contract, and (b) contracts that were so challenged but fully settled against the Supplier. Non performance shall not include contracts where Purchaser's decision was overruled by the dispute resolution mechanism. Non performance must be based on all information on fully settled disputes or litigation, i.e. dispute or litigation that has been resolved in accordance with the dispute resolution mechanism under the respective contract and where all appeal instances available to the Bidder have been exhausted.

[2] This requirement also applies to contracts executed by the Bidder as JV member.

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
				Joint Venture (existing or intended)			
No.	Subject	Requirement	Single Entity	All Members Combined	Each Member	One Member	Submission Requirements
	Contracts	Supplier's default since 1st January 2018.					
2.2	**Suspension Based on Execution of Bid/Proposal Securing Declaration by the Purchaser**	Not under suspension based on execution of a Bid/Proposal Securing Declaration pursuant to ITB 4.7.	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Bid Submission Letter
2.3	**Pending Litigation**	Bidder's financial position and prospective long term profitability still sound according to criteria established in 3.1 below and assuming that all pending litigation will be resolved against the Bidder	Must meet requirement	N/A	Must meet requirement	N/A	Form PER-1
2.4	**Litigation History**	No consistent history of court/arbitral award decisions against the Bidder since 1st January *2018*	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Form PER-1
2.5	**Bank's SEA and/or SH Disqualification**	At the time of Contract Award, not subject to disqualification by the Bank for non-compliance with SEA/ SH obligations	Must meet requirement (including each subcontractor)	N/A	Must meet requirement (including each subcontractor proposed by the Applicant)	N/A	Bid Submission Letter, Form PER-2
3. Financial Situation and Performance							
3.1	**Financial Capabilities**	The audited balance sheets or, if not required by the laws of the Bidder's country, other financial statements acceptable to the Purchaser, for the last *3* years	Must meet requirement	N/A	Must meet requirement	N/A	

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
				Joint Venture (existing or intended)			
No.	Subject	Requirement	Single Entity	All Members Combined	Each Member	One Member	Submission Requirements
		shall be submitted and must demonstrate the current soundness of the Bidder's financial position and indicate its prospective long-term profitability.					
3.2	**Average Annual Turnover**	Average annual turnover (Average Annual Sales Revenue) from supply of Health Sector Goods of US$ *13,629,000.00– US Dollars thirteen million six hundred and twenty nine thousand)* calculated as total certified payments received for contracts in progress and/or completed during the last three years.	Must meet requirement	Must meet requirement	50% of the total	50% of the total	Form FIN – 3.2
3.3	**Current Commitments**	The Bidder shall also demonstrate, to the satisfaction of the Purchaser, that it has adequate sources of finance to meet the cash flow requirements on contracts currently in progress and for future contract commitments.					Form CON -1
4. Experience							
4.1	**General Experience**	Experience in supply of Health Sector Goods for at least the last three years	Must meet requirement	N/A	Must meet requirement	N/A	Form EXP –1
4.2 (a)	**Specific Experience**	(i) Documentary evidence of the Bidder's qualifications to perform the Contract in accordance with 4.2 (b)(i)	Must meet requirement	Must meet requirement	N/A	Must meet requirement	

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
No.	Subject	Requirement	Single Entity	Joint Venture (existing or intended)			Submission Requirements
				All Members Combined	Each Member	One Member	
		below (ii) Technical and Production Capability in accordance with 4.2(b)(ii) as below. (iii) Experience on Packaging, Distribution in accordance with 4.2(b)(iii) below.	Must meet requirement Must meet requirement	Must meet requirement Must meet requirement	N/A N/A	Must meet requirement Must meet requirement	
4.2 (b)	See below for details						

Specific Experience Requirements

The Specific Experience Requirements under 4.2 (b) (from the table above) are as follows:

4.2 (b)(i) Documentary evidence in accordance with BDS ITB 11.1

4.2(b)(ii) Technical and Production Capability

The Bidder shall provide evidence that it has the technical, and production capability necessary to perform the Contract:

(i) that it has successfully completed or substantially completed at least 3 - similar contracts for supply of the goods and within the last five years. Similar contracts are those of approximately the same size and that includes comparable products, e.g., capsules, tablets, vaccines.

The goods may have been supplied by the Bidder as a manufacturer or by its agent, with references being submitted to confirm satisfactory performance,

(ii) that it has achieved an annual average production rate of 645,000 bottles during the last three years

4.2 (b)(iii) Experience on Packaging, Distribution and Transportation

The Bidder should provide proof of experience with and knowledge of modes of packing, distribution, and transportation of pharmaceuticals similar to those subject to Bidding under logistical and climatic conditions similar to the ones in the purchaser's country. It should provide names of countries to which the Bidder has supplied (including packaged, distributed, and transported) products worth at least the amount USD 2,726,000.00 within the past three years.

Section IV - Bidding Forms

Table of Forms

Letter of Bid

INSTRUCTIONS TO BIDDERS: DELETE THIS BOX ONCE YOU HAVE COMPLETED THE DOCUMENT

The Bidder must prepare this Letter of Bid on stationery with its letterhead clearly showing the Bidder's complete name and business address.

Note: All italicized text is to help Bidders in preparing this form.

Date of this Bid submission: [*insert date (as day, month and year) of Bid submission*]
Request for Bid No.: ***LK-SPC-370471-GO-RFB***
Alternative No.: [*insert identification No if this is a Bid for an alternative*]

To: **[*insert complete name of Purchaser*]**

(a) **No reservation:** We have examined and have no reservations to the bidding document, including Addenda issued in accordance with Instructions to Bidders (ITB 8);

(b) **Eligibility:** We meet the eligibility requirements and have no conflict of interest in accordance with ITB 4;

(c) We have not been suspended nor declared ineligible by the Purchaser based on execution of a Bid-Securing Declaration or Proposal-Securing Declaration in the Purchaser's Country in accordance with ITB 4.7;

(d) **Sexual Exploitation and Abuse (SEA) and/or Sexual Harassment (SH):** [*select the appropriate option from (i) to (iii) below and delete the others. In case of JV members and/or subcontractors, indicate the status of disqualification by the Bank of each JV member and/or subcontractor]*.

We, including any of our subcontractors:

(i) [have not been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations.]

(ii) [are subject to disqualification by the Bank for non-compliance with SEA/ SH obligations.]

(iii) [had been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations, and were removed from the disqualification list. An arbitral award on the disqualification case has been made in our favor.]

(e) **Conformity:** We offer to supply in conformity with the bidding document and in accordance with the Delivery Schedules specified in the Schedule of Requirements the following Goods: [*insert a brief description of the Goods and Related Services*];

(f) **Bid Price:** The total price of our Bid, excluding any discounts offered in item (f) below is: *[Insert one of the options below as appropriate]*

Option 1, in case of one lot: Total price is: [*insert the total price of the Bid in words and figures, indicating the various amounts and the respective currencies*];

Or

Option 2, in case of multiple lots: (a) Total price of each lot [*insert the total price of each lot in words and figures, indicating the various amounts and the respective currencies*]; and (b) Total price of all lots (sum of all lots) [*insert the total price of all lots in words and figures, indicating the various amounts and the respective currencies*];

(g) **Discounts:** The discounts offered and the methodology for their application are:

(i) The discounts offered are: [*Specify in detail each discount offered.*]

(ii) The exact method of calculations to determine the net price after application of discounts is shown below: [*Specify in detail the method that shall be used to apply the discounts*];

(h) **Bid Validity**: Our Bid shall be valid until *[insert day, month and year in accordance with ITP 18.1],* and it shall remain binding upon us and may be accepted at any time before the expiration of that period;

(i) **Performance Security**: If our Bid is accepted, we commit to obtain a Performance Security in accordance with the bidding document;

(j) **One Bid per Bidder**: We are not submitting any other Bid(s) as an individual Bidder, and we are not participating in any other Bid(s) as a Joint Venture partner or as a subcontractor, and meet the requirements of ITB 4.3, other than alternative Bids submitted in accordance with ITB 13;

(k) **Suspension and Debarment:** We, along with any of our subcontractors, suppliers, consultants, manufacturers, or service providers for any part of the contract, are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the World Bank Group or a debarment imposed by the World Bank Group in accordance with the Agreement for Mutual Enforcement of Debarment Decisions between the World Bank and other development banks. Further, we are not ineligible under the Purchaser's Country laws or official regulations or pursuant to a decision of the United Nations Security Council;

(l) **State-owned enterprise or institution:** [*select the appropriate option and delete the other*] [*We are not a state-owned enterprise or institution*] / [*We are a state-owned enterprise or institution but meet the requirements of ITB 4.6*];

(m) **Commissions, gratuities, fees:** We have paid, or will pay the following commissions, gratuities, or fees with respect to the Bidding process or execution of the Contract: [*insert complete name of each Recipient, its full address, the reason for which each commission or gratuity was paid and the amount and currency of each such commission or gratuity*]

Name of Recipient	Address	Reason	Amount

(If none has been paid or is to be paid, indicate "none.")

(n) **Binding Contract:** We understand that this Bid, together with your written acceptance thereof included in your Letter of Acceptance, shall constitute a binding contract between us, until a formal contract is prepared and executed;

(o) **Purchaser Not Bound to Accept:** We understand that you are not bound to accept the lowest evaluated cost Bid, the Most Advantageous Bid or any other Bid that you may receive; and

(p) **Fraud and Corruption:** We hereby certify that we have taken steps to ensure that no person acting for us or on our behalf engages in any type of Fraud and Corruption.

Name of the Bidder: *[*insert complete name of the Bidder*]

Name of the person duly authorized to sign the Bid on behalf of the Bidder: **[*insert complete name of person duly authorized to sign the Bid*]

Title of the person signing the Bid: [*insert complete title of the person signing the Bid*]

Signature of the person named above: [*insert signature of person whose name and capacity are shown above*]

Date signed [*insert date of signing*] **day of** [*insert month*], [*insert year*]

*: In the case of the Bid submitted by a Joint Venture specify the name of the Joint Venture as Bidder.

**: Person signing the Bid shall have the power of attorney given by the Bidder. The power of attorney shall be attached with the Bid Schedules.

Bidder Information Form

[The Bidder shall fill in this Form in accordance with the instructions indicated below. No alterations to its format shall be permitted and no substitutions shall be accepted.]

Date: *[insert date (as day, month and year) of Bid submission*]
RFB No.: ***[LK-SPC-370471-GO-RFB***]
Alternative No.: *[insert identification No if this is a Bid for an alternative]*

Page _____ of_ _____ pages

1. Bidder's Name *[insert Bidder's legal name]*
2. In case of JV, legal name of each member : *[insert legal name of each member in JV]*
3. Bidder's actual or intended country of registration: *[insert actual or intended country of registration]*
4. Bidder's year of registration: *[insert Bidder's year of registration]*
5. Bidder's Address in country of registration: *[insert Bidder's legal address in country of registration]*
6. Bidder's Authorized Representative Information Name: *[insert Authorized Representative's name]* Address: *[insert Authorized Representative's Address]* Telephone/Fax numbers: *[insert Authorized Representative's telephone/fax numbers]* Email Address: *[insert Authorized Representative's email address]*
7. Attached are copies of original documents of*[check the box(es) of the attached original documents]* ☐ Articles of Incorporation (or equivalent documents of constitution or association), and/or documents of registration of the legal entity named above, in accordance with ITB 4.4. ☐ In case of JV, letter of intent to form JV or JV agreement, in accordance with ITB 4.1. ☐ In case of state-owned enterprise or institution, in accordance with ITB 4.6 documents establishing:

- Legal and financial autonomy
- Operation under commercial law
- Establishing that the Bidder is not under the supervision of the Purchaser

8. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership. *[If required under BDS ITB 45.1, the successful Bidder shall provide additional information on beneficial ownership, using the Beneficial Ownership Disclosure Form.]*

Form ELI -1.1 (continued)

Bidder Information Form

Date: *[insert day, month, year]*
RFB No. and title: ***LK-SPC-370471-GO-RFB*** *Human Albumin Solution 20% in 50ml bottle*
Page *[insert page number]* of *[insert total number]* pages

1. Bidder's name			
2. 2. Street Address:	Postal Code:	City:	Country:
3. P.O. Box and Mailing Address:			
4. Telephone Number:			
5. Fax Number:			
6. E-mail Address:			
7. Web Site:			
8. Contact Name:			
9. Contact Title:			
10. Type of Business:			
11. If Other, specify:			
12. Nature of Business:			
13. Year Established:			
14. Dates, Numbers, and Expiration Dates of Current Licenses and Permits:			
15. Current health authority registration information:			
16. Proof of product and facility registrations with purchaser's country regulatory authority and international agencies (e.g., WHO Certification Scheme, GMP)			
17. Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods: Date of last inspection:			

18. Quality Assurance Certification (Please include a copy of your latest certificate):	
19. Production capacity: *[insert peak and average production capacity over the last three years in units/day or units/month, etc.]*	
20. List of names and addresses of sources of raw material and what products they will be used in:	
21. List product recalls linked to defects during the last 36 months. Include reason and date of recall.	
22. Are technical documents available in: ***[Purchaser should insert language]*** Yes No	

Bidder's JV Members Information Form

[The Bidder shall fill in this Form in accordance with the instructions indicated below. The following table shall be filled in for the Bidder and for each member of a Joint Venture]].

Date: *[insert date (as day, month and year) of Bid submission*]
RFB No.: ***LK-SPC-370471-GO-RFB***
Alternative No.: *[insert identification No if this is a Bid for an alternative]*

Page _____ of_ _____ pages

1. Bidder's Name: *[insert Bidder's legal name]*
2. Bidder's JV Member's name: *[insert JV's Member legal name]*
3. Bidder's JV Member's country of registration: *[insert JV's Member country of registration]*
4. Bidder's JV Member's year of registration: *[insert JV's Member year of registration]*
5. Bidder's JV Member's legal address in country of registration: *[insert JV's Member legal address in country of registration]*
6. Bidder's JV Member's authorized representative information Name: *[insert name of JV's Member authorized representative]* Address: *[insert address of JV's Member authorized representative]* Telephone/Fax numbers: *[insert telephone/fax numbers of JV's Member authorized representative]* Email Address: *[insert email address of JV's Member authorized representative]*
7. Attached are copies of original documents of*[check the box(es) of the attached original documents]* ☐ Articles of Incorporation (or equivalent documents of constitution or association), and/or registration documents of the legal entity named above, in accordance with ITB4.4. ☐ In case of a state-owned enterprise or institution, documents establishing legal and financial autonomy, operation in accordance with commercial law, and not under the supervision of the Purchaser, in accordance with ITB4.6. 8. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership. *[If required under BDS ITB 45.1, the successful Bidder shall provide additional information on beneficial ownership for each JV member using the Beneficial Ownership Disclosure Form.]*

Form FIN – 3.1
Financial Situation and Performance

[The following table shall be filled in for the Bidder and for each member of a Joint Venture]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370471-GO-RFB*** *Human Albumin Solution 20% in 50ml bottle*

1. Financial data

Type of Financial information in (currency)	**Historic information for previous** *[insert number] years, [insert in words]* **(amount in currency, currency, exchange rate, USD equivalent)**				
	Year 1	Year 2	Year 3		
Statement of Financial Position (Information from Balance Sheet)					
Total Assets (TA)					
Total Liabilities (TL)					
Total Equity/Net Worth (NW)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital (WC)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					
Cash Flow Information					

Cash Flow from Operating Activities					

3. Financial documents

The Bidder and its parties shall provide copies of financial statements for *[number]* years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

(a) reflect the financial situation of the Bidder or in case of JV member, and not an affiliated entity (such as parent company or group member).

(b) be independently audited or certified in accordance with local legislation.

(c) be complete, including all notes to the financial statements.

(d) correspond to accounting periods already completed and audited.

☐ Attached are copies of financial statements[3] for the *[number]* years required above; and complying with the requirements

[3] If the most recent set of financial statements is for a period earlier than 12 months from the date of bidding, the reason for this should be justified.

Form FIN - 3.2
Average Annual Turnover (Annual Sales Value)

[The following table shall be filled in for the Bidder and for each member of a Joint Venture]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370471-GO-RFB*** *Human Albumin Solution 20% in 50ml bottle*

Annual turnover data			
Year	**Amount** **Currency**	**Exchange rate**	**USD equivalent**
[indicate calendar year]	*[insert amount and indicate currency]*		
		Average Annual Turnover *	

* Total USD equivalent for all years divided by the total number of years.

Form CON-1
Current Contract Commitments / Contracts in Progress Form

1. Name of Contract(s)
2. Purchaser Contact Information *[insert address, telephone, fax, e-mail address]*
3. Value of outstanding contracts *[current US$ equivalent]*
4. Estimated delivery date
5. Average monthly invoices over the last six months (US$/mon.)

