



TENDER DOCUMENT

Procurement of Health Sector Goods (Surgical Consumables)

Single-Stage: One-Envelope Tendering Procedure

National Competitive Tendering Procurement Method

Procurement of Cochlear Implants and Accessories

Purchaser : Ministry of Health

Project : Emergency Health Components of: (i) Support to Colombo
Urban Regeneration Project (SCURP)- Loan No. L0081A and (ii)
Reduction of Landslide Vulnerability by Mitigation Measures
Project (RLVMMP)- Loan No. L0124A

Country : Sri Lanka

Tender No : HSRP/PMU/PRO/G/MS/S/14

Issued on : 03.11.2024

Abbreviations

AIIB	Asian Infrastructure Investment Bank
GOSL	Government of Sri Lanka
MOH	Ministry of Health
MSD	Medical Supplies Division
NMRA	National Medicines Regulatory Authority
NMQAL	National Medicines Quality Assurance Laboratory
GCC	General Conditions of Contract
ITT	Instructions to Tenderers
PIR	Procurement Instructions for Recipients
SCC	Special Conditions of Contract
SPD	Standard Procurement Document
SPN	Specific Procurement Notice
TDS	Tender Data Sheet
TS	Technical Specifications



Specific Procurement Notice (SPN)

Procurement of Health Sector Goods

Purchaser : Ministry of Health
Project : Emergency Health Components of: (i) Support to Colombo Urban Regeneration Project (SCURP)- Loan No. L0081A and (ii) Reduction of Landslide Vulnerability by Mitigation Measures Project (RLVMMP)- Loan No. L0124A
Contract : Procurement of Cochlear Implants and Accessories
Country : Sri Lanka
Tender No : HSRP/PMU/PRO/G/MS/S/14
Issued on : 03.11.2024

1. Government of Democratic Socialistic Republic of Sri Lanka has received financing from the Asian Infrastructure Investment Bank (AIIB or the Bank) toward the cost of the Emergency Health Components of: (i) SCURP; and (ii) RLVMMP under Ministry of Health and intends to apply part of the proceeds toward the payments for purchase of medical supplies (Pharmaceuticals, Surgical Consumables & Laboratory Items).
2. The Chairman, Project Procurement Committee of Ministry of Health invites sealed Tenders from qualified and eligible medical suppliers for **Procurement of Cochlear Implants and Accessories** as specified in the Schedule of Requirements under one single tender package as follows.

Item No	SR No	Item	Unit	Quantity
1	13201301	Cochlear Implants with Accessories.	Nos	150

Tenderers shall submit tenders for 100% of the quantity to be qualified for further evaluation.

3. Tendering will be conducted through National Competitive Tendering [NCT] as specified in the AIIB Directive on Procurement Instructions for Recipients (July 26, 2024) and is open to all eligible Tenderers.
4. Interested eligible Tenderers may obtain further information from Senior Procurement Officer, Emergency Health Components of: (i) SCURP; and (ii) RLVMMP under Ministry of Health and inspect the Tender Document during business day office hours [9.00 am to 3.00 pm] at the address given below.

5. The Tender Document in English may be obtained/purchased by interested Tenderers upon the submission of a written request to the address below or through an electronic portal and upon payment of a nonrefundable fee of LKR. 35,000.00. The method of payment will be Bank Deposit to the Account No 7040690 (Account Name: Emergency Assistance of USD 100Mn for the Procurement of Essential Pharmaceuticals and Medical Supplies, Bank of Ceylon, Regent Street, Colombo 10, Sri Lanka) The document will be sent by post, courier or hand over at the address given below. (Courier charges to be borne by the Tenderer) if so desired by the Tenderer. The complete set of SPD can also be downloaded from the website (<https://www.hsep.lk/index.php/aiib/projects-tenders/tenders>).

However, the Tenderer is required to provide evidence of payment of the required fee along with the Tender submission.

6. Tenders must be delivered to the address below on or before **18th November 2024 at 10.00 am**. Electronic tendering will not be permitted. Late Tenders will be rejected. Tenders will be publicly opened in the presence of the Tenderers' designated representatives and anyone who chooses to attend at the address below on **18th November 2024 at 10.00 am**.
7. A Tender Security shall be required for the amount specified in ITT 19.1 of the Tender Document in the currencies and forms specified as therein.