Form- EXP-1
Experience

Contracts over *[insert amount]* during the last three years:				
Purchaser	Value	Year	Goods/Services Supplied	Country of Destination

Form- PER 1

Historical Contract Non-Performance, and Pending Litigation and Litigation History

[The following table shall be filled in for the Bidder and for each member of a Joint Venture]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370471-GO-RFB*** *Human Albumin Solution 20% in 50ml bottle*
Page *[insert page number]* of *[insert total number]* pages

Non-Performed Contracts in accordance with Section III, Evaluation and Qualification Criteria *(In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document)*			
☐ Contract non-performance did not occur since 1st January *[insert year]* ☐ Contract(s) not performed since 1st January *[insert year]*			
Year	**Non-performed portion of contract**	**Contract Identification**	**Total Contract Amount (current value, currency, exchange rate and US$ equivalent)**
[insert year]	*[insert amount and percentage]*	Contract Identification: *[indicate complete contract name/ number, and any other identification]* Name of Purchaser: *[insert full name]* Address of Purchaser: *[insert street/city/country]* Reason(s) for nonperformance: *[indicate main reason(s)]*	*[insert amount]*
Pending Litigation, in accordance with Section III, Evaluation and Qualification Criteria *(In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document)*			
☐ No pending litigation ☐ Pending litigation as indicated below.			
Year of	**Amount in**	**Contract Identification**	**Total Contract**

dispute	dispute (currency)		Amount (currency), USD Equivalent (exchange rate)
[insert year]	*[insert amount]*	Contract Identification: [indicate complete contract name, number, and any other identification] Name of Purchaser: *[insert full name]* Address of Purchaser: *[insert street/city/country]* Matter in dispute: *[indicate main issues in dispute]* Party who initiated the dispute: *[indicate "Purchaser" or "Supplier"]* Status of dispute:	*[insert amount]*
Litigation History in accordance with Section III, Evaluation and Qualification Criteria *(In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document)*			
☐ No Litigation History ☐ Litigation History as indicated below:			
Year of award	**Outcome as percentage of Net Worth**	**Contract Identification**	**Total Contract Amount (currency), USD Equivalent (exchange rate)**
[insert year]	*[insert percentage]*	Contract Identification: [indicate complete contract name, number, and any other identification] Name of Purchaser: *[insert full name]* Address of Purchaser: *[insert street/city/country]* Matter in dispute: *[indicate main issues in dispute]* Party who initiated the dispute: *[indicate "Purchaser" or "Supplier"]* Reason(s) for Litigation and award decision *[indicate main reason(s)]*	*[insert amount]*

Form PER –2
Sexual Exploitation and Abuse (SEA) and/or Sexual Harassment Performance Declaration

[The following table shall be filled in by the Bidder, each member of a Joint Venture and each subcontractor proposed by the Bidder]

Bidder's Name: *[insert full name]*
Date: *[insert day, month, year]*
Joint Venture Member's or Subcontractor's Name: *[insert full name]*
RFB No. and title: ***LK-SPC-370471-GO-RFB*** *Human Albumin Solution 20% in 50ml bottle*
Page *[insert page number]* of *[insert total number]* pages

SEA and/or SH Declaration **in accordance with Section III, Qualification Criteria, and Requirements**
We: ☐ (a) have not been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations ☐ (b) are subject to disqualification by the Bank for non-compliance with SEA/ SH obligations ☐ (c) had been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations, and were removed from the disqualification list. An arbitral award on the disqualification case has been made in our favor.
[*If (c) above is applicable, attach evidence of an arbitral award reversing the findings on the issues underlying the disqualification.]*

Price Schedule Forms

*[The Bidder shall fill in these Price Schedule Forms in accordance with the instructions indicated. The list of line items in column 1 of the **Price Schedules** shall coincide with the List of Goods and Related Services specified by the Purchaser in the Schedule of Requirements.]*

Price Schedule: Goods Manufactured Outside the Purchaser's Country, to be Imported

(Group C Bids, goods to be imported)

Currencies in accordance with ITB 15

Date:_____
RFB No: LK-SPC-370471-GO-RFB

Alternative No: _____
Page N° _____ of _____

1	2	3	4	5	6	7			8	9	10	11	12	13	14
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices			Total unit price [a+b+c]	Total price per item [6 x 8]	Local agent's commission as a % of CIP price included in quoted price	Shipment weight and volume	Name of Manufacturer	Cnty. Of origin	Pharma-copoeial standard
						[a] CIP named place of destination (specify one)	[b] Inland transp., insurance & other local costs incidental to delivery if specified	[c] Other incidental costs as defined in the SCC							

Total Bid Price:
Currency:
In figures:
In words:

Name of Bidder *[insert complete name of Bidder]* Signature of Bidder *[signature of person signing the Bid]* Date *[Insert Date]*

In the capacity of: *[insert:* ***title or other appropriate designation*** *]*

Price Schedule: Goods Manufactured Outside the Purchaser's Country, already imported*

(Group C Bids, Goods already imported) Currencies in accordance with ITB 15												Date:_____ RFB No: LK-SPC-370471-GO-RFB Alternative No: _____ Page N° _____ of _____					
1	2	3	4	5	6	7					8	9	10	11	12	13
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices					Total Unit price [c+d+e]	Total price per line item [6x8]	Sales and other taxes payable per item if Contract is awarded	Name of manufactu re-	Ctry. of origin	Pharma-copoeial standard
						[a] Unit price includin g Custom Duties and Import Taxes paid and payable	[b] Custom Duties and Import Taxes paid and payable per unit	[c]=a-b Unit Price net of custom duties and import taxes	[d] Inland transp., insurance & other local costs incidental to delivery	[e] Other incident-al costs as defined in the SCC						
Note: (i) Column 7[b] Custom Duties and Import Taxes paid should be supported by documentary evidence..									Total Bid Price: _____ Currency: _____ In figures: _____ In words: _____							

Name of Bidder *[insert complete name of Bidder]* Signature of Bidder *[signature of person signing the Bid]* Date *[insert date]*

* *[For previously imported Goods, the quoted price shall be distinguishable from the original import value of these Goods declared to customs and shall include any rebate or mark-up of the local agent or representative and all local costs except import duties and taxes, which have been and/or have to be paid by the Purchaser. For clarity the Bidders are asked to quote the price including import duties, and additionally to provide the import duties and the price net of import duties which is the difference of those values.]*

Price Schedule: Goods Manufactured in the Purchaser's Country

Purchaser's Country _____						(Group A and B Bids) Currencies in accordance with ITB 15						Date:_____ RFB No: LK-SPC-370471-GO-RFB Alternative No: _____ Page N° _____ of _____		
1	2	3	4	5	6	7			8	9	10	11	12	13
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices			Total unit price [a+b+c]	Total price	Sales and other taxes payable if contract is awarded	Name of manufacturer	Pharma-copoeial standard	Local input in the cost as % of ex-factory price in column 7[a]
						[a] Ex-factory Ex-warehouse Ex-showroom Off the shelf	[b] Inland transp., insurance & other local costs incidental to delivery	[c] Other incident-al costs as defined in the SCC						
									Total Bid Price: _____ Currency: _____ In figures: _____ In words: _____					
Name of Bidder *[insert complete name of Bidder]* Signature of Bidder *[signature of person signing the Bid]* Date *[insert date]* In the capacity of:*[insert: title or other appropriate designation]*														

Form of Bid Security - (Bank guarantee)

[The bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]

[Guarantor letterhead or SWIFT identifier code]

Beneficiary: *[Purchaser to insert its name and address]*

RFB No.: *LK-SPC-370471-GO-RFB*

Alternative No.*: [Insert identification No if this is a Bid for an alternative]*

Date: *[Insert date of issue]*

BID GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that _____ *[insert name of the Bidder, which in the case of a joint venture shall be the name of the joint venture (whether legally constituted or prospective) or the names of all members thereof]* (hereinafter called "the Applicant") has submitted or will submit to the Beneficiary its Bid (hereinafter called "the Bid") for the execution of _____ under Request for Bids No. _____ ("the RFB").

Furthermore, we understand that, according to the Beneficiary's conditions, Bids must be supported by a Bid guarantee.

At the request of the Applicant, we, as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of _____ (_____) upon receipt by us of the Beneficiary's complying demand, supported by the Beneficiary's statement, whether in the demand itself or a separate signed document accompanying or identifying the demand, stating that either the Applicant:

(a) has withdrawn its Bid prior to the Bid validity expiry date set forth in the Applicant's Letter of Bid, or any extended date provided by the Applicant; or

(b) having been notified of the acceptance of its Bid by the Beneficiary prior to the expiry date of the Bid validity or any extension thereof provided by the Applicant has failed to: (i) sign the contract agreement, or (ii) furnish the performance security, in accordance with the Instructions to Bidders ("ITB") of the Beneficiary's bidding document.

This guarantee will expire: (a) if the Applicant is the successful Bidder, upon our receipt of copies of the contract agreement signed by the Applicant and the Performance Security issued to the Beneficiary in relation to such contract agreement; or (b) if the Applicant is not the successful Bidder, upon the earlier of (i) our receipt of a copy of the Beneficiary's notification to the Applicant of the results of the Bidding process; or (ii) twenty-eight days after the expiry date of the Bid validity.

Consequently, any demand for payment under this guarantee must be received by us at the office indicated above on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No. 758.

_____

[Signature(s)]

Note: All italicized text is for use in preparing this form and shall be deleted from the final product.

Form of Bid Security (Bid Bond)

[The Surety shall fill in this Bid Bond Form in accordance with the instructions indicated.]

BOND NO. _____

BY THIS BOND *[name of Bidder]* as Principal (hereinafter called "the Principal"), and *[name, legal title, and address of surety],***authorized to transact business in** *[name of country of Purchaser],* as Surety (hereinafter called "the Surety"), are held and firmly bound unto *[name of Purchaser]* as Obligee (hereinafter called "the Purchaser") in the sum of *[amount of Bond]*[4]*[amount in words]*, for the payment of which sum, well and truly to be made, we, the said Principal and Surety, bind ourselves, our successors and assigns, jointly and severally, firmly by these presents.

WHEREAS the Principal has submitted or will submit a written Bid to the Purchaser dated the ___ day of _____, 20__, for the supply of *[name of Contract]* (hereinafter called the "Bid").

NOW, THEREFORE, THE CONDITION OF THIS OBLIGATION is such that if the Principal:

(a) withdraws its Bid prior to the Bid validity expiry date set forth in the Principal's Letter of Bid, or any extended date provided by the Principal; or

(b) having been notified of the acceptance of its Bid by the Purchaser prior to the expiry date of the Bid validity or any extension thereto provided by the Applicant has failed to: (i) execute the Contract agreement; or (ii) furnish the Performance Security, in accordance with the Instructions to Bidders ("ITB") of the Purchaser's bidding document.

then the Surety undertakes to immediately pay to the Purchaser up to the above amount upon receipt of the Purchaser's first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser shall state that the demand arises from the occurrence of any of the above events, specifying which event(s) has occurred.

The Surety hereby agrees that its obligation will remain in full force and effect up to and including the date 28 days after the date of expiry of the Bid validity set forth in the Principal's Letter of Bid or any extension thereto provided by the Principal.

IN TESTIMONY WHEREOF, the Principal and the Surety have caused these presents to be executed in their respective names this ____ day of _____ 20__.

Principal: _____ Surety: _____
Corporate Seal (where appropriate)

_____ _____
(Signature) *(Signature)*
(Printed name and title) *(Printed name and title)*

Manufacturer's Authorization

[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its Bid, if so indicated in the ***BDS.****]*

Date: *[insert date (as day, month and year) of Bid submission]*
RFB No.: ***LK-SPC-370471-GO-RFB***
Alternative No.: *[insert identification No if this is a Bid for an alternative]*

To: *[insert complete name of Purchaser]*

WHEREAS

We *[insert complete name of Manufacturer],* who are official manufacturers of *[insert type of goods manufactured],* having factories at [insert full address of Manufacturer's factories], do hereby authorize *[insert complete name of Bidder]* to submit a Bid the purpose of which is to provide the following Goods, manufactured by us *[insert name and or brief description of the Goods],* and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 28 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

We confirm that we do not engage or employ forced labor or persons subject to trafficking or child labor, in accordance with Clause 14 of the General Conditions of Contract. We also confirm that we comply with applicable health and safety obligations in accordance with Clause 14 of the General Conditions of Contract.

Signed: *[insert signature(s) of authorized representative(s) of the Manufacturer]*

Name: *[insert complete name(s) of authorized representative(s) of the Manufacturer]*

Title: *[insert title]*

Dated on _____ day of _____, _____ *[insert date of signing]*

Specimen Certificate of a Pharmaceutical Product

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization *(general instructions and explanatory notes attached).*

No. of certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredients[2] and amount(s) per unit dose.[3]

_____

_____

_____

For complete qualitative composition including excipients, see attached.[4]

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] yes/no *(key in as appropriate)*

1.3 Is this product actually on the market in the exporting country? yes/no/unknown *(key in as appropriate)*

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B.[6]

2A. 1 Number of product license[7] and date of issue:

_____

2A.2 Product-license holder (name and address):

_____

_____

_____

2A.3 Status of product-license holder:[8] a/b/c *(key in appropriate category as defined in note 8)*

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are: [9]

_____

_____

_____

2A.4 Is Summary Basis of Approval appended?[10] yes/no *(key in as appropriate)*

2A.5 Is the attached, officially approved product information complete and consonant with the license?[11] yes/no/not provided *(key in as appropriate)*

2A.6 Applicant for certificate, if different from license holder (name and address):[12]

2B. 1 Applicant for certificate (name and address):

2B.2 Status of applicant: a/b/c *(key in appropriate category as defined in note 8)*

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

_____

_____

_____

2B.3 Why is marketing authorization lacking?

not required/not requested/under consideration/refused *(key in as appropriate)*

2B.4 Remarks:[13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

yes/no/not applicable[14] *(key in as appropriate)*

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): _____

3.2 Has the manufacture of this type of dosage form been inspected?

yes/no *(key in as appropriate)*

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

yes/no/not applicable[16] *(key in as appropriate)*

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? [11]

yes/no *(key in as appropriate)*

If no, explain: _____

_____

Address of certifying authority: _____

Telephone number: _____ Fax number: _____

Name of authorized person:

_____

Signature:

_____

Stamp and date:

_____

General instructions

Please refer to the guidelines: https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/guidelines/en/for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

1 This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2 Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

3 The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4 Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.

5 When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.

6 Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the license is provisional or if the product has not yet been approved.

[8] Specify whether the person responsible for placing the product on the market:
(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in none of the above.

[9] This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Noncompletion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.

[10] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[11] This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).

[12] In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.

[13] Please indicate the reason that the applicant has provided for not requesting registration:
(a) The product has been developed exclusively for the treatment of conditions—particularly tropical diseases—not endemic in the country of export.
(b) The product has been reformulated with a view to improving its stability under tropical conditions.
(c) The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.
(d) The product has been reformulated to meet a different maximum dosage limit for an active ingredient.
(e) Any other reason, please specify.

[14] Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

Section V - Eligible Countries

Eligibility for the Provision of Goods, Works and Non Consulting Services in Bank-Financed Procurement

In reference to ITB 4.8and 5.1, for the information of the Bidders, at the present time firms, goods and services from the following countries are excluded from this Bidding process:

Under ITB 4.8(a) and 5.1: **None**

Under ITB 4.8(b) and 5.1: **None**

Section VI - Fraud and Corruption

(Section VI shall not be modified)

1. Purpose

1.1 The Bank's Anti-Corruption Guidelines and this annex apply with respect to procurement under Bank Investment Project Financing operations.

2. Requirements

2.1 The Bank requires that Borrowers (including beneficiaries of Bank financing); bidders (applicants/proposers), consultants, contractors and suppliers; any sub-contractors, sub-consultants, service providers or suppliers; any agents (whether declared or not); and any of their personnel, observe the highest standard of ethics during the procurement process, selection and contract execution of Bank-financed contracts, and refrain from Fraud and Corruption.

2.2 To this end, the Bank:

a. Defines, for the purposes of this provision, the terms set forth below as follows:

i. "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

ii. "fraudulent practice" is any act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;

iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

v. "obstructive practice" is:

(a) deliberately destroying, falsifying, altering, or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive, or collusive practice; and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(b) acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under paragraph 2.2 e. below.

b. Rejects a proposal for award if the Bank determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub-consultants, sub-contractors, service providers, suppliers and/ or their employees, has, directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question;

c. In addition to the legal remedies set out in the relevant Legal Agreement, may take other appropriate actions, including declaring misprocurement, if the Bank determines at any time that representatives of the Borrower or of a recipient of any part of the proceeds of the loan engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices during the procurement process, selection and/or execution of the contract in question, without the Borrower having taken timely and appropriate action satisfactory to the Bank to address such practices when they occur, including by failing to inform the Bank in a timely manner at the time they knew of the practices;

d. Pursuant to the Bank's Anti- Corruption Guidelines and in accordance with the Bank's prevailing sanctions, policies and procedures, may sanction a firm or individual, either indefinitely or for a stated period of time, including by publicly declaring such firm or individual ineligible (i) to be awarded or otherwise benefit from a Bank-financed contract, financially or in any other manner;1 (ii) to be a nominated2 sub-contractor, consultant, manufacturer or supplier, or service provider of an otherwise eligible firm being awarded a Bank-financed contract; and (iii) to receive the proceeds of any loan made by the Bank or otherwise to participate further in the preparation or implementation of any Bank-financed project;

e. Requires that a clause be included in bidding/request for proposals documents and in contracts financed by a Bank loan, requiring (i) bidders (applicants/proposers), consultants, contractors, and suppliers, and their sub-contractors, sub-consultants, service providers, suppliers, agents personnel, permit the Bank to inspect[3] all

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1 For the avoidance of doubt, a sanctioned party's ineligibility to be awarded a contract shall include, without limitation, (i) applying for pre-qualification, expressing interest in a consultancy, and bidding, either directly or as a nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider, in respect of such contract, and (ii) entering into an addendum or amendment introducing a material modification to any existing contract.

2 A nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider (different names are used depending on the particular bidding document) is one which has been: (i) included by the bidder in its pre-qualification application or bid because it brings specific and critical experience and know-how that allow the bidder to meet the qualification requirements for the particular bid; or (ii) appointed by the Borrower.