LKR	4,000,000.00
	<i>Or Equivalent in USD</i>

8. The address(es) referred to above is (are):

Project Director

Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP

81/4, Rosmead Place, Colombo 07, Sri Lanka

Telephone : +94 112 683 547

Email : hsrp.pmu.aiib@gmail.com

Web : www.hsep.lk

Table of Contents

PART 1 – Tendering Procedures	5
Section I - Instructions to Tenderers	7
Section II - Tender Data Sheet (TDS)	41
Section III - Evaluation and Qualification Criteria	47
Section IV - Tendering Forms	55
Section V - Eligible Countries.....	79
PART 2 – Supply Requirements	82
Section VII - Schedule of Requirements	83
PART 3 - Contract	111
Section VIII - General Conditions of Contract	113
Section IX - Special Conditions of Contract	136
Section X - Contract Forms	143

PART 1 – Tendering Procedures

Section I - Instructions to Tenderers

Contents

A General	9
1. Scope of Tender	9
2. Source of Funds.....	9
3. Prohibited Practices.....	10
4. Eligible Tenderers.....	10
5. Eligible Goods and Related Services	13
B. Contents of Tendering Document.....	13
6. Sections of Tendering Document	13
7. Clarification of Tendering Document.....	14
8. Amendment of Tendering Document.....	14
C. Preparation of Tenders	15
9. Cost of Tendering.....	15
10. Language of Tender	15
11. Documents Comprising the Tender	15
12. Letter of Tender and Price Schedules.....	16
13. Alternative Tenders	16
14. Tender Prices and Discounts.....	16
15. Currencies of Tender and Payment	19
16. Documents Establishing the Eligibility and Conformity of the Goods and Related Services	19
17. Documents Establishing the Eligibility and Qualifications of the Tenderer	21
18. Period of Validity of Tenders	21
19. Tender Security	22
20. Format and Signing of Tender	24
D. Submission and Opening of Tenders	25
21. Sealing and Marking of Tenders	25
22. Deadline for Submission of Tenders.....	25
23. Late Tenders.....	26
24. Withdrawal, Substitution, and Modification of Tenders.....	26
25. Tender Opening	26
E. Evaluation and Comparison of Tenders.....	28
26. Confidentiality.....	28
27. Clarification of Tenders.....	28
28. Deviations, Reservations, and Omissions	29

29. Determination of Responsiveness	29
30. Nonconformities, Errors and Omissions	30
31. Correction of Arithmetical Errors	30
32. Conversion to Single Currency	31
33. Margin of Preference	31
34. Evaluation of Tenders	31
35. Comparison of Tenders.....	33
36. Abnormally Low Tenders	33
37. Qualification of the Tenderer	33
38. Purchaser’s Right to Accept Any Tender, and to Reject Any or All Tenders	34
39. Standstill Period	34
40. Notification of Intention to Award	34
F. Award of Contract	35
41. Award Criteria	35
42. Purchaser’s Right to Vary Quantities at Time of Award	35
43. Notification of Award.....	35
44. Debriefing by the Purchaser	36
45. Signing of Contract.....	37
46. Performance Security	38
47. Procurement Related Complaint	38

Section I - Instructions to Tenderers

[NCT]

A General

- 1. Scope of Tender**
- 1.1 In connection with the Specific Procurement Notice - Request for Tenders (RFT), specified **in the Tender Data Sheet (TDS)**, the Purchaser, **as specified in the TDS**, issues this Tendering document for the supply of Goods (pharmaceuticals, laboratory items, surgical consumables) and Related Services incidental there to as specified in Section VII, Schedule of Requirements. The name, identification, and number of lots (contracts) of this RFT are specified **in the TDS**.
- 1.2 Throughout this tendering document:
- (a) the term “in writing” means communicated in written form (e.g., by mail, e-mail, fax, including if specified **in the TDS**, 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 Recipient. It excludes the Recipient’s official public holidays.
- 2. Source of Funds**
- 2.1 The Recipient specified **in the TDS** has received financing (hereinafter called “funds”) from the Asian Infrastructure Investment Bank (hereinafter called “AIIB” or “the Bank”) in an amount specified **in TDS**, toward the project named **in TDS**. The Recipient intends to apply a portion of the funds to eligible payments under the contract for which this tendering document is issued.
- 2.2 Payment by the Bank will be made only at the request of the Recipient and upon approval by the Bank in accordance with the terms and conditions of the Loan Agreement. The Loan Agreement prohibits a withdrawal from the Loan 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 Recipient shall derive any rights from the Loan Agreement or have any claim to the proceeds other Loan

3. Fraud and Corruption

- 3.1 The Bank requires compliance with the Bank's Policy on Prohibited Practices as set forth in Section VI.
- 3.2 In further pursuance of this policy, Tenderer 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, tender submission, proposal submission, and contract performance (in the case of award), and to have them audited by auditors appointed by the Bank.