3 Inspections in this context usually are investigative (i.e., forensic) in nature. They involve fact-finding activities undertaken by the Bank or persons appointed by the Bank to address specific matters related to investigations/audits, such as evaluating the veracity of an allegation of possible Fraud and Corruption, through the appropriate mechanisms. Such activity includes but is not limited to: accessing and examining a firm's or individual's financial records and information, and making copies thereof as relevant; accessing and examining any other documents, data and

accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have them audited by auditors appointed by the Bank.

information (whether in hard copy or electronic format) deemed relevant for the investigation/audit, and making copies thereof as relevant; interviewing staff and other relevant individuals; performing physical inspections and site visits; and obtaining third party verification of information.

PART 2 – Supply Requirements

Section VII - Schedule of Requirements

Contents

1. List of Goods and Delivery Schedule

Line Item N°	Description of Goods	Quantity	Physical unit	Final (Project Site) Destination as specified in BDS	Delivery (as per Incoterms) Date		
					Earliest Delivery Date	Latest Delivery Date	Bidder's offered Delivery date [*to be provided by the Bidder*]
004053 01	*Human Albumin Solution 20% in 50ml bottle*	*215,000*	*Bottle*	***Foreign bidders*** *: Sea/Air Colombo/ Sri Lanka* ***Import & Supply*** *: Medical Supplies Division, No 357, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10.*	*30 Nov.2023*	*15 Dec. 2023*	*[insert the number of days following the date of effectiveness the Contract]*

2. Technical Specifications

Technical Specifications Pharmaceuticals

PHARMACEUTICALS

1. Product and Package Specifications

Human Albumin Solution 20% in 50ml bottle

Each 50ml to contain at least 95% of the Albumin Protein derived from human plasma serum.

Note:
1.The product should fulfill the requirement of virus elimination to include both enveloped and non-enveloped viruses (including HIV,HBV,HCV,HAV, Parvo virus B19) using virus reduction inactivation methods with pasteurization of the final product as per the current WHO approved techniques. (WHO,TRS, No 941,2007 & WHO,TRS, No 924,2004)
2. The product should be stable for minimum of 02 years when stored under the storage condition stipulated by the manufacturer.
3. The product should be protected from light.
4. Each bottle should be labelled according to the point No 2 Labeling Instructions of Section VII – Schedule of Requirements
5. The manufacturer should submit a certificate for each batch of the product that it has been tested free of Hepatitis B, Hepatitis C, and HIV infections.

Pack Size : 10 bottles in a pack

The product should be complied with British Pharmacopoeia/United States Pharmacopoeia/European Pharmacopoeia or any other pharmacopeial standard acceptable to NMRA

1. The consignments supplied in respect of an order concerned, shall exactly match with the product information (item descriptions, shelf life, manufacturer's name, country of manufacture, country of origin, etc.) provided in the bidding document by the Bidder, which has been accepted by the procurement committee, and included in the Contract, issued by the Purchaser.

2. Maintaining the validity of the product registration /

waiver of registration during the period of supply (delivery schedule) &/ import license / manufacture licensing at NMRA, is a requirement for the supply of pharmaceutical items. Hence all Suppliers shall produce relevant valid registration certificates/licenses or equivalent documentation acceptable to the NMRA, 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.

3. 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.

Shelf life & Warrantees

4. 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 75% of the product shelf life specified in the Contract or as certified in the product registration certificate or indicated in any other way by NMRA.

When the shelf life is not specified in the contract/item spec; the requested shelf life shall be considered as 24 months for Pharma. 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.

In the violation of bidding 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.

Storage Conditions & Temperature

5. 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.

6. 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.5 - Standards of quality control for supply of Section VII – Schedule of Requirements)**

Documents & Information

7. 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.
8. 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 security.

After releasing the Contract or establishing letter of credit, the latest logistical position of manufacturing & supply on the Contract, shall be updated biweekly through e-mails to Purchaser by the supplier. (follow instructions in the website www.msd.gov.lk)

Abbreviations *NMRA; National Medicines Regulatory Authority/Sri Lanka,* SPC; Ministry of Health, Sri Lanka*, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka*
L/C ; Letter of Credit.

2. Labeling Instructions

1. 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 MOH.

2. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No / Lot No, Name and address of manufacturer and "STATE LOGO" of Sri Lanka Government (Annexure 1) shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure (vial/ampoule, pre-filled syringe or bottle), 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 MOH and DOM & DOE shall consist of at least the year & month.

3. All outer most cartons (shipping packages) shall bear the MSD order list No, SPC Contract 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.

4. 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).

5. In respect of purchaser imported supplies, if the local agent does not follow suit as above, such extra expenses incurred

to purchaser shall be recovered from the supplier.

3.	**Case Identification**	Amalgamated in the labelling requirement above
4.	**Unique Identifiers**	Export packing should be in seaworthy strong cases or cartons to prevent damage in transit and should:- a. Indicate recommended storage temperature specially for goods which require cool/cold or freezer storage. b. Stenciled blue bands in the form of a cross on each face. c. Carry shipping marks – details provided by SPC with order. d. Be palletized and shrink wrapped if required by the bidding conditions. 5.4.5 Should carry Batch No./Exp. Date.
5.	**Standards of Quality Control for Supply**	1. Standards; In respect of all Pharmaceutical products supplied, shall comply Pharmacopeial Standards that are indicated in the item specifications or other Pharmacopeial Standards accepted in the product registration by the National Medicines Regulatory Authority. 2. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the Pharmaceutical items, with information to users regarding the; storage conditions, shall be provided with the product, for acceptance of goods by Purchaser. 3. Any product deficient of or not at the specified quality standards, shall be rejected. 4. 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. (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. 06 - Product and Package Specifications)

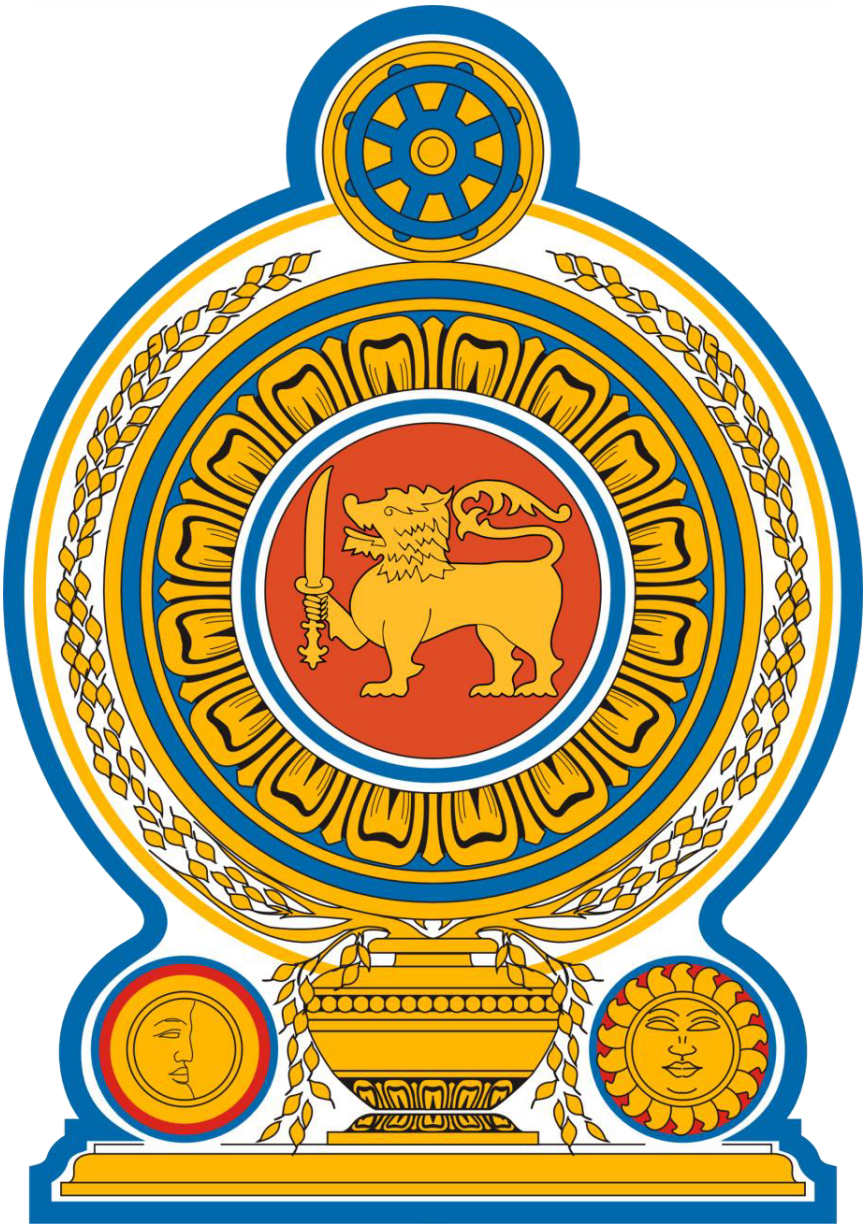
If the offered product, deviate from NMRA registered product features, supplier must provide with the bid, a declaration to certify the NMRA accepted product details such as; storage conditions, pack details/contents/sizes and standard batch quantity/size of the product.

5. 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.

Consignments supplied to MOH 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. 4. **Standards of Quality Control for Supply**)

Annexure I



3. Inspections and Tests

The following inspections and tests shall be performed: *[insert list of inspections and tests]*

The supplier should submit pre-shipment sample test reports for each batch/lot supplied from a WHO accredited testing laboratory or NABL (National Accreditation Board for Testing and Calibration Laboratories) in India nominated by Purchaser for the parameters listed in the relevant pharmacopeia, if the supplier has not supplied the item previously or any quality issue reported on previous supplies.

PART 3 - Contract

Section VIII - General Conditions of Contract

Table of Clauses

Section VIII - General Conditions of Contract

1. Definitions

1.1. The following words and expressions shall have the meanings hereby assigned to them:

(a) "Bank" means the World Bank and refers to the International Bank for Reconstruction and Development (IBRD) or the International Development Association (IDA).

(b) "Contract" means the Contract Agreement entered into between the Purchaser and the Supplier, together with the Contract Documents referred to therein, including all attachments, appendices, and all documents incorporated by reference therein.

(c) "Contract Documents" means the documents listed in the Contract Agreement, including any amendments thereto.

(d) "Contract Price" means the price payable to the Supplier as specified in the Contract Agreement, subject to such additions and adjustments thereto or deductions therefrom, as may be made pursuant to the Contract.

(e) "Day" means calendar day.

(f) "Completion" means the fulfillment of the Related Services by the Supplier in accordance with the terms and conditions set forth in the Contract.

(g) "GCC" means the General Conditions of Contract.

(h) "Goods" means all of the pharmaceuticals including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms Supplier is required to supply to the Purchaser under the Contract.

(i) "Purchaser's Country" is the country specified **in the Special Conditions of Contract** (SCC).

(j) "Purchaser" means the entity purchasing the Goods and Related Services, as specified **in the SCC.**

(k) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser's Country in accordance with the Applicable Law.

(l) "Related Services" means the services incidental to the

supply of the goods, such as insurance, installation, training and initial maintenance and other such obligations of the Supplier under the Contract.

(m) "SCC" means the Special Conditions of Contract.

(n) "Supplier" means the person, private or government entity, or a combination of the above, whose Bid to perform the Contract has been accepted by the Purchaser and is named as such in the Contract Agreement.

(o) "The Project Site," where applicable, means the place named **in the SCC.**

2. Contract Documents

2.1 Subject to the order of precedence set forth in the Contract Agreement, all documents forming the Contract (and all parts thereof) are intended to be correlative, complementary, and mutually explanatory. The Contract Agreement shall be read as a whole.

3. Fraud and Corruption

3.1 The Bank requires compliance with the Bank's Anti-Corruption Guidelines and its prevailing sanctions policies and procedures as set forth in the WBG's Sanctions Framework, as set forth in Appendix 1 to the GCC.

3.2 The Purchaser requires the Supplier to disclose any commissions or fees that may have been paid or are to be paid to agents or any other party with respect to the Bidding process or execution of the Contract. The information disclosed must include at least the name and address of the agent or other party, the amount and currency, and the purpose of the commission, gratuity or fee.

4. Interpretation

4.1 If the context so requires it, singular means plural and vice versa.

4.2 Incoterms

(a) Unless inconsistent with any provision of the Contract**,** the meaning of any trade term and the rights and obligations of parties thereunder shall be as prescribed by Incoterms specified **in the SCC**.

(b) The terms EXW, CIP, FCA, CFR and other similar terms, when used, shall be governed by the rules prescribed in the current edition of Incoterms specified **in the SCC** and published by the International Chamber of Commerce in Paris, France.

4.3 Entire Agreement

The Contract constitutes the entire agreement between the Purchaser and the Supplier and supersedes all communications, negotiations and agreements (whether written or oral) of the parties with respect thereto made prior to the date of Contract.

4.4 Amendment

No amendment or other variation of the Contract shall be valid unless it is in writing, is dated, expressly refers to the Contract, and is signed by a duly authorized representative of each party thereto.

4.5 Nonwaiver

(a) Subject to GCC Sub-Clause 4.5(b) below, no relaxation, forbearance, delay, or indulgence by either party in enforcing any of the terms and conditions of the Contract or the granting of time by either party to the other shall prejudice, affect, or restrict the rights of that party under the Contract, neither shall any waiver by either party of any breach of Contract operate as waiver of any subsequent or continuing breach of Contract.

(b) Any waiver of a party's rights, powers, or remedies under the Contract must be in writing, dated, and signed by an authorized representative of the party granting such waiver, and must specify the right and the extent to which it is being waived.

4.6 Severability

If any provision or condition of the Contract is prohibited or rendered invalid or unenforceable, such prohibition, invalidity or unenforceability shall not affect the validity or enforceability of any other provisions and conditions of the Contract.

5. Language

5.1 The Contract as well as all correspondence and documents relating to the Contract exchanged by the Supplier and the Purchaser, shall be written in the language specified **in the SCC.** Supporting documents and printed literature that are part of the Contract may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified**,** in which case, for purposes of interpretation of the Contract, this translation shall govern.

5.2 The Supplier shall bear all costs of translation to the governing language and all risks of the accuracy of such translation, for

documents provided by the Supplier.

6. Joint Venture, Consortium or Association

6.1 If the Supplier is a joint venture, consortium, or association, all of the parties shall be jointly and severally liable to the Purchaser for the fulfillment of the provisions of the Contract and shall designate one party to act as a leader with authority to bind the joint venture, consortium, or association. The composition or the constitution of the joint venture, consortium, or association shall not be altered without the prior consent of the Purchaser.

7. Eligibility

7.1 The Supplier and its Subcontractors shall have the nationality of an eligible country. A Supplier or Subcontractor shall be deemed to have the nationality of a country if it is a citizen or constituted, incorporated, or registered, and operates in conformity with the provisions of the laws of that country.

7.2 All Goods and Related Services to be supplied under the Contract and financed by the Bank shall have their origin in Eligible Countries. For the purpose of this Clause, origin means the country where the goods have been grown, mined, cultivated, produced, manufactured, or processed; or through manufacture, processing, or assembly, another commercially recognized article results that differs substantially in its basic characteristics from its components.

8. Notices

8.1 Any notice given by one party to the other pursuant to the Contract shall be in writing to the address specified **in the SCC.** The term "in writing" means communicated in written form with proof of receipt.

8.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

9. Governing Law

9.1 The Contract shall be governed by and interpreted in accordance with the laws of the Purchaser's Country, unless otherwise specified **in the SCC.**

9.2 Throughout the execution of the Contract, the Supplier shall comply with the import of goods and services prohibitions in the Purchaser's Country when

(a) as a matter of law or official regulations, the Borrower's country prohibits commercial relations with that country; or

(b) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Borrower's Country prohibits any import of goods from that country or any payments to any

country, person, or entity in that country.

10 Settlement of Disputes

10.1 The Purchaser and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

10.2 If, after twenty-eight (28) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given. Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract. Arbitration proceedings shall be conducted in accordance with the rules of procedure specified **in the SCC.**

10.3 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and

(b) the Purchaser shall pay the Supplier any monies due the Supplier.

11. Inspections and Audit by the Bank

11.1 The Supplier shall keep, and shall make all reasonable efforts to cause its Subcontractors and subconsultants to keep, accurate and systematic accounts and records in respect of the Goods in such form and details as will clearly identify relevant time changes and costs.

11.2 Pursuant to paragraph 2.2 e. of Appendix 1 to the General Conditions the Supplier shall permit and shall cause its agents (where declared or not), subcontractors, subconsultants, service providers, suppliers, and personnel, to permit, the Bank and/or persons appointed by the Bank to inspect the site and/or the accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have such accounts, records and other documents audited by auditors appointed by the Bank. The Supplier's and its Subcontractors' and subconsultants' attention is drawn to Sub-Clause 3.1 (Fraud and Corruption) which provides, inter alia, that acts intended to materially impede the exercise of the Bank's

inspection and audit rights constitute a prohibited practice subject to contract termination (as well as to a determination of ineligibility pursuant to the Bank's prevailing sanctions procedures).

12. Scope of Supply

12.1 The Goods and Related Services to be supplied shall be as specified in the Schedule of Requirements.

13. Delivery and Documents

13.1 Subject to GCC Sub-Clause 33.1, the Delivery of the Goods and Completion of the Related Services shall be in accordance with the Delivery and Completion Schedule specified in the Schedule of Requirements. The details of shipping and other documents to be furnished by the Supplier are specified **in the SCC.**

14. Supplier's Responsibilities

14.1. The Supplier shall supply all the Goods and Related Services included in the Scope of Supply in accordance with GCC Clause 12, and the Delivery and Completion Schedule, as per GCC Clause 13.

14.2. The Supplier, including its Subcontractors, shall not employ or engage forced labor or persons subject to trafficking, as described in GCC Sub-Clauses 14.3 and 14.4.

14.3. Forced labor consists of any work or service, not voluntarily performed, that is exacted from an individual under threat of force or penalty, and includes any kind of involuntary or compulsory labor, such as contractured labor, bonded labor or similar labor-contracting arrangements.

14.4. Trafficking in persons is defined as the recruitment, transportation, transfer, harbouring or receipt of persons by means of the threat or use of force or other forms of coercion, abduction, fraud, deception, abuse of power, or of a position of vulnerability, or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purposes of exploitation.

14.5. The Supplier, including its Subcontractors, shall not employ or engage a child under the age of 14 unless the national law specifies a higher age (the minimum age).

14.6. The Supplier, including its Subcontractors, shall not employ or engage a child between the minimum age and the age of 18 in a manner that is likely to be hazardous, or to interfere with, the child's education, or to be harmful to the child's health or physical, mental, spiritual, moral, or social development.

14.7. Work considered hazardous for children is work that, by its nature or the circumstances in which it is carried out, is likely to

jeopardize the health, safety, or morals of children. Such work activities prohibited for children include work:

(a) with exposure to physical, psychological or sexual abuse;

(b) underground, underwater, working at heights or in confined spaces;

(c) with dangerous machinery, equipment or tools, or involving handling or transport of heavy loads;

(d) in unhealthy environments exposing children to hazardous substances, agents, or processes, or to temperatures, noise or vibration damaging to health; or

(e) under difficult conditions such as work for long hours, during the night or in confinement on the premises of the employer.

14.8. The Supplier shall comply, and shall require its Subcontractors if any to comply, with all applicable health and safety regulations, laws, guidelines, and any other requirement stated in the Technical Specifications.

15 Contract Price

15.1. Prices charged by the Supplier for the Goods supplied and the Related Services performed under the Contract shall not vary from the prices quoted by the Supplier in its Bid, with the exception of any price adjustments authorized **in the SCC.**

16. Terms of Payment

16.1 The Contract Price, including any Advance Payments, if applicable, shall be paid as specified **in the SCC.**

16.2 The Supplier's request for payment shall be made to the Purchaser in writing, accompanied by invoices describing, as appropriate, the Goods delivered and Related Services performed, and by the documents submitted pursuant to GCC Clause 13 and upon fulfillment of all other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or request for payment by the Supplier, and after the Purchaser has accepted it.

16.4 The currencies in which payments shall be made to the Supplier under this Contract shall be those in which the Bid price is expressed.

16.5 In the event that the Purchaser fails to pay the Supplier any payment by its due date or within the period set forth **in the SCC,** the Purchaser shall pay to the Supplier interest on the

amount of such delayed payment at the rate shown **in the SCC,** for the period of delay until payment has been made in full, whether before or after judgment or arbitrage award.

17. Taxes and Duties

17.1 For goods manufactured outside the Purchaser's Country, the Supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the Purchaser's Country.

17.2 For goods Manufactured within the Purchaser's Country, the Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser.

17.3 If any tax exemptions, reductions, allowances or privileges may be available to the Supplier in the Purchaser's Country, the Purchaser shall use its best efforts to enable the Supplier to benefit from any such tax savings to the maximum allowable extent.

18. Performance Security

18.1 If required as specified in the SCC, the Supplier shall, within twenty-eight (28) days of the notification of contract award, provide a Performance Security for the performance of the Contract in the amount specified **in the SCC.**

18.2 The proceeds of the Performance Security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

18.3 As specified in the SCC, the Performance Security, if required, shall be denominated in the currency(ies) of the Contract, or in a freely convertible currency acceptable to the Purchaser; and shall be in one of the format stipulated by the Purchaser **in the SCC,** or in another format acceptable to the Purchaser.

18.4 The Performance Security shall be discharged by the Purchaser and returned to the Supplier not later than twenty-eight (28) days following the date of Completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise **in the SCC.**

19. Certification of Goods in Accordance with Laws of the Purchaser's Country

19.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in the Purchaser's Country. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Purchaser's Country as specified **in the SCC**.

19.2 Unless otherwise specified **in the SCC,** the Contract shall become

effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's Country that the Goods have been registered for use in the Purchaser's Country.

19.3 If thirty (30) days, or such longer period specified **in the SCC,** elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 19.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's Performance Security shall be promptly returned.

20. Confidential Information

20.1 The Purchaser and the Supplier shall keep confidential and shall not, without the written consent of the other party hereto, divulge to any third party any documents, data, or other information furnished directly or indirectly by the other party hereto in connection with the Contract, whether such information has been furnished prior to, during or following completion or termination of the Contract. Notwithstanding the above, the Supplier may furnish to its Subcontractor such documents, data, and other information it receives from the Purchaser to the extent required for the Subcontractor to perform its work under the Contract, in which event the Supplier shall obtain from such Subcontractor an undertaking of confidentiality similar to that imposed on the Supplier under GCC Clause 20.

20.2 The Purchaser shall not use such documents, data, and other information received from the Supplier for any purposes unrelated to the contract. Similarly, the Supplier shall not use such documents, data, and other information received from the Purchaser for any purpose other than the performance of the Contract.

20.3 The obligation of a party under GCC Sub-Clauses 20.1 and 20.2 above, however, shall not apply to information that:

(a) the Purchaser or Supplier need to share with the Bank or other institutions participating in the financing of the Contract;

(b) now or hereafter enters the public domain through no fault of that party;

(c) can be proven to have been possessed by that party at the time of disclosure and which was not previously obtained, directly or indirectly, from the other party; or

(d) otherwise lawfully becomes available to that party from a

third party that has no obligation of confidentiality.

20.4 The above provisions of GCC Clause 20 shall not in any way modify any undertaking of confidentiality given by either of the parties hereto prior to the date of the Contract in respect of the Supply or any part thereof.

20.5 The provisions of GCC Clause 20 shall survive completion or termination, for whatever reason, of the Contract.

21. Subcontracting

21.1 The Supplier shall notify the Purchaser in writing of all subcontracts awarded under the Contract if not already specified in the Bid. Notification by the Supplier, for addition of any Subcontractor not named in the Contract, shall also include the Subcontractor's declaration in accordance with Appendix 2 to the GCC- Sexual exploitation and Abuse (SEA) and/or Sexual Harassment (SH) Performance Declaration. Such notification, in the original Bid or later shall not relieve the Supplier from any of its obligations, duties, responsibilities, or liability under the Contract.

21.2 Subcontracts shall comply with the provisions of GCC Clauses 3 and 7.

22. Specifications and Standards

22.1 The Goods supplied under this Contract shall conform to technical specifications and standards mentioned in Section VII, Schedule of Requirements and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

23. Packing and Documents

23.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. During transit, the packing shall be sufficient to withstand, without limitation, rough handling and exposure to extreme temperatures, salt and precipitation, and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.

23.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified **in the SCC,** and in any other instructions ordered by the Purchaser.

24. Insurance

24.1 Unless otherwise specified **in the SCC,** the Goods supplied under the Contract shall be fully insured—in a freely

convertible currency from an eligible country—against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery, in accordance with the applicable Incoterms or in the manner specified in the **SCC.**

25. Transportation and Incidental Services

25.1 Unless otherwise specified **in the SCC,** responsibility for arranging transportation of the Goods shall be in accordance with the specified Incoterms.

25.2 The Supplier may be required to provide any or all of the following services, including additional services, if any, specified **in SCC:**

(a) performance or supervision of on-site assembly and/or start-up of the supplied Goods;

(b) furnishing of tools required for assembly and/or maintenance of the supplied Goods;

(c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods;

(d) performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and

(e) training of the Purchaser's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.

25.3 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services

26. Inspections and Tests

26.1 The Supplier shall at its own expense and at no cost to the Purchaser carry out all such tests and/or inspections of the Goods and Related Services as are specified **in the SCC.**

26.2 The inspections and tests may be conducted on the premises of the Supplier or the manufacturer, at point of delivery, and/or at the Goods' final destination, or in another place in the Purchaser's Country as specified **in the SCC.** Subject to GCC Sub-Clause 26.3, if conducted on the premises of the Supplier or the manufacturer, all reasonable facilities and assistance, including access to production data, shall be furnished to the inspectors at no charge to the Purchaser.

26.3 The Purchaser or its designated representative shall be entitled to attend the tests and/or inspections referred to in GCC Sub-Clause 26.2, provided that the Purchaser bear all of its own costs and expenses incurred in connection with such attendance including, but not limited to, all traveling and board and lodging expenses.

26.4 Whenever the Supplier is ready to carry out any such test and inspection, it shall give a reasonable advance notice, including the place and time, to the Purchaser. The Supplier shall obtain from any relevant third party or manufacturer any necessary permission or consent to enable the Purchaser or its designated representative to attend the test and/or inspection.

(a) Said inspection and testing is for the Purchaser's account. In the event that inspection and testing is required prior to dispatch, the Goods shall not be shipped unless a satisfactory inspection and quality control report has been issued in respect of those Goods.

(b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.

(c) Upon receipt of the Goods at place of final destination, the Purchaser's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

26.5 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 26.4 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party;

26.6 The Purchaser may require the Supplier to carry out any test

and/or inspection not required by the Contract but deemed necessary to verify that the characteristics and performance of the Goods comply with the technical specifications codes and standards under the Contract, provided that the Supplier's reasonable costs and expenses incurred in the carrying out of such test and/or inspection shall be added to the Contract Price. Further, if such test and/or inspection impedes the progress of manufacturing and/or the Supplier's performance of its other obligations under the Contract, due allowance will be made in respect of the Delivery Dates and Completion Dates and the other obligations so affected.

26.7 The Supplier shall provide the Purchaser with a report of the results of any such test and/or inspection.

26.8 The Purchaser may reject any Goods or any part thereof that fail to pass any test and/or inspection or do not conform to the specifications. The Supplier shall either rectify or replace such rejected Goods or parts thereof or make alterations necessary to meet the specifications at no cost to the Purchaser, and shall repeat the test and/or inspection, at no cost to the Purchaser, upon giving a notice pursuant to GCC Sub-Clause 26.4.

26.9 The Supplier agrees that neither the execution of a test and/or inspection of the Goods or any part thereof, nor the attendance by the Purchaser or its representative, nor the issue of any report pursuant to GCC Sub-Clause 26.7, shall release the Supplier from any warranties or other obligations under the Contract.

27. Liquidated Damages

27.1 Except as provided under GCC Clause 32, if the Supplier fails to deliver any or all of the Goods by the Date(s) of delivery or perform the Related Services within the period specified in the Contract, the Purchaser may without prejudice to all its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified **in the SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified **in the SCC.** Once the maximum is reached, the Purchaser may terminate the Contract pursuant to GCC Clause 35.

28. Warranty

28.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of

the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with a shelf life of two years or less, unless otherwise specified **in the SCC;** have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

28.2 The Purchaser shall have the right to make claims under the above warranty for three months after the Goods have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Purchaser, the Supplier shall, with all reasonable speed, replace the defective Goods without cost to the Purchaser. The Supplier will be entitled to remove, at his own risk and cost, the defective Goods once the replacement Goods have been delivered.

28.3 In the event of a dispute by the Supplier, a counter-analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Purchaser and the Supplier. If the counter-analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.

28.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 28.2 above, the Supplier fails to replace the defective Goods within the period specified **in the SCC,** the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

28.5 *Recalls.* In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the

Purchaser will, at the Supplier's expense, carry out the recall.

29. Patent Indemnity

29.1 The Supplier shall, subject to the Purchaser's compliance with GCC Sub-Clause 29.2, indemnify and hold harmless the Purchaser and its employees and officers from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Purchaser may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design, trademark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract by reason of the use of the Pharmaceuticals in the Purchaser's Country.

Such indemnity shall not cover any use of the Goods or any part thereof other than for the purpose indicated by or to be reasonably inferred from the Contract, neither any infringement resulting from the use of the Goods or any part thereof, or any products produced thereby in association or combination with any other equipment, plant, or materials not supplied by the Supplier, pursuant to the Contract.

29.2 If any proceedings are brought or any claim is made against the Purchaser arising out of the matters referred to in GCC Sub-Clause 29.1, the Purchaser shall promptly give the Supplier a notice thereof, and the Supplier may at its own expense and in the Purchaser's name conduct such proceedings or claim and any negotiations for the settlement of any such proceedings or claim.

29.3 If the Supplier fails to notify the Purchaser within twenty-eight (28) days after receipt of such notice that it intends to conduct any such proceedings or claim, then the Purchaser shall be free to conduct the same on its own behalf.

29.4 The Purchaser shall, at the Supplier's request, afford all available assistance to the Supplier in conducting such proceedings or claim, and shall be reimbursed by the Supplier for all reasonable expenses incurred in so doing.

29.5 The Purchaser shall indemnify and hold harmless the Supplier and its employees, officers, and Subcontractors from and against any and all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which the Supplier may suffer as a result of any infringement or alleged infringement of any patent, utility model, registered design,

trademark, copyright, or other intellectual property right registered or otherwise existing at the date of the Contract arising out of or in connection with any design, data, drawing, specification, or other documents or materials provided or designed by or on behalf of the Purchaser.

30 Limitation of Liability

30.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 29,

(a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and

(b) (b)the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment, or to any obligation of the supplier to indemnify the Purchaser with respect to patent infringement.

31. Change in Laws and Regulations

31.1 Unless otherwise specified in the Contract, if after the date of 28 days prior to date of Bid submission, any law, regulation, ordinance, order or bylaw having the force of law is enacted, promulgated, abrogated, or changed in the place of the Purchaser's Country where the Site is located (which shall be deemed to include any change in interpretation or application by the competent authorities) that subsequently affects the Delivery Date and/or the Contract Price, then such Delivery Date and/or Contract Price shall be correspondingly increased or decreased, to the extent that the Supplier has thereby been affected in the performance of any of its obligations under the Contract. Notwithstanding the foregoing, such additional or reduced cost shall not be separately paid or credited if the same has already been accounted for in the price adjustment provisions where applicable, in accordance with GCC Clause 15.

32. Force Majeure

32.1 The Supplier shall not be liable for forfeiture of its Performance Security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

32.2 For purposes of this Clause, "Force Majeure" means an event

or situation beyond the control of the Supplier that is not foreseeable, is unavoidable, and its origin is not due to negligence or lack of care on the part of the Supplier. Such events may include, but not be limited to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

32.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

33. Change Orders and Contract Amendments

33.1 The Purchaser may at any time order the Supplier through notice in accordance GCC Clause 8, to make changes within the general scope of the Contract in any one or more of the following:

(a) drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and

(d) the Related Services to be provided by the Supplier.

33.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or in the Delivery/Completion Schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this Clause must be asserted within twenty-eight (28) days from the date of the Supplier's receipt of the Purchaser's change order.

33.3 Prices to be charged by the Supplier for any Related Services that might be needed but which were not included in the Contract shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the Supplier for similar services.

33.4 Subject to the above, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties. This includes, if specified **in**

the SCC, any variation to the contract resulting from a value engineering proposal agreed between the parties.

34. Extensions of Time

34.1 If at any time during performance of the Contract, the Supplier or its subcontractors should encounter conditions impeding timely delivery of the Goods or completion of Related Services pursuant to GCC Clause 13, the Supplier shall promptly notify the Purchaser in writing of the delay, its likely duration, and its cause. As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, in which case the extension shall be ratified by the parties by amendment of the Contract.

34.2 Except in case of Force Majeure, as provided under GCC Clause 32, a delay by the Supplier in the performance of its Delivery and Completion obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 27, unless an extension of time is agreed upon, pursuant to GCC Sub-Clause 34.1.

35. Termination

35.1 Termination for Default

(a) The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate the Contract in whole or in part:

(i) if the Supplier fails to deliver any or all of the Goods within the period specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 34;

(ii) if the Supplier fails to perform any other obligation under the Contract; or

(iii) if the Supplier, in the judgment of the Purchaser has engaged in Fraud and Corruption, as defined in paragraph 2.2 a of the Appendix 1 to the GCC, in competing for or in executing the Contract.

(b) In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 35.1(a), the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Related Services similar to those undelivered or not performed, and the Supplier shall be liable to the Purchaser for any additional costs for such similar Goods or Related Services. However, the Supplier shall continue

performance of the Contract to the extent not terminated.

35.2 Termination for Insolvency.

(a) The Purchaser may at any time terminate the Contract by giving notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In such event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser

35.3 Termination for Convenience.

(a) The Purchaser, by notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

(b) The Goods that are complete and ready for shipment within twenty-eight (28) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect:

(i) to have any portion completed and delivered at the Contract terms and prices; and/or

(ii) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Related Services and for materials and parts previously procured by the Supplier.

36. Assignment

36.1 Neither the Purchaser nor the Supplier shall assign, in whole or in part, their obligations under this Contract, except with prior written consent of the other party.

37. Export Restriction

37.1 Notwithstanding any obligation under the Contract to complete all export formalities, any export restrictions attributable to the Purchaser, to the country of the Purchaser, or to the use of the products/goods, systems or services to be supplied, which arise from trade regulations from a country supplying those products/goods, systems or services, and which substantially impede the Supplier from meeting its obligations under the Contract, shall release the Supplier from the obligation to provide deliveries or services, always provided, however, that

the Supplier can demonstrate to the satisfaction of the Purchaser and of the Bank that it has completed all formalities in a timely manner, including applying for permits, authorizations and licenses necessary for the export of the products/goods, systems or services under the terms of the Contract. Termination of the Contract on this basis shall be for the Purchaser's convenience pursuant to Sub-Clause 35.3.