4. Eligible Tenderers

- 4.1 A Tenderer may be a firm that is a private entity, a state-owned enterprise or institution subject to ITT 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 Tendering process and, in the event the JV is awarded the Contract, during contract execution. Unless specified **in the TDS**, there is no limit on the number of members in a JV.
- 4.2 A Tenderer shall not have a conflict of interest. Any Tenderer found to have a conflict of interest shall be disqualified. A Tenderer may be considered to have a conflict of interest for the purpose of this Tendering process, if the Tenderer:
- (a) directly or indirectly controls, is controlled by or is under common control with another Tenderer; or
 - (b) receives or has received any direct or indirect subsidy from another Tenderer; or
 - (c) has the same legal representative as another Tenderer; or
 - (d) has a relationship with another Tenderer, directly or through common third parties, that puts it in a

position to influence the Tender of another Tenderer, or influence the decisions of the Purchaser regarding this Tendering 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 Tender; or
- (f) or any of its affiliates has been hired (or is proposed to be hired) by the Purchaser or Recipient 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 TDS ITT 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 Recipient (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 Tendering document or specifications of the Contract, and/or the Tender 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 Tendering process and execution of the Contract.

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

4.4 A Tenderer may have the nationality of any country, subject to the restrictions pursuant to ITT 4.8. A Tenderer shall be deemed to have the nationality of a country if the Tenderer 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 Tenderer that has been sanctioned by the Bank, in accordance with the provisions of the Bank's Policy on Prohibited Practices as described in Section VI, shall be ineligible to be prequalified for, initially selected for, tender 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 TDS.
- 4.6 Tenderers 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 Tenderer shall not be under suspension from Tendering by the Purchaser as the result of the operation of a Tender-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 Recipient'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 Recipient'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 Tenderer 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 Recipient from being awarded a contract is eligible to participate in this procurement, unless the Bank, at the

Recipient's request, is satisfied that the debarment; (a) relates to fraud or corruption or prohibited practices, 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 ITT, the term "goods" includes any goods that are the subject of this Request for Tenders, 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 Tendering Document

6. Sections of Tendering Document

- 6.1 The Tendering 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 ITT 8.

PART 1 Tendering Procedures

- Section I - Instructions to Tenderers (ITT)
- Section II - Tendering Data Sheet (TDS)
- Section III - Evaluation and Qualification Criteria
- Section IV -Tendering Forms
- Section V - Eligible Countries
- Section VI - Prohibited Practices

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 Tenders (RFT) issued by the Purchaser is not part of this Tendering 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 Tendering document in accordance with ITT 8. In case of any contradiction, documents obtained directly from the Purchaser shall prevail.
- 6.4 The Tenderer is expected to examine all instructions, forms, terms, and specifications in the Tendering document and to furnish with its Tender all information or documentation as is required by the Tendering document.
- 7. Clarification of Tendering Document**
- 7.1 A Tenderer requiring any clarification of the Tendering document shall contact the Purchaser in writing at the Purchaser's address specified **in the TDS**. The Purchaser will respond in writing to any request for clarification, provided that such request is received prior to the deadline for submission of Tenders within a period specified **in the TDS**. The Purchaser shall forward copies of its response to all Tenderers who have acquired the Tendering document in accordance with ITT 6.3, including a description of the inquiry but without identifying its source. If so, specified **in the TDS**, the Purchaser shall also promptly publish its response at the web page identified **in the TDS**. Should the clarification result in changes to the essential elements of the Tendering document, the Purchaser shall amend the Tendering document following the procedure under ITT 8 and ITT 22.2.
- 8. Amendment of Tendering Document**
- 8.1 At any time prior to the deadline for submission of Tenders, the Purchaser may amend the Tendering document by issuing addenda.
- 8.2 Any addendum issued shall be part of the Tendering document and shall be communicated in writing to all who have obtained the Tendering document from the Purchaser in accordance with ITT 6.3. The Purchaser shall also promptly publish the addendum on the Purchaser's web page in accordance with ITT 7.1.
- 8.3 To give prospective Tenderers reasonable time in which to take an addendum into account in preparing their Tenders, the Purchaser may, at its discretion, extend the

deadline for the submission of Tenders, pursuant to ITT 22.2.