APPENDIX 1 TO GENERAL CONDITIONS

Fraud and Corruption

(Text in this Appendix shall not be modified)

1. Purpose

1.1 The Bank's Anti-Corruption Guidelines and this annex apply with respect to procurement under Bank Investment Project Financing operations.

2. Requirements

2.1 The Bank requires that Borrowers (including beneficiaries of Bank financing); bidders (applicants/proposers), consultants, contractors and suppliers; any sub-contractors, sub-consultants, service providers or suppliers; any agents (whether declared or not); and any of their personnel, observe the highest standard of ethics during the procurement process, selection and contract execution of Bank-financed contracts, and refrain from Fraud and Corruption.

2.2 To this end, the Bank:

a. Defines, for the purposes of this provision, the terms set forth below as follows:

i. "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

ii. "fraudulent practice" is any act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;

iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

v. "obstructive practice" is:

(a) deliberately destroying, falsifying, altering, or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive, or collusive practice; and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(b) acts intended to materially impede the exercise of the Bank's inspection and audit rights provided for under paragraph 2.2 e. below.

b. Rejects a proposal for award if the Bank determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub-consultants, sub-contractors, service providers, suppliers and/ or their employees, has, directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question;

c. In addition to the legal remedies set out in the relevant Legal Agreement, may take other appropriate actions, including declaring misprocurement, if the Bank determines at any time that representatives of the Borrower or of a recipient of any part of the proceeds of the loan engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices during the procurement process, selection and/or execution of the contract in question, without the Borrower having taken timely and appropriate action satisfactory to the Bank to address such practices when they occur, including by failing to inform the Bank in a timely manner at the time they knew of the practices;

d. Pursuant to the Bank's Anti- Corruption Guidelines, and in accordance with the Bank's prevailing sanctions policies and procedures, may sanction a firm or individual, either indefinitely or for a stated period of time, including by publicly declaring such firm or individual ineligible (i) to be awarded or otherwise benefit from a Bank-financed contract, financially or in any other manner;1 (ii) to be a nominated[2] sub-contractor, consultant, manufacturer or supplier, or service provider of an otherwise eligible firm being awarded a Bank-financed contract; and (iii) to receive the proceeds of any loan made by the Bank or otherwise to participate further in the preparation or implementation of any Bank-financed project;

e. Requires that a clause be included in bidding/request for proposals documents and in contracts financed by a Bank loan, requiring (i) bidders (applicants/proposers), consultants, contractors, and suppliers, and their sub-contractors, sub-consultants, service providers, suppliers, agents personnel, permit the Bank to inspect[3] all accounts, records and other documents relating to the procurement process, selection and/or contract execution, and to have them audited by auditors appointed by the Bank.

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1 For the avoidance of doubt, a sanctioned party's ineligibility to be awarded a contract shall include, without limitation, (i) applying for pre-qualification, expressing interest in a consultancy, and bidding, either directly or as a nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider, in respect of such contract, and (ii) entering into an addendum or amendment introducing a material modification to any existing contract.

2 A nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider (different names are used depending on the particular bidding document) is one which has been: (i) included by the bidder in its pre-qualification application or bid because it brings specific and critical experience and know-how that allow the bidder to meet the qualification requirements for the particular bid; or (ii) appointed by the Borrower.

3 Inspections in this context usually are investigative (i.e., forensic) in nature. They involve fact-finding activities undertaken by the Bank or persons appointed by the Bank to address specific matters related to investigations/audits, such as evaluating the veracity of an allegation of possible Fraud and Corruption, through the appropriate mechanisms. Such activity includes but is not limited to: accessing and examining a firm's or individual's financial records and information, and making copies thereof as relevant; accessing and examining any other documents, data and information (whether in hard copy or electronic format) deemed relevant for the investigation/audit, and making copies thereof as relevant; interviewing staff and other relevant individuals; performing physical inspections and site visits; and obtaining third party verification of information.

APPENDIX 2
Sexual Exploitation and Abuse (SEA) and/or Sexual Harassment (SH) Performance Declaration for Subcontractors

[The following table shall be filled in by each subcontractor proposed by the Supplier, that was not named in the Contract]

Subcontractor's Name: *[insert full name]*
Date: *[insert day, month, year]*
Contract reference *[insert contract reference]*
Page *[insert page number]* of *[insert total number]* pages

SEA and/or SH Declaration
We: ☐ (a) have not been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations. ☐ (b) are subject to disqualification by the Bank for non-compliance with SEA/ SH obligations. ☐ (c) had been subject to disqualification by the Bank for non-compliance with SEA/ SH obligations, and were removed from the disqualification list. An arbitral award on the disqualification case has been made in our favor.
[*If (c) above is applicable, attach evidence of an arbitral award reversing the findings on the issues underlying the disqualification.]*
Period of disqualification: From: _____ To: _____

Name of the Subcontractor_____

Name of the person duly authorized to sign on behalf of the Subcontractor_____

Title of the person signing on behalf of the Subcontractor_____

Signature of the person named above_____

Date signed _____ day of _____, _____

Countersignature of authorized representative of the Supplier:

Signature: _____

Date signed _____ day of _____, _____

Section IX - Special Conditions of Contract

The following Special Conditions of Contract (SCC) shall supplement and / or amend the General Conditions of Contract (GCC). Whenever there is a conflict, the provisions herein shall prevail over those in the GCC.

[The Purchaser shall select insert the appropriate wording using the samples below or other acceptable wording, and delete the text in italics]

GCC 1.1(i)	The Purchaser's Country is: Democratic Socialist Republic of *Sri Lanka*
GCC 1.1(j)	The Purchaser is: *Ministry of Health, Sri Lanka*
GCC 1.1 (o)	The Project Site(s)/Final Destination(s) is/are: *Medical Supplies Division,* 357, Ven Baddegama Wimalawansa Thero Mawatha, Colombo 010
GCC 1.1 (p)	The term **SEA/SH** where used in the Contract has the following meaning: • "**Sexual Exploitation and Abuse" "(SEA)"** means the following: **Sexual Exploitation** is defined as any actual or attempted abuse of position of vulnerability, differential power or trust, for sexual purposes, including, but not limited to, profiting monetarily, socially or politically from the sexual exploitation of another. **Sexual Abuse** is defined as the actual or threatened physical intrusion of a sexual nature, whether by force or under unequal or coercive conditions. • **"Sexual Harassment" "(SH)"** is defined as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature by contractor's personnel with other contractor's, or employer's personnel.
GCC 4.2 (a)	The meaning of the trade terms shall be as prescribed by Incoterms. If the meaning of any trade term and the rights and obligations of the parties thereunder shall not be as prescribed by Incoterms, they shall be as prescribed by: *[exceptional; refer to other internationally accepted trade terms]*
GCC 4.2 (b)	The version edition of Incoterms shall be *Incoterms 2020*
GCC 5.1	The language shall be: *English*

GCC 8.1	For **notices**, the Purchaser's address shall be: Attention: *The Chairman* *State Pharmaceuticals Corporation of Sri Lanka* Street Address: *"Mehewara Piyasa", Kirula Road, Colombo 05* Floor/ Room number*: 16th Floor* City: *Colombo* ZIP Code: *00500* Country: Sri Lanka Telephone: *+94 11 2338500* Facsimile number: *+94 11 2055800* Electronic mail address*: chairman@spc.lk*
GCC 9.1	The governing law shall be the law of: Democratic Socialist Republic of Sri Lanka
GCC 10.2	The rules of procedure for arbitration proceedings pursuant to GCC Clause 10.2 shall be as follows: ***(a) Contract with foreign Supplier:*** GCC 10.2 (a)—All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said Rules & shall be held in Singapore. ***(b) Contracts with Supplier national of the Purchaser's Country:*** In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's Country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's Country & shall be held in Singapore.
GCC 13.1	***For Goods supplied from abroad:*** Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. The Supplier shall fax and then send by

	courier the following documents to the Purchaser, with a copy to the insurance company: (i) three originals and two copies of the Supplier's invoice, showing Purchaser as *Ministry of Health, Sri Lanka of Sri Lanka;* the Contract number, loan number, Goods description, quantity, unit price, and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal; (ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as *Ministry of Health, Sri Lanka of Sri Lanka* and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements; (iii) four copies of the packing list identifying contents of each package; (iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied; (vi) one original of the Supplier's Certificate of Origin covering all items supplied; (vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required); (viii) any other procurement-specific documents required for delivery/payment purposes. ***For Goods from within the Purchaser's Country:*** Upon or before delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser: (i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, loan number; Goods' description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed

	with the company stamp/seal; (ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as *Ministry of Health, Sri Lanka of Sri Lanka* and delivery through to final destination as stated in the Contract; (iii) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (iv) four copies of the packing list identifying contents of each package; (v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied; (vi) one original of the Supplier's Certificate of Origin covering all items supplied; (vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required) (viii) other procurement-specific documents required for delivery/payment purposes. The above documents shall be received by the Purchaser before arrival of the Goods and, if not received, the Supplier will be responsible for any consequent expenses.
GCC 15.1	The prices charged for the Goods supplied and the related Services performed *"shall not"* be adjustable.
GCC 16.1	GCC 16.1—The method and conditions of payment to be made to the Supplier under this Contract shall be as follows: **Payment for Goods supplied from abroad:** Payment of foreign currency portion shall be made in USD in the following manner: (i) **On Shipment:** Seventy Five (75) percent of the Contract Price of the Goods shipped shall be paid through irrevocable confirmed letter of credit opened in favor of the Supplier in a bank in its country, upon submission of documents specified in GCC Clause 12.

	(ii) **On Acceptance:** Twenty five (25) percent of the Contract Price of Goods received shall be paid within sixty (60) days of receipt of the Goods upon submission of claim supported by the acceptance certificate issued by the Purchaser. Payment of local currency portion shall be made in LKR within sixty (60) days of presentation of claim supported by a certificate from the Purchaser declaring that the Goods have been delivered and that all other contracted Services have been performed. **Payment for Goods and Services supplied from within the Purchaser's Country:** Payment for Goods and Services supplied from within the Purchaser's Country shall be made in LKR, as follows: (i) **On Delivery:** Seventy five (75) percent of the Contract Price shall be paid on receipt of the Goods and upon submission of the documents specified in GCC Clause 13. (ii) **On Acceptance:** The remaining twenty five (25) percent of the Contract Price shall be paid to the Supplier within sixty (60) days after the date of the acceptance certificate for the respective delivery issued by the Purchaser.
GCC 16.5	The payment-delay period after which the Purchaser shall pay interest to the supplier shall be 60 days. The interest rate that shall be applied is *0.5 %*
GCC 18.1	A Performance Security *"shall" be required* *The amount of the Performance Security shall be:10% from contract value*
GCC 18.3	The Performance Security shall be in the form of : *Performance Bond* If required, the Performance security shall be denominated in 10% from the contract price by *USD for foreign suppliers LKR from local suppliers*
GCC 18.4	Discharge of the Performance Security shall take place: *30 days after final consignment.*
GCC19.1	The registration and other certification necessary to prove registration in Purchaser's Country is *NMRA Registration certificate, in the absence of NMRA registration Waiver of registration issued by NMRA may be considered.*

GCC19.2	The Effective Date of the Contract is *: **date of Contract signing** if EITHER: (i) the Goods have already been registered at the time of Contracting signing*
GCC19.3	***"NOT USED."***
GCC 23.2	The packing, marking and documentation within and outside the packages shall be: 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
GCC 24.1	The insurance coverage shall be as specified in the Incoterms.
GCC 25.1	Responsibility for transportation of the Goods shall be as specified in the Incoterms. If not in accordance with Incoterms, responsibility for transportations shall be as follows: *Not applicable*
GCC 25.2	Incidental services to be provided are: *Not applicable*
GCC 26.1	The inspections and tests shall be: Immediately after delivery at MSD, the consignments shall be subject to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory
GCC 26.2	The Inspections and tests shall be conducted at: *NMQAL (National Medicines Quality Assurance Laboratory)*
GCC 27.1	The liquidated damage shall be: 3.5% per week
GCC 27.1	The maximum amount of liquidated damages shall be: *10%*
GCC 28.1	[*Insert any alternative warranty requirements or indicate: not applicable*

GCC 28.4	The period for replacement shall be: *N/A*
GCC 33.4	~~*[Value engineering may be included if it has been specified here and agreed by the Bank]*~~ Value Engineering: *NOT APPLICABLE*

Special Conditions of Contract

PHARMACEUTICALS

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in bidding document for the procurement of pharmaceuticals.	
GCC 13.1	***For Goods supplied from abroad**:* (ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied. (x) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods. (xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

Attachment: Price Adjustment Formula

If in accordance with GCC 15.1, prices shall be adjustable, the following method shall be used to calculate the price adjustment:

15.1 Prices payable to the Supplier, as stated in the Contract, shall be subject to adjustment during performance of the Contract to reflect changes in the cost of labor and material components in accordance with the formula:

$$P_1 = P_0 \left[a + \frac{bL_1}{L_0} + \frac{cM_1}{M_0}\right] - P_0$$

$$a+b+c = 1$$

in which:

P_1	=	adjustment amount payable to the Supplier.
P_0	=	Contract Price (base price).
a	=	fixed element representing profits and overheads included in the Contract Price and generally in the range of five (5) to fifteen (15) percent.
b	=	estimated percentage of labor component in the Contract Price.
c	=	estimated percentage of material component in the Contract Price.
L_0, L_1	=	*labor indices applicable to the appropriate industry in the country of origin on the base date and date for adjustment, respectively.
M_0, M_1	=	*material indices for the major raw material on the base date and date for adjustment, respectively, in the country of origin.

The Bidder shall indicate the source of the indices, and the source of exchange rate (if applicable) and the base date indices in its Bid.

The coefficients a, b, and c as specified by the Purchaser are as follows:

a = *[insert value of coefficient]*
b= *[insert value of coefficient]*
c= *[insert value of coefficient]*

Base date = thirty (30) days prior to the deadline for submission of the Bids.

Date of adjustment = *[insert number of weeks]* weeks prior to date of shipment (representing the mid-point of the period of manufacture).

The above price adjustment formula shall be invoked by either party subject to the following further conditions:

(a) No price adjustment shall be allowed beyond the original delivery dates. As a rule, no price adjustment shall be allowed for periods of delay for which the

Supplier is entirely responsible. The Purchaser will, however, be entitled to any decrease in the prices of the Goods and Services subject to adjustment.

(b) If the currency in which the Contract Price P_0 is expressed is different from the currency of origin of the labor and material indices, a correction factor will be applied to avoid incorrect adjustments of the Contract Price. The correction factor shall be: Z_0 / Z_1, where,

Z_0 = the number of units of currency of the origin of the indices which equal to one unit of the currency of the Contract Price P_0 on the Base date, and

Z_1 = the number of units of currency of the origin of the indices which equal to one unit of the currency of the Contract Price P_0 on the Date of Adjustment.

(c) No price adjustment shall be payable on the portion of the Contract Price paid to the Supplier as advance payment.

Section X - Contract Forms

Table of Forms

Notification of Intention to Award

[*This Notification of Intention to Award shall be sent to each Bidder that submitted a Bid.*]

[*Send this Notification to the Bidder's Authorized Representative named in the Bidder Information Form*]
For the attention of Bidder's Authorized Representative
Name: *[insert Authorized Representative's name]*
Address: *[insert Authorized Representative's Address]*
Telephone/Fax numbers: *[insert Authorized Representative's telephone/fax numbers]*
Email Address: *[insert Authorized Representative's email address]*

[IMPORTANT: insert the date that this Notification is transmitted to Bidders. The Notification must be sent to all Bidders simultaneously. This means on the same date and as close to the same time as possible.]
DATE OF TRANSMISSION: This Notification is sent by: [*email/fax*] on [*date*] (local time)

Notification of Intention to Award

Purchaser: *[insert the name of the Purchaser]*
Project: *[insert name of project]*
Contract title: *[insert the name of the contract]*
Country: *[insert country where RFB is issued]*
Loan No. /Credit No. / Grant No.: *[insert reference number for loan/credit/grant]*
RFB No: *[insert RFB reference number from Procurement Plan]*

This Notification of Intention to Award (Notification) notifies you of our decision to award the above contract. The transmission of this Notification begins the Standstill Period. During the Standstill Period you may:

a) request a debriefing in relation to the evaluation of your Bid, and/or

b) submit a Procurement-related Complaint in relation to the decision to award the contract.

1. The successful Bidder

Name:	[*insert name of successful Bidder*]
Address:	[*insert address of the successful Bidder*]
Contract price:	[*insert contract price of the successful Bid*]

2. Other Bidders ***[INSTRUCTIONS: insert names of all Bidders that submitted a Bid. If the Bid's price was evaluated include the evaluated price as well as the Bid price as read out.]***

Name of Bidder	Bid price	Evaluated Bid price (if applicable)
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]
[*insert name*]	[*insert Bid price*]	[*insert evaluated price*]

3. Reason/s why your Bid was unsuccessful

[INSTRUCTIONS: State the reason/s why <u>this</u> Bidder's Bid was unsuccessful. Do NOT include: (a) a point by point comparison with another Bidder's Bid or (b) information that is marked confidential by the Bidder in its Bid.]

4. How to request a debriefing

DEADLINE: The deadline to request a debriefing expires at midnight on [*insert date*] (local time).

You may request a debriefing in relation to the results of the evaluation of your Bid. If you decide to request a debriefing your written request must be made within three (3) Business Days of receipt of this Notification of Intention to Award.