C. Preparation of Tenders

- 9. Cost of Tendering** 9.1 The Tenderer shall bear all costs associated with the preparation and submission of its Tender, and the Purchaser shall not be responsible or liable for those costs, regardless of the conduct or outcome of the Tendering process.
- 10. Language of Tender** 10.1 The Tender, as well as all correspondence and documents relating to the Tender exchanged by the Tenderer and the Purchaser, shall be written in the language specified **in the TDS**. Supporting documents and printed literature that are part of the Tender may be in another language provided they are accompanied by an accurate translation of the relevant passages into the language specified **in the TDS**, in which case, for purposes of interpretation of the Tender, such translation shall govern.
- 11. Documents Comprising the Tender** 11.1 The Tender shall comprise the following:
- (a) **Letter of Tender** prepared in accordance with ITT 12;
 - (b) **Price Schedules**: completed in accordance with ITT 12 and ITT 14;
 - (c) **Tender Security or Tender-Securing Declaration**, in accordance with ITT 19.1;
 - (d) **Alternative Tender**, if permissible, in accordance with ITT 13;
 - (e) **Authorization**: written confirmation authorizing the signatory of the Tender to commit the Tenderer, in accordance with ITT 20.3;
 - (f) **Tenderer's Qualifications**: documentary evidence in accordance with ITT 17 establishing the Tenderer's qualifications to perform the Contract if its Tender is accepted;
 - (g) **Tenderer's Eligibility**: documentary evidence in accordance with ITT 17 establishing the Tenderer's eligibility to Tender;
 - (h) **Eligibility of Goods and Related Services**: documentary evidence in accordance with ITT 16,

establishing the eligibility of the Goods and Related Services to be supplied by the Tenderer;

- (i) **Conformity:** documentary evidence in accordance with ITT 16, that the Goods and Related Services conform to the Tendering document; and
- (j) any other document required **in the TDS.**

11.2 In addition to the requirements under ITT 11.1, Tenders 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 Tender shall be signed by all members and submitted with the Tender, together with a copy of the proposed Agreement.

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

12. Letter of Tender and Price Schedules

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

13. Alternative Tenders

13.1 Unless otherwise specified **in the TDS**, alternative Tenders shall not be considered.

14. Tender Prices and Discounts

14.1 The prices and discounts quoted by the Tenderer in the Letter of Tender 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 Tender in accordance with ITT 12.1 shall be the total price of the Tender, excluding any discounts offered.

14.4 The Tenderer shall quote any discounts and indicate the methodology for their application in the Letter of Tender, in accordance with ITT 12.1.

14.5 Prices quoted by the Tenderer shall be fixed during the Tenderer's performance of the Contract and not subject to variation on any account, unless otherwise specified

in the TDS. A Tender submitted with an adjustable price quotation shall be treated as nonresponsive and shall be rejected, pursuant to ITT 29. However, if in accordance with the TDS, prices quoted by the Tenderer shall be subject to adjustment during the performance of the Contract, a Tender 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 ITT 1.1, Tenders are being invited for individual lots (contracts) or for any combination of lots (packages). Unless otherwise specified **in the TDS**, 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. Tenderers wishing to offer discounts for the award of more than one Contract shall specify in their Tender the price reductions applicable to each package, or alternatively, to individual Contracts within the package. Discounts shall be submitted in accordance with ITT 14.4 provided the Tenders 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 TDS**.
- 14.8 Prices shall be quoted as specified in each Price Schedule included in Section IV, Tendering Forms. The disaggregation of price components is required solely for the purpose of facilitating the comparison of Tenders 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 Tenderer shall be free to use transportation through carriers registered in any eligible country, in accordance with Section V, Eligible Countries. Similarly, the Tenderer 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 Tenderer; 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 TDS;**
- (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 TDS;** 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 TDS;**
- (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 Tenderer; 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 TDS.**

(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 Tender and Payment

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

15.2 The Tenderer may express the Tender price in any currency. If the Tenderer 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 ITT 5, Tenderers shall complete the country-of-origin declarations in the Price Schedule Forms, included in Section IV, Tendering Forms.