Provide the contract name, reference number, name of the Bidder, contact details; and address the request for debriefing as follows:

Attention: [*insert full name of person, if applicable*]

Title/position: [*insert title/position*]

Agency: [*insert name of Purchaser*]

Email address: [*insert email address*]

Fax number: [*insert fax number*] ***delete if not used***

If your request for a debriefing is received within the 3 Business Days deadline, we will provide the debriefing within five (5) Business Days of receipt of your request. If we are unable to provide the debriefing within this period, the Standstill Period shall be extended by five (5) Business Days after the date that the debriefing is provided. If this happens, we will notify you and confirm the date that the extended Standstill Period will end.

The debriefing may be in writing, by phone, video conference call or in person. We shall

promptly advise you in writing how the debriefing will take place and confirm the date and time.

If the deadline to request a debriefing has expired, you may still request a debriefing. In this case, we will provide the debriefing as soon as practicable, and normally no later than fifteen (15) Business Days from the date of publication of the Contract Award Notice.

5. How to make a complaint

Period: Procurement-related Complaint challenging the decision to award shall be submitted by midnight, [*insert date*] (local time).

Provide the contract name, reference number, name of the Bidder, contact details; and address the Procurement-related Complaint as follows:

Attention: [*insert full name of person, if applicable*]

Title/position: [*insert title/position*]

Agency: [*insert name of Purchaser*]

Email address: [*insert email address*]

Fax number: [*insert fax number*] ***delete if not used***

At this point in the procurement process, you may submit a Procurement-related Complaint challenging the decision to award the contract. You do not need to have requested, or received, a debriefing before making this complaint. Your complaint must be submitted within the Standstill Period and received by us before the Standstill Period ends.

Further information:

For more information see the Procurement Regulations for IPF Borrowers (Procurement Regulations)[https://policies.worldbank.org/sites/ppf3/PPFDocuments/Forms/DispPage.aspx?docid=4005] (Annex III). You should read these provisions before preparing and submitting your complaint. In addition, the World Bank's Guidance "How to make a Procurement-related Complaint" [http://www.worldbank.org/en/projects-operations/products-and-services/brief/procurement-new-framework#framework] provides a useful explanation of the process, as well as a sample letter of complaint.

In summary, there are four essential requirements:

1. You must be an 'interested party'. In this case, that means a Bidder who submitted a Bid in this bidding process, and is the recipient of a Notification of Intention to Award.
2. The complaint can only challenge the decision to award the contract.
3. You must submit the complaint within the period stated above.
4. You must include, in your complaint, all of the information required by the Procurement Regulations (as described in Annex III).

6. Standstill Period

DEADLINE: The Standstill Period is due to end at midnight on [*insert date*] (local time).

The Standstill Period lasts ten (10) Business Days after the date of transmission of this Notification of Intention to Award.

The Standstill Period may be extended as stated in Section 4 above.

If you have any questions regarding this Notification please do not hesitate to contact us.

On behalf of the Purchaser:

Signature: _____

Name: _____

Title/position: _____

Telephone: _____

Email: _____

Beneficial Ownership Disclosure Form

INSTRUCTIONS TO BIDDERS: DELETE THIS BOX ONCE YOU HAVE COMPLETED THE FORM

This Beneficial Ownership Disclosure Form ("Form") is to be completed by the successful Bidder. In case of joint venture, the Bidder must submit a separate Form for each member. The beneficial ownership information to be submitted in this Form shall be current as of the date of its submission.

For the purposes of this Form, a Beneficial Owner of a Bidder is any natural person who ultimately owns or controls the Bidder by meeting one or more of the following conditions:

- *directly or indirectly holding 25% or more of the shares*
- *directly or indirectly holding 25% or more of the voting rights*
- *directly or indirectly having the right to appoint a majority of the board of directors or equivalent governing body of the Bidder*

RFB No.: [*insert number of RFB process*]
Request for Bid No.: [*insert identification*]

To: **[*insert complete name of Purchaser*]**

In response to your request in the Letter of Acceptance *dated [insert date of letter of Acceptance]* to furnish additional information on beneficial ownership: *[select one option as applicable and delete the options that are not applicable]*

(i) we hereby provide the following beneficial ownership information.

Details of beneficial ownership

Identity of Beneficial Owner	Directly or indirectly holding 25% or more of the shares (Yes / No)	Directly or indirectly holding 25 % or more of the Voting Rights (Yes / No)	Directly or indirectly having the right to appoint a majority of the board of the directors or an equivalent governing body of the Bidder (Yes / No)
[include full name (last, middle, first), nationality, country			

of residence]			

OR

(ii) *We declare that there is no Beneficial Owner meeting one or more of the following conditions:*

- directly or indirectly holding 25% or more of the shares
- directly or indirectly holding 25% or more of the voting rights
- directly or indirectly having the right to appoint a majority of the board of directors or equivalent governing body of the Bidder

OR

(iii) We declare that we are unable to identify any Beneficial Owner meeting one or more of the following conditions. [If this option is selected, the Bidder shall provide explanation on why it is unable to identify any Beneficial Owner]

- directly or indirectly holding 25% or more of the shares
- directly or indirectly holding 25% or more of the voting rights
- directly or indirectly having the right to appoint a majority of the board of directors or equivalent governing body of the Bidder]"

Name of the Bidder: *[*insert complete name of the Bidder*]_____

Name of the person duly authorized to sign the Bid on behalf of the Bidder: **[*insert complete name of person duly authorized to sign the Bid*]_____

Title of the person signing the Bid: [*insert complete title of the person signing the Bid*]_____

Signature of the person named above: [*insert signature of person whose name and capacity are shown above*]_____

Date signed [*insert date of signing*] **day of** [*insert month*], [*insert year*]_____

* In the case of the Bid submitted by a Joint Venture specify the name of the Joint Venture as Bidder. In the event that the Bidder is a joint venture, each reference to "Bidder" in the Beneficial Ownership Disclosure Form (including this Introduction thereto) shall be read to refer to the joint venture member.

** Person signing the Bid shall have the power of attorney given by the Bidder. The power of attorney shall be attached with the Bid Schedules.

Letter of Acceptance

[letterhead paper of the Purchaser]

[date]

To: *[name and address of the Supplier]*

Subject: ***Notification of Award Contract No.*** . . . . . .

This is to notify you that your Bid dated . . . . ***[insert date] . .*** . . for execution of the . . . . . ***.[insert name of the contract and identification number, as given in the SCC]***. . . . . for the Accepted Contract Amount of . . . . . ***.[insert amount in numbers and words and name of currency]***, as corrected and modified in accordance with the Instructions to Bidders is hereby accepted by our Agency.

You are requested to furnish (i) the Performance Security within 28 days in accordance with the Conditions of Contract, using for that purpose one of the Performance Security Form*s* and (ii) the additional information on beneficial ownership in accordance with BDS ITB 45.1 within eight (8) Business days using the Beneficial Ownership Disclosure Form, included in Section X, - Contract Forms, of the Bidding Document.

Authorized Signature: _____
Name and Title of Signatory: _____
Name of Agency: _____

Attachment: Contract Agreement

Contract Agreement

[The successful Bidder shall fill in this form in accordance with the instructions indicated]

THIS AGREEMENT made

the *[insert:* ***number*** *]* day of *[insert:* ***month*** *]*, *[insert:* ***year*** *]*.

BETWEEN

(1) *[insert complete name of Purchaser]*, a *[insert description of type of legal entity, for example, an agency of the Ministry of .... of the Government of { insert name of Country of Purchaser }, or corporation incorporated under the laws of { insert name of Country of Purchaser }]* and having its principal place of business at *[insert address of Purchaser]* (hereinafter called "the Purchaser"), of the one part, and

(2) *[insert name of Supplier]*, a corporation incorporated under the laws of *[insert: country of Supplier]* and having its principal place of business at *[insert: address of Supplier]* (hereinafter called "the Supplier"), of the other part:

WHEREAS the Purchaser invited Bids for certain Goods and ancillary services, viz., *[insert brief description of Goods and Services]* and has accepted a Bid by the Supplier for the supply of those Goods and Services

The Purchaser and the Supplier agree as follows:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Contract documents referred to.

2. The following documents shall be deemed to form and be read and construed as part of this Agreement. This Agreement shall prevail over all other contract documents.

   (a) the Letter of Acceptance

   (b) the Letter of Bid

   (c) the Addenda Nos._____ (if any)

   (d) Special Conditions of Contract

   (e) General Conditions of Contract

   (f) the Specification (including Schedule of Requirements and Technical Specifications)

   (g) the completed Schedules (including Price Schedules)

(h) any other document listed in GCC as forming part of the Contract

3. In consideration of the payments to be made by the Purchaser to the Supplier as specified in this Agreement, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with the laws of *[insert the name of the Contract governing law country]* on the day, month and year indicated above.

For and on behalf of the Purchaser

Signed: *[insert signature]*
in the capacity of *[insert title or other appropriate designation]*
in the presence of *[insert identification of official witness]*

For and on behalf of the Supplier

Signed: *[insert signature of authorized representative(s) of the Supplier]*
in the capacity of *[insert title or other appropriate designation]*
in the presence of *[insert identification of official witness]*

Performance Security

Bank Guarantee

[The bank, as requested by the successful Bidder, shall fill in this form in accordance with the instructions indicated]

[Guarantor letterhead or SWIFT identifier code]

Beneficiary: *[insert name and Address of Purchaser]*

Date: _ *[Insert date of issue]*

PERFORMANCE GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that _ *[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (hereinafter called "the Applicant") has entered into Contract No. *[insert reference number of the contract]* dated *[insert date]* with the Beneficiary, for the supply of _ *[insert name of contract and brief description of Health Goods and related Services]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Applicant, we as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of *[insert amount in figures]* ()*[insert amount in words]*,[1] such sum being payable in the types and proportions of currencies in which the Contract Price is payable, upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating that the Applicant is in breach of its obligation(s) under the Contract, without the Beneficiary needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire, no later than the …. Day of ……, 2… [2], and any demand for payment under it must be received by us at this office indicated above on or before that date.

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[1] *The Guarantor shall insert an amount representing the percentage of the Accepted Contract Amount specified in the Letter of Acceptance, and denominated either in the currency(ies) of the Contract or a freely convertible currency acceptable to the Beneficiary.*

[2] *Insert the date twenty-eight days after the expected completion date as described in GC Clause 18.4. The Purchaser should note that in the event of an extension of this date for completion of the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be*

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No. 758, except that the supporting statement under Article 15(a) is hereby excluded.

_____

[signature(s)]

Note: All italicized text (including footnotes) is for use in preparing this form and shall be deleted from the final product.

in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Beneficiary's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

Advance Payment Security

[Guarantor letterhead or SWIFT identifier code]

Beneficiary: *[Insert name and Address of Purchaser]*

Date: *[Insert date of issue]*

ADVANCE PAYMENT GUARANTEE No.: *[Insert guarantee reference number]*

Guarantor: *[Insert name and address of place of issue, unless indicated in the letterhead]*

We have been informed that *[insert name of Supplier, which in the case of a joint venture shall be the name of the joint venture]* (hereinafter called "the Applicant") has entered into Contract No. *[insert reference number of the contract]* dated *[insert date]* with the Beneficiary, for the execution of *[insert name of contract and brief description of Health Goods and related Services]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance payment in the sum *[insert amount in figures]* () *[insert amount in words]* is to be made against an advance payment guarantee.

At the request of the Applicant, we as Guarantor, hereby irrevocably undertake to pay the Beneficiary any sum or sums not exceeding in total an amount of *[insert amount in figures]* () *[insert amount in words]*[1] upon receipt by us of the Beneficiary's complying demand supported by the Beneficiary's statement, whether in the demand itself or in a separate signed document accompanying or identifying the demand, stating either that the Applicant:

(a) has used the advance payment for purposes other than toward delivery of Goods; or

(b) has failed to repay the advance payment in accordance with the Contract conditions, specifying the amount which the Applicant has failed to repay.

[1] *The Guarantor shall insert an amount representing the amount of the advance payment and denominated either in the currency(ies) of the advance payment as specified in the Contract, or in a freely convertible currency acceptable to the Purchaser.*

A demand under this guarantee may be presented as from the presentation to the Guarantor of a certificate from the Beneficiary's bank stating that the advance payment referred to above has been credited to the Applicant on its account number *[insert number]* at *[insert name and address of Applicant's bank]*.

The maximum amount of this guarantee shall be progressively reduced by the amount of the advance payment repaid by the Applicant as specified in copies of interim statements or payment certificates which shall be presented to us. This guarantee shall expire, at the latest, upon our receipt of a copy of the interim payment certificate indicating that ninety (90) percent of the Accepted Contract Amount, has been certified for payment, or on the *[insert day]* day of *[insert month]*, 2 *[insert year]*, whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees (URDG) 2010 Revision, ICC Publication No.758, except that the supporting statement under Article 15(a) is hereby excluded.

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_____
[signature(s)]

Note: All italicized text (including footnotes) is for use in preparing this form and shall be deleted from the final product.

ANNEX – 1

BID NO. : DHS/SUS/WW/101/24
DATE OF ISSUE : 25TH JULY 2023
CLOSING DATE & TIME : 04TH SEPTEMBER 2023 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka
2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
3. 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.
4. The volume of the total quantity of each item should be given in cubic meters (m^3)
5. **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.**
6. **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 Bids" of the bid document in this regard.**
7. If awarded supplier is unable to adhere 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.
8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
9. We reserve the right to reject offers which do not comply above.
10. The offer should be valid up to 02.03.2024

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

(a) Part A-General Order Conditions (GOC) 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, manufacturer²s name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.

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

3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge 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 consumables; 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 it²s sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

   The supplier²s 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, repair and 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 in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 surgical items. (Shelf life of 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 1/6th (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 Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia 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 Pharmaceuticals 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 manufacturer²s/Supplier²s 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 charged the total **cost involved for MSD, of the quality failed supplies** with 25% administrative charge 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 and 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 and 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).

15. **Pack size, Labeling & Packaging**

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

16. In respect of bulk packs (not applicable for blister/strip packs), ³DHS´ 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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots **or** when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)**

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue Nos of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and ³STATE LOGO´ of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Non-consumables) & date of Manufacture (in any form as ³Year & Month´ or ³No Exp.´), in the innermost pack and supplier²s invoice.

18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ³STATE LOGO´ of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
Format shall be according to Code 128 or 2D standards.
Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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

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

Storage Conditions & Temperature

22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30^0c +/- 2^0c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

23. Maintenance of Cold Chain;

a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer²s 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 break² is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

24. In respect of the products requiring controlled temperature storage (Eg. < 25^0c, 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

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

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.

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

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

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its² 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 charge.

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its² amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

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

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier²s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.
As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

30. The extension of L/C²s overstepping delivery schedules in the Indent/PO/its² amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its² amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No²s, 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.

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

35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD 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 condition No. 27 will not be applicable.

Common conditions

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

37. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. **(eg. As in conditions No. 08,05,10,13)**

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

(b) Part B-Special Order Conditions (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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

(i) -

(ii) -

(iii) -

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

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

- 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.

- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.

- 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.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name And designation of the signatory) or by the representative. Representatives submit 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.

- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.

- **All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.**

BID NO: DHS/SUS/WW/101/24 CLOSING ON : 04.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/S/00049

ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	21209103	Wire Instrument Set, with all standard instruments, stainless steel, in sterilizing tray. Packing: 1 Nos.	20 Nos.	20-Mar/2024	518,800.00
2	21209105	External Fixation Instrument Set, for Distal Radial Fracture Fixation with facility for distraction, with implants for 20 patients. Packing: 1 set	23 sets	23-Mar/2024	1,380,000.00
3	21209201	LRS Limb Reconstruction System, railing type, adult, set of 3 sizes, consisting of 5 Nos large size,3 Nos medium size and 2 Nos small size, with 100nos schanz screws(50 large,30 medium,20 small) of different lengths and different threaded lengths, and T clamp to fit rail system, with 2 swivel clamps. Packing: 1 Nos.	20 Nos.	20-May/2024	135,150.00

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value mentioned in the item list. Bid Bond should be submitted with valid up to 01.04.2024 together with the tender

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

1. Page 10 Condition No. 20. a
   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.

Contract:
The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.

A non refundable fee of Rs. 35,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) **Clause 8**

(a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.

(b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) **Clause 12**

Amend as **REIMBURSEMENT**

12.1 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 labeling.

(3) **Clause 16.6**

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) **Clause 28.0**

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in www.spc.lk Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX – 1

ANNEX – 1

BID NO/ BID REFERENCE :
(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :
(SRI LANKAN TIME)

ORDER LIST NO :

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR …….. or USD …….. to be submitted along with the Bid Bond valid till …… (date)

Bid validity period : Bid should be valid till …….. (date)

Bid Document Fee : ……
(should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.
2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of *1957)*
"Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA
AGREEMENT

SPC Ref. No   Date :
Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05, 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 **FIRST PART**

AND

M/s ……………………………………………………………………..
…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 **SECOND PART.**

AND

M/s ……………………………………………………………………..
…business under the time, style and firm of a company duly registered and carrying business (hereinafter called "the Local Agent" 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 **THIRD PART.**

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s ……………………………………………………………………………… for the supply and delivery of……………………………………… as per the attached indent for ……………… marked SPC ………………………………… . Dated ……………………………… and M/s ………………………………………………… will act as local agent of the supplier for all matters arising out of supplies here of.

<u>NOW IT IS HEREBY AGREED AS FOLLOWS:</u>

1. The following documents: -

   (a) Conditions of Contract marked – Annex 1
   (b) Bid Documents marked – Annex 2
   (c) Copy of Indent marked – Annex 3

(hereinafter called ñthe Contract Documentsò) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial 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, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

   The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

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

   In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and é é é é é é é é é and é é é é é é é é é é . of State Pharmaceuticals Corporation have set their hands and Supplier and the Local Agent has placed its hand/caused its Common Seal to be affixed hereunto and to two other of the same tenor on this é é é é é .20é

   The Common Seal of M/s (supplier)é é é é é é é é é é é é é é é é é é ... herein.

1. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   President/Managing Director/C.E.O.

2. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

The Common Seal of M/s. é é é é é é é é é é é é é é é (Local Agent) herein.

é é é é é é é é é é é é é é é .
President/Managing Director/C.E.O.

é é é é é é é é é é é é é é é .
Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

3.1.1 Short packing
3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
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/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.

3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 **Withdrawal from use of Item due to quality failure.**

a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 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 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

hereto é)
é .)
é .)
é .)

Authorized signatory

Authorized signatory

Witnesses

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

KM/ns

ANNEX – 1

BID NO. : DHS/SUS/WW/100/24
DATE OF ISSUE : 25TH JULY 2023
CLOSING DATE & TIME : 04TH SEPTEMBER 2023 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka
2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
3. 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.
4. The volume of the total quantity of each item should be given in cubic meters (m^3)
5. **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.**
6. **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 Bids" of the bid document in this regard.**
7. If awarded supplier is unable to adhere 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.
8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
9. We reserve the right to reject offers which do not comply above.
10. The offer should be valid up to 02.03.2024.

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

(a) Part A-General Order Conditions (GOC) 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, manufacturer²s name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.

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

3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge 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 consumables; 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 it²s sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

   The supplier²s 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, repair and 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 in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 surgical items. (Shelf life of 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 1/6th (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 Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia 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 Pharmaceuticals 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 manufacturer²s/Supplier²s 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 charged the total **cost involved for MSD, of the quality failed supplies** with 25% administrative charge 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 and 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 and 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).

15. **Pack size, Labeling & Packaging**

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

16. In respect of bulk packs (not applicable for blister/strip packs), ³DHS´ 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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots **or** when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)**

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue Nos of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and ³STATE LOGO´ of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Non-consumables) & date of Manufacture (in any form as ³Year & Month´ or ³No Exp.´), in the innermost pack and supplier²s invoice.

18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ³STATE LOGO´ of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
Format shall be according to Code 128 or 2D standards.
Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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

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

Storage Conditions & Temperature

22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30^0c +/- 2^0c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

23. Maintenance of Cold Chain;

a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer²s 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 break² is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

24. In respect of the products requiring controlled temperature storage (Eg. < 25^0c, 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

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

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.

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

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

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its² 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 charge.

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its² amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

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

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier²s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.
As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

30. The extension of L/C²s overstepping delivery schedules in the Indent/PO/its² amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its² amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No²s, 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.

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

35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD 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 condition No. 27 will not be applicable.

Common conditions

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

37. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. **(eg. As in conditions No. 08,05,10,13)**

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

(b) Part B-Special Order Conditions (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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

(i) -

(ii) -

(iii) -

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

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

- 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.

- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.

- 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.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name And designation of the signatory) or by the representative. Representatives submit 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.

- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.

- **All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.**

BID NO: DHS/SUS/WW/100/24 CLOSING ON : 04.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/S/00208

ITEM NO	SR NO	ITEM	QTY Nos.	DELIVERY	Bid Bond value (LKR)
2	10301004	Non absorbable Synthetic Monofilament Suture Polypropylene, BP/USP Standard or Equivalent Standard,Gauge size 0, blue, 70cm - 90cm length, attached to a 28mm - 30mm half circle round bodied eyeless needle, sterile.	500	250-Jan/2024 250-Jun/2024	N/A
3	10301103	Surgical Suture, Non absorbable Monofilament Polypropylene Suture BP/USP Standard or Equivalent Standards, Gauge size 1, approx.75cm length attached to a 30mm (approx.) half circle heavy eyeless needle and sterile.	1,000	500-Jan/2024 500-Jun/2024	N/A
4	10400020	Vascular Tape, for occlusion of veins, red, radiopaque silicone, 30cm - 40cm length, sterile.	1,300	600-Jan/2024 700-Jun/2024	N/A
6	10600709	Surgical Suture, Non absorbable Coated Braided Silk Suture BP/USP Standard or Equivalent Standards, Gauge size 4/0, black, 75cm length attached to a 16mm (approx.) half circle round bodied eyeless needle and sterile. Each sterile suture packed individually in a peel/tear open foil pack and labelled accordingly for cardiothoracic use.	3,600	2,000-Jan/2024 1,600-Jun/2024	N/A

ORDER LIST NUMBER: 2024/SPC/Z/C/S/00308

ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	10300704	Surgical Suture, Non absorbable Monofilament polypropylene Suture BP/USP Standard or Equivalent Standards, Gauge size 4/0, 90cm length with each end attached to a 16mm (approx.) half circle taper point eyeless needle(double arm) and sterile.Each sterile suture packed individually in peel open foil and peel/tear open over wrap and labeled accordingly.	6,500	3,500-Jan/2024 3,000-Jun/2024	50,050.00

Packing: 1 Nos.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value mentioned in the item list. Bid Bond should be submitted with valid up to 01.04.2024 together with the tender

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

1. Page 10 Condition No. 20. a
   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.

Contract:
The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.
Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.
A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) **Clause 8**

(a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.

(b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) **Clause 12**

Amend as **REIMBURSEMENT**

12.1 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 labeling.

(3) **Clause 16.6**

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) **Clause 28.0**

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in www.spc.lk Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX – 1

ANNEX – 1

BID NO/ BID REFERENCE :
(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :
(SRI LANKAN TIME)

ORDER LIST NO :

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR …….. or USD …….. to be submitted along with the Bid Bond valid till …… (date)

Bid validity period : Bid should be valid till …….. (date)

Bid Document Fee : ……
(should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.
2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of *1957)*
"Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA
AGREEMENT

SPC Ref. No Date :
Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05, 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 **FIRST PART**

AND

M/s ……………………………………………………………………………………..
…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 **SECOND PART.**

AND

M/s ……………………………………………………………………………………..
…business under the time, style and firm of a company duly registered and carrying business (hereinafter called "the Local Agent" 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 **THIRD PART.**

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s ………… ………………………………………………………… for the supply and delivery of………………………………………… as per the attached indent for ………… marked SPC ……………………… . Dated ……………………… and M/s ……………………………………… will act as local agent of the supplier for all matters arising out of supplies here of.

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. The following documents: -

   (a) Conditions of Contract marked – Annex 1
   (b) Bid Documents marked – Annex 2
   (c) Copy of Indent marked – Annex 3

(hereinafter called ñthe Contract Documentsò) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial 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, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

   The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

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

   In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and é é é é é é é é é and é é é é é é é é é é . of State Pharmaceuticals Corporation have set their hands and Supplier and the Local Agent has placed its hand/caused its Common Seal to be affixed hereunto and to two other of the same tenor on this é é é é é .20é

   The Common Seal of M/s (supplier)é é é é é é é é é é é é é é é é é é ... herein.

1. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   President/Managing Director/C.E.O.

2. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

The Common Seal of M/s. é é é é é é é é é é é é é é é (Local Agent) herein.

é é é é é é é é é é é é é é é .
President/Managing Director/C.E.O.

é é é é é é é é é é é é é é é .
Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

3.1.1 Short packing
3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
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/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.

3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or itôs fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 **Withdrawal from use of Item due to quality failure.**

a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 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 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

hereto é)
é .)
é .)
é .)

Authorized signatory

Authorized signatory

Witnesses

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

KM/ns

ANNEX – 1

BID NO. : DHS/S/WW/87/24
DATE OF ISSUE : 25TH JULY 2023
CLOSING DATE & TIME : 05TH SEPTEMBER 2023 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka
2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
3. 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.
4. The volume of the total quantity of each item should be given in cubic meters (m^3)
5. **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.**
6. **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 Bids" of the bid document in this regard.**
7. If awarded supplier is unable to adhere 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.
8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
9. We reserve the right to reject offers which do not comply above.
10. The offer should be valid up to 03.03.2024

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

(a) Part A-General Order Conditions (GOC) 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, manufacturer²s 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 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 consumables; 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 it²s sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

   The supplier²s 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, repair and 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 in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 of 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, 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 Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia 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 Pharmaceuticals 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 manufacturer²s 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 charged 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 and 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 and testing charges, etc, will be recovered from the supplier.

14. Consignments supplied to MSD violating the storage conditions indicated on product labels and/or product information leaflet (as accepted for product registration at NMRA), shall be considered as quality affected consignments and quality assurance of such consignments shall be carried out by post-delivery testing at government / semi government laboratory in Sri Lanka or at an accredited laboratory (foreign/local). All the expenses on such an event, including storage cost shall be borne by the supplier. If found to be quality affected the consignment will be treated as quality failed (as clause No.11).

Pack size, Labeling & Packaging

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

16. In respect of bulk packs of all pharmaceuticals (not applicable for blister/strip packs), ³DHS´ 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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots **or** when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)**

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue No.s of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and ³STATE LOGO´ of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Non-consumables) & date of Manufacture (in any form as ³Year & Month´ or ³No Exp.´), in the innermost pack and supplier²s invoice.

18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ³STATE LOGO´ of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
Format shall be according to Code 128 or 2D standards.
Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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

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

Storage Conditions & Temperature

22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30^0c +/- 2^0c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

23. Maintenance of Cold Chain;

a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer²s 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 break² is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

24. In respect of the products requiring controlled temperature storage (Eg. < 25^0c, 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

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

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.

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

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

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its² latest amended delivery schedules.

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

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its² amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

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

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m.

In the event of failure to meet this deadline due to supplier²s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.
As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

30. The extension of L/C²s overstepping delivery schedules in the Indent/PO/its² amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its² amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No²s, 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.

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

35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD 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 condition No. 27 will not be applicable.

Common conditions

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

37. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. **(eg. As in conditions No. 08,05,10,13)**

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

(b) Part B-Special Order Conditions (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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.
- In the event of an award made to you on this tender, SPC reserve the right to cancel/suspend the procuring of said order in any stage, if you would be placed the defaulted supplier's list due to quality failure found in your previous supplies made to SPC or non compliance of contractual agreement.
- 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.
- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.
- 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.
- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name and designation of the signatory) or by the representative. Representatives submit 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.
- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.
- **All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.**

BID NO: DHS/S/WW/87/24 CLOSING ON : 05.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/A/R/S/00242

ITEM NO	SR NO	ITEM	QTY Nos.	DELIVERY	Bid Bond value (LKR)
1	13300904	Thoracic Drainage (Chest Drainage) Catheter, for post-operative pleural drainage, size 28Fr, angled, 45cm (approx.) length, with 6 eyes, open distal end, with radiopaque line throughout the length, with 2cm markings, made from surgical quality PVC, with connector, sterile.	200	100-Jan/2024 100-Jun/2024	N/A
2	13300905	Thoracic Drainage (Chest Drainage) Catheter, for post-operative pleural drainage, size 32Fr, angled, 45cm (approx.) length, with 6 eyes, open distal end, with radiopaque line throughout the length, with 2cm markings, made from surgical quality PVC, with connector, sterile.	400	200-Jan/2024 200-Jun/2024	N/A
3	13301103	Thoracic Drainage (Chest Drainage) Catheter, for post-operative pleural drainage, size 24Fr, straight, 45cm (approx.) length, with 6 eyes, open distal end, with radiopaque line throughout the length, with 2cm markings, made from surgical quality PVC, with connector, sterile.	800	400-Jan/2024 400-Jun/2024	N/A
4	13301104	Thoracic Drainage (Chest Drainage) Catheter, for post-operative pleural drainage, size 28Fr, straight, 45cm (approx.) length, with 6 eyes, open distal end, with radiopaque line throughout the length, with 2cm markings, made from surgical quality PVC, with connector, sterile.	3,000	2000-Jan/2024 1000-Jun/2024	43,680.00
5	13301105	Thoracic Drainage (Chest Drainage) Catheter, for post-operative pleural drainage, size 32Fr, straight, 45cm (approx.) length, with 6 eyes, open distal end, with radiopaque line throughout the length, with 2cm markings, made from surgical quality PVC, with connector, sterile.	3,000	2000-Jan/2024 1000-Jun/2024	43,680.00
6	13301106	Thoracic Drainage (Chest Drainage) Catheter, for post-operative pleural drainage, size 36Fr, straight, 45cm (approx.) length, with 6 eyes, open distal end, with radiopaque line throughout the length, with 2cm markings, made from surgical quality PVC, with connector, sterile.	200	100-Jan/2024 100-Jun/2024	N/A
7	13302901	Diathermy Quiver, for holding sucker handles and diathermy probes etc.	6	6-Jan/2024	N/A

8	13303101	Pleural Drainage System (water sealed drainage system), adult,comprising 1800ml - 2000ml graduated PVC bottle with handle, tubing set with connector and inlet/outlet port with cap, sterile.	2,600	1600-Jan/2024 1000-Jun/2024	68,760.00
9	13304000	Diathermy Scotch Pad, with rear sticker, sterile.	800	400-Jan/2024 400-Jun/2024	N/A
10	13401102	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 20Fr, sterile.	10	10-Jan/2024	N/A
11	13401103	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 22Fr, sterile.	10	10-Jan/2024	N/A
12	13401104	Wire Reinforced Venous Return Catheter, straight, with open tapered tip,size 24Fr, sterile.	20	10-Jan/2024 10-Jun/2024	N/A
13	13401105	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 26Fr, sterile.	100	50-Jan/2024 50-Jun/2024	37,440.00
14	13401106	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 28Fr, sterile.	200	100-Jan/2024 100-Jun/2024	74,880.00
15	13401107	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 30Fr, sterile.	170	100-Jan/2024 70-Jun/2024	63,650.00
16	13401108	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 32Fr, sterile.	50	30-Jan/2024 20-Jun/2024	N/A
17	13401109	Wire Reinforced Venous Return Catheter, straight, with open tapered tip, size 34Fr, sterile.	10	10-Jan/2024	N/A
18	13401200	Wire Reinforced two stage Venous Return Cannula with obturator, open tapered tip, size 32Fr/40Fr, sterile.	20	20-Jan/2024	N/A
19	13401505	Aortic Perfusion Cannula, angled, with cap, size 18Fr, sterile.	10	10-Jan/2024	N/A
20	13401605	Aortic Perfusion Cannula, angled, with shoulder and a cap, size 21Fr, sterile.	170	100-Jan/2024 70-Jun/2024	N/A
21	13401606	Aortic Perfusion Cannula, angled, with a suture ring with shoulder and a cap, size 24Fr, sterile.	820	400-Jan/2024 420-Jun/2024	115,130.00

Packing: 1 Nos.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value mentioned in the item list. Bid Bond should be submitted with valid up to 03.04.2024 together with the tender

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

1. Page 10 Condition No. 20. A

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.

Contract:
The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.

Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.

A non refundable fee of Rs. 12,500/= + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) **Clause 8**

(a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.

(b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) **Clause 12**

Amend as **REIMBURSEMENT**

12.1 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 labeling.

(3) **Clause 16.6**

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) **Clause 28.0**

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in www.spc.lk Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX – 1

ANNEX – 1

BID NO/ BID REFERENCE :
(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :
(SRI LANKAN TIME)

ORDER LIST NO :

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR …….. or USD …….. to be submitted along with the Bid Bond valid till …… (date)

Bid validity period : Bid should be valid till …….. (date)

Bid Document Fee : ……
(should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.
2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of *1957)*
"Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka.
Telephone (00)94-1-2335008 Fax: (00)94-11-2582495
E-mail: dgmsurgical@spc.lk or mgrsurgical@spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA
AGREEMENT

SPC Ref. No Date :
Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05, 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 **FIRST PART**

AND

M/s ……………………………………………………………………………..
…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 **SECOND PART.**

AND

M/s ……………………………………………………………………………..
…business under the time, style and firm of a company duly registered and carrying business (hereinafter called "the Local Agent" 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 **THIRD PART.**

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s ………………………………………………………………………………………… for the supply and delivery of………………………………………… as per the attached indent for ……………… marked SPC ………………………………. Dated ……………………………… and M/s ………………………………………………… will act as local agent of the supplier for all matters arising out of supplies here of.

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. The following documents: -

   (a) Conditions of Contract marked – Annex 1
   (b) Bid Documents marked – Annex 2
   (c) Copy of Indent marked – Annex 3

(hereinafter called ñthe Contract Documentsò) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial 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, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

   The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

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

   In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and é é é é é é é é é and é é é é é é é é é é . of State Pharmaceuticals Corporation have set their hands and Supplier and the Local Agent has placed its hand/caused its Common Seal to be affixed hereunto and to two other of the same tenor on this é é é é é .20é

   The Common Seal of M/s (supplier)é é é é é é é é é é é é é é é é é é é ... herein.

1. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   President/Managing Director/C.E.O.

2. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

The Common Seal of M/s. é é é é é é é é é é é é é é é (Local Agent) herein.

é é é é é é é é é é é é é é é .
President/Managing Director/C.E.O.

é é é é é é é é é é é é é é é .
Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

3.1.1 Short packing
3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
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/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.

3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or its fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 **Withdrawal from use of Item due to quality failure.**

a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 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 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

heretoé)
é .)
é .)
é .)

Authorized signatory

Authorized signatory

<u>Witnesses</u>

Signature Name, Address and ID No

1……………….. ……………………………………………

2………………… ……………………………………………

JT/ns

ANNEX – 1

BID NO. : DHS/SUS/WW/100/24
DATE OF ISSUE : 25TH JULY 2023
CLOSING DATE & TIME : 04TH SEPTEMBER 2023 AT 09.00 HOURS SRI LANKA TIME

Special Conditions for tendering :

1. Offers should be accompanied with the valid registration certificate issued by the National Medicine Regulatory Authority in Sri Lanka
2. Offered item should bear both our SR number and the Item number. However at the bid opening only the item numbers will be read out. Therefore price quoted should be shown against each item number.
3. 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.
4. The volume of the total quantity of each item should be given in cubic meters (m^3)
5. **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.**
6. **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 Bids" of the bid document in this regard.**
7. If awarded supplier is unable to adhere 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.
8. The original payment receipt has to be annexed to the offer. Offers without same will be rejected.
9. We reserve the right to reject offers which do not comply above.
10. The offer should be valid up to 02.03.2024.