16.2 To establish the conformity of the Health Sector Goods and Related Services to the Tendering document, the Tenderer shall furnish as part of its Tender 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 TDS**.

16.4 Unless the **TDS** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in the Purchaser's Country. A Tenderer who has already registered its Goods by the time of Tendering should submit a copy of the Registration Certificate with its Tender. Otherwise, the successful Tenderer, 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 Tenderer has complied with all the documentary requirements for registration as specified **in the TDS**.

16.5 The Purchaser shall at all times cooperate with the successful Tenderer 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 TDS**.

16.6 If the Goods of the successful Tenderer 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 Tenderer 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 Tenderer**

17.1 To establish Tenderer's eligibility in accordance with ITT 4, Tenderers shall complete the Letter of Tender, included in Section IV, Tendering Forms.

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

(a) that a Tenderer 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, Tendering 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 Tenderer not doing business within the Purchaser's Country (or for other reasons will not itself carry out service obligations), the Tenderer 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 Tenderer's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

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

**18. Period of Validity
of Tenders**

18.1 Tenders shall remain valid until the date **specified in the TDS** or any extended date if amended by the Purchaser in accordance with ITP 8. A Tender that is not valid until the date **specified in the TDS**, 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 Tender validity, the Purchaser may request Tenderers to extend the period of validity of their Tenders. The request and the responses shall be made in writing. If a Tender Security is requested in accordance with ITT 19, it shall also be extended for a corresponding period. A Tenderer may refuse the request without forfeiting its Tender Security. A Tenderer granting the request shall

not be required or permitted to modify its Tender, except as provided in ITT 18.3.

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

- (a) in the case of **fixed price** contracts, the Contract price shall be the Tender price adjusted by the factor specified **in the TDS**;
- (b) in the case of **adjustable price** contracts, no adjustment shall be made; or
- (c) in any case, Tender evaluation shall be based on the Tender price without taking into consideration the applicable correction from those indicated above.

19. Tender Security

19.1 The Tenderer shall furnish as part of its Tender, either a Tender-Securing Declaration or a Tender Security, as specified **in the TDS**, in original form and, in the case of a Tender Security, in the amount and currency specified **in the TDS**.

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

19.3 If a Tender Security is specified pursuant to ITT 19.1, the Tender Security shall be a demand guarantee in any of the following forms at the Tenderer'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 TDS**,

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 Tender submission, that a correspondent financial institution is not required. In the case of a bank guarantee, the Tender

Security shall be submitted either using the Tender Security Form included in Section IV, Tendering Forms, or in another substantially similar format approved by the Purchaser prior to Tender submission. The Tender Security shall be valid for twenty-eight (28) days beyond the original date of expiry of the Tender validity, or beyond any extended date if requested under ITT 18.2.

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

19.5 If a Tender Security is specified pursuant to ITT 19.1, the Tender Security of unsuccessful Tenderers shall be returned as promptly as possible upon the successful Tenderer's signing the Contract and furnishing the Performance Security pursuant to ITT 46.

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

19.7 The Tender Security may be forfeited:

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

(b) if the successful Tenderer fails to:

(i) sign the Contract in accordance with ITT45;
or

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

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

19.9 If a Tender Security is not required **in the TDS**, pursuant to ITT 19.1, and:

- (a) if a Tenderer withdraws its Tender during the period of Tender validity specified by the Tenderer on the Letter of Tender, or any extended date provided by the Tenderer; or
- (b) if the successful Tenderer fails to:
 - (i) sign the Contract in accordance with ITT 45; or
 - (ii) furnish a Performance Security in accordance with ITT 46;

the Recipient may, if provided for **in the TDS**, declare the Tenderer ineligible to be awarded a contract by the Purchaser for a period of time as stated **in the TDS**.

20. Format and Signing of Tender

- 20.1 The Tenderer shall prepare one original of the documents comprising the Tender as described in ITT 11 and clearly mark it "ORIGINAL." Alternative Tenders, if permitted in accordance with ITT 13, shall be clearly marked "ALTERNATIVE." In addition, the Tenderer shall submit copies of the Tender, in the number specified **in the TDS** and clearly mark them "COPY." In the event of any discrepancy between the original and the copies, the original shall prevail.
- 20.2 Tenderers shall mark as "CONFIDENTIAL" information in their Tenders 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 Tender shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Tenderer. This authorization shall consist of a written confirmation as specified **in the TDS** and