CONDITIONS FOR SUPPLY OF SURGICAL ITEMS

(a) Part A-General Order Conditions (GOC) 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, manufacturer²s name, country of manufacture, country of origin, etc.) provided in the bid document by the supplier, which has been accepted by the procurement committee, and included in the Indent / Purchase Order (PO), issued by SPC.

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

3. Maintaining the validity of the product registration during the period of supply(delivery schedule), obtaining import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical 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 consignment, with deviations from certain tender conditions (eg: with regard to labeling/packaging or any other rectifiable defect at the time of receipt in Sri Lanka 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% administrative charge 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 consumables; 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 it²s sub components/articles supplied (eg: Special Instrument sets), unless otherwise agreed upon prior to awarding the tender.

   The supplier²s 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, repair and 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 in Sri Lanka/MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in 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 surgical items. (Shelf life of 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 1/6th (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 Pharmacopoeia Standards that are indicated in the item specifications, other Pharmacopoeia 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 Pharmaceuticals 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 manufacturer²s/Supplier²s 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 charged the total **cost involved for MSD, of the quality failed supplies** with 25% administrative charge 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 and 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 and 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).

15. **Pack size, Labeling & Packaging**

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

16. In respect of bulk packs (not applicable for blister/strip packs), ³DHS´ 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 purchase order quantity is less than 100,000 tablets/capsules, with deliveries in one/more lots **or** when an exemption is notified in the special order conditions of the relevant MSD order list (**This clause No. 16 is not applicable for all consumable and Non consumable Surgical and Laboratory Items)**

17. Each; innermost pack, vial/ampoule, pre-filled syringe or bottle, shall bear the item Description, SR No, Batch No/Lot no., Product Reference/Catalogue Nos of Surgical items), Date of Manufacture, Date of Expiry (of consumables only) and ³STATE LOGO´ of Government of Sri Lanka.

It is essential to include and exactly match the dates of Expiry (not applicable for Surgical Non-consumables) & date of Manufacture (in any form as ³Year & Month´ or ³No Exp.´), in the innermost pack and supplier²s invoice.

18. Description of the Item, SR No, Date of Manufacture, Date of Expiry, Batch No, Name and address of manufacturer and ³STATE LOGO´ of Sri Lanka Government shall be clearly marked on the outer covering of the individual/innermost pack containing the minimum unit of measure, including blister & strip cards and on the outer cover of the carton/box.
Any deviations of the Date of Manufacture (DOM)/ Date of Expiry(DOE)declared in the offer shall be approved by MSD and DOM & DOE shall consist of at least the year & month.

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

20. Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
Format shall be according to Code 128 or 2D standards.
Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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

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

Storage Conditions & Temperature

22. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30^0c +/- 2^0c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.

23. Maintenance of Cold Chain;

a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer²s 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 break² is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD / SPC in arranging the cold storage shall be recovered from the supplier.

d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.

e. The suppliers shall dispatch consignments of the items, which require coldchain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD and SPC, to Custom clear/store/receive such consignments shall be recovered from the supplier.

24. In respect of the products requiring controlled temperature storage (Eg. < 25^0c, 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

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

Contravening the above directions, if the delivery schedule is violated by the supplier for no fault of MSD/SPC/MOH and in the event MSD decides to accept any such consignment in full or part thereof, that is delivered after the due delivery date, Condition No. 27 on delayed deliveries, shall be applied.

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

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

(a). A penalty of 0.5% per day of the consignment value, calculated commencing from the 15th day up to 60th day delay from the due delivery date, as per the indent/PO or its² 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 charge.

28. (i). If any local purchases were to be made by MSD/SPC to ensure continuity of supply (due to noncompliance of Indent/PO/its² amended; delivery schedule); in the ensuing period inclusive of the grace period for delivery from due delivery date, extra expenditure incurred on such local purchases, over the landed cost of relevant SPC main order, shall be recovered from the supplier.

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

29. In respect of local manufacturers/ local suppliers, all deliveries shall be made only on week days excluding public holidays, also allowing adequate time to enable the completion of the receiving process at MSD stores before 3.30 p.m. In the event of failure to meet this deadline due to supplier²s fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per No. 27 (regarding defaulted consignment) of the conditions of supply.
As an alternative, supplier can request MSD to take over the consignment on the same day, subject to settling all other expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

30. The extension of L/C²s overstepping delivery schedules in the Indent/PO/its² amendments, shall not in any way affect the recovery of late delivery charges, as per Condition No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs/liquidated damages, relating/consequent to extension of L/C.

31. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Indent/PO/its² amendments) under the condition No. 27, any additional expenses caused to MSD or SPC in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

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

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

The product artwork or dimensional detail diagrams, product Catalogues and Catalog No²s, 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.

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

35. After releasing the Indent/PO or establishing L/C, the latest logistical position of manufacturing & supply on the Indent/PO, shall be updated biweekly through e-mails to SPC with a copy to MSD 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 condition No. 27 will not be applicable.

Common conditions

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

37. Administrative surcharge of 25%(on the value of goods), will be applied for tender condition violations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision. **(eg. As in conditions No. 08,05,10,13)**

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

(b) Part B-Special Order Conditions (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. and SR No. s, shall be indicated separately against each clause of SOC, with the counter signature of Director (MSD) to make it effective.

(i) -

(ii) -

(iii) -

Sufficient quantity of samples should be forwarded for evaluation.

Special Conditions

- Suppliers should submit all shipping documents including the Bill of lading or Air Way Bill to SPC at least 2-3 days prior to arrival of the consignments to prevent any delay in clearance.

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

- 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.

- Where a purchase for a particular item is being made for the first time from a supplier, or where there are previous quality failures on goods supplied by a Particular supplier payments will only be made upon testing the quality and standards of the goods and comparing the bulk supply with the samples provided along with the offer.

- 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.

- The bid submitted should be duly signed and endorsed by the Bidder/ Tenderer him self (with the name And designation of the signatory) or by the representative. Representatives submit 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.

- In the event of delivery of consignments deviating from given delivery schedule by MSD due to default of supplier and same is rejected due lack of storage space available at MSD warehouses, any resulting demurrage charges incurred shall be borne by the suppliers concerned.

- **All Shipment 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 vessels of the Ceylon Shipping Corporation do not call at the Port of Shipment or if they are not available for timely shipment of cargo. In which event the supplier should attach a waiver certificate issued by Ceylon Shipping Corporation on their Authorized Agent in the supplier's country.**

BID NO: DHS/SUS/WW/100/24 CLOSING ON : 04.09.2023 at 9.00 a.m.

ORDER LIST NUMBER: 2024/SPC/N/C/S/00208

ITEM NO	SR NO	ITEM	QTY Nos.	DELIVERY	Bid Bond value (LKR)
2	10301004	Non absorbable Synthetic Monofilament Suture Polypropylene, BP/USP Standard or Equivalent Standard,Gauge size 0, blue, 70cm - 90cm length, attached to a 28mm - 30mm half circle round bodied eyeless needle, sterile.	500	250-Jan/2024 250-Jun/2024	N/A
3	10301103	Surgical Suture, Non absorbable Monofilament Polypropylene Suture BP/USP Standard or Equivalent Standards, Gauge size 1, approx.75cm length attached to a 30mm (approx.) half circle heavy eyeless needle and sterile.	1,000	500-Jan/2024 500-Jun/2024	N/A
4	10400020	Vascular Tape, for occlusion of veins, red, radiopaque silicone, 30cm - 40cm length, sterile.	1,300	600-Jan/2024 700-Jun/2024	N/A
6	10600709	Surgical Suture, Non absorbable Coated Braided Silk Suture BP/USP Standard or Equivalent Standards, Gauge size 4/0, black, 75cm length attached to a 16mm (approx.) half circle round bodied eyeless needle and sterile. Each sterile suture packed individually in a peel/tear open foil pack and labelled accordingly for cardiothoracic use.	3,600	2,000-Jan/2024 1,600-Jun/2024	N/A

ORDER LIST NUMBER: 2024/SPC/Z/C/S/00308

ITEM NO	SR NO	ITEM	QTY	DELIVERY	Bid Bond value (LKR)
1	10300704	Surgical Suture, Non absorbable Monofilament polypropylene Suture BP/USP Standard or Equivalent Standards, Gauge size 4/0, 90cm length with each end attached to a 16mm (approx.) half circle taper point eyeless needle(double arm) and sterile.Each sterile suture packed individually in peel open foil and peel/tear open over wrap and labeled accordingly.	6,500	3,500-Jan/2024 3,000-Jun/2024	50,050.00

Packing: 1 Nos.

All tenderers should furnish an unconditional Bid Bond encashable on demand to the value mentioned in the item list. Bid Bond should be submitted with valid up to 01.04.2024 together with the tender

1. Page 9 Condition No. 19.b

Registrar of public contracts

This clause should be amended as awards over Sri Lanka rupees Five Million instead of (LKR) Ten Million.

1. Page 10 Condition No. 20. a
   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.

Contract:
The successful supplier should agree to enter into a contract/Agreement is applicable normally for awards which are over LKR 500,000.00 instead of 10.0 Million.
Bidding Document Fee- As per the guideline 6.1.1 (a) of the Government Procurement Guidelines 2006.
A non refundable fee of Rs. 3,000.00 + taxes should be paid in cash to SPC for each set of Tender Documents

Amendments of Bidding Document for Procurement of Surgical/Lab items

(1) **Clause 8**

(a) Bid Bonds to be submitted for each item (SR Number) when estimated value of each item exceeds LKR 01 Million.

(b) Value and validity applicable for the submission of Bid Bond for each item should be as indicated therein.

08.2 The Bid Bond should be valid for at least 30 days beyond the validity of the Bid.

(c) To be deleted.

(2) **Clause 12**

Amend as **REIMBURSEMENT**

12.1 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 labeling.

(3) **Clause 16.6**

Any request for a price increment due to LKR depreciating against foreign currency will not be accepted and such bid will be rejected at the preliminary stage of bid evaluation.

(4) **Clause 28.0**

Evaluation will be done as per Bid Form (Annex – II B) and Bid Evaluation Summary Sheet. (Annex – II C, to be submitted along with the Bid and a soft copy as per instruction given in www.spc.lk Web Site)

(5) 2nd column of Annex II B amend as "FULL DESCRIPTION OF ITEM OFFERED THE STANDARD & STORAGE CONDITION"

(6) Annex – 1 to be amend as follows.

SPECIMEN OF ANNEX – 1

ANNEX – 1

BID NO/ BID REFERENCE :
(TENDER NO)

DATE OF ISSUE :

CLOSING DATE & TIME :
(SRI LANKAN TIME)

ORDER LIST NO :

SR No	Item Description/ Specifications	Quantity	Delivery Schedule

Amount of Bid Bond : LKR …….. or USD …….. to be submitted along with the Bid Bond valid till …… (date)

Bid validity period : Bid should be valid till …….. (date)

Bid Document Fee : ……
(should be paid in cash to SPC for each set of Bid Documents)

MSD CONDITIONS OF SUPPLY

1.
2.

Abbreviations : SPC ; State Pharmaceuticals Corporation, MSD; Medical Supplies Division

Annex VI

SPECIMEN OF CONTRACT FORM (IB)

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

(Established under the State Industrial Corporation Act, No. 49 of *1957)*
"Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05,Sri Lanka.
Telephone (00)94-1-326227 or 2391538 Fax: (00)94-11-2446204
E-mail: dgmcomm@spc.lk or managerimp2spc.lk

DEMOCRATIC SOCIALISTREPUBLIC OF SRI LANKA
AGREEMENT

SPC Ref. No Date :
Bid Ref.

This **AGREEMENT** made and entered into between the State Pharmaceuticals Corporation of Sri Lanka, a Corporation established under the State Industrial Corporation Act. No. 49 of 1957 and having its Head Office at "Mehewara Piyasa", 16th Floor, No. 41, Kirula Road, Colombo 05, 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 **FIRST PART**

AND

M/s ………………………………………………………………………………………..
…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 **SECOND PART.**

AND

M/s ………………………………………………………………………………………..
…business under the time, style and firm of a company duly registered and carrying business (hereinafter called "the Local Agent" 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 **THIRD PART.**

Whereas the State Pharmaceuticals Corporation has accepted the bid of M/s ………………
…………………………………………………………………… for the supply and delivery of……………………………………………… as per the attached indent for ……………… marked SPC ……………………………… . Dated ……………………………… and M/s ……………………………………………… will act as local agent of the supplier for all matters arising out of supplies here of.

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. The following documents: -

   (a) Conditions of Contract marked – Annex 1
   (b) Bid Documents marked – Annex 2
   (c) Copy of Indent marked – Annex 3

(hereinafter called ñthe Contract Documentsò) showing and describing the nature and scope of the agreement duly signed by three parties shall be deemed to form and be read and construed as part and partial 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, and the local agent will be responsible for all the matters regarding the supplies which do not confirm to required standard..

   The supplier shall be paid for such supply and delivery of the goods according to the Indent marked and in the manner and at the times hereinafter specified.

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

   In witness whereof the State Pharmaceuticals Corporation has caused its Common Seal to be affixed and é é é é é é é é é and é é é é é é é é é é . of State Pharmaceuticals Corporation have set their hands and Supplier and the Local Agent has placed its hand/caused its Common Seal to be affixed hereunto and to two other of the same tenor on this é é é é é .20é

   The Common Seal of M/s (supplier)é é é é é é é é é é é é é é é é é é ... herein.

1. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   President/Managing Director/C.E.O.

2. ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ¥ ..

   Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

The Common Seal of M/s. é é é é é é é é é é é é é é é (Local Agent) herein.

é é é é é é é é é é é é é é é .
President/Managing Director/C.E.O.

é é é é é é é é é é é é é é é .
Director

Witnesses

Signature	Name, Address and ID No./Passport No.
1. é é é é é é é é é é é .	é é é é é é é é é é é é é é é ..
2. é é é é é é é é é é é .	é é é é é é é é é é é é é é é é

CONDITIONS OF CONTRACT

3.FREE REPLACEMENT /REIMBURSEMENT

3.1 SPC reserves the right to call for Free Replacement/Reimbursement in the event of

3.1.1 Short packing
3.1.2 Loss/damage or deterioration of goods supplied (within shelf-life if applicable)
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/or quality standards to the satisfaction of Medical Supplies Division of Sri Lanka/ State Pharmaceuticals Corporation of Sri Lanka.

3.2 In the event of a quality problem, Batch samples would be tested by SPC its authorized personnel at the NMQAL or SPC Quality Assurance Laboratory or any other Quality Assurance Laboratory nominated by SPC or itôs fitness for use will be determined by and expert Committee appointed by the relevant authority.

3.3 **Withdrawal from use of Item due to quality failure.**

a) In case of batch withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire batch quantity supplied.
b) In case of product withdrawal due to quality failure, the supplier/ manufacturer shall reimburse the value of entire product quantity supplied.
c) In the event of either a) or b) above the supplier/ manufacturer shall be surcharged additional 25% of the total value concerned as administrative cost.

Samples from the available batches will be retained by SPC and the balance will be destroyed by SPC in the presence of the Local Agent and a certificate of destruction issued by SPC.

The supplier and the Local Agent agreed to reimburse the SPC the landed cost and an additional 25% surcharge of the total quantity supplied.

20. FORCE MAJEURE

20.1 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 7 working days of receipt of same in writing. Parties however shall endeavours to remove any obstacles to performance (when possible) and co-operate to remove the harmful effects as far as practicable.

21 . NOTICE

21.1 All notices given in respect of this contract shall be deemed to be sufficiently given if sent by registered post addressed to the parties at the respective addresses at the beginning hereof written.

The common seal of State Pharmaceuticals Corporation of Sri Lanka was affixed)

hereto é)
é .)
é .)
é .)

Authorized signatory

Authorized signatory

Witnesses

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

KM/ns

PROCUREMENT NOTICE - GLOBAL

STATE PHARMACEUTICALS CORPORATION OF SRI LANKA

The Chairman, Departmental Procurement Committee of the State Pharmaceuticals Corporation of Sri Lanka will receive sealed bids for supply of following items to the Ministry of Health.

Bid Number	Closing Date & Time	Item Description	Date of issuing of Bid Documents	Non-refundable Bid Fee (LKR)
DHS/SUS/WW/129/22	04.09.2023 at 9.00 am	Activated Clotting Time Tube, for whole blood, compatible for Hemochrone ACT machine	25.07.2023	12,500/- + taxes
DHS/SUS/WW/100/24	04.09.2023 at 9.00 am	Non absorbable Synthetic Monofilament Suture, Surgical Suture and Vascular Tape	25.07.2023	3,000/- + taxes
DHS/SUS/WW/101/24	04.09.2023 at 9.00 am	Wire Instrument Set, External Fixation Instrument Set and LRS Limb Reconstruction System.	25.07.2023	35,000/- + taxes
DHS/S/WW/86/24	05.09.2023 at 9.00 am	Endoscopic Accessories	25.07.2023	12,500/- + taxes
DHS/S/WW/87/24	05.09.2023 at 9.00 am	Cardio-Thoracic (Surgery) Consumable Items	25.07.2023	12,500/- + taxes

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

Wherever necessary 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 authorized representatives will be permitted to be present at the time of opening of Bids.

Contd….2/-

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.

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On behalf of
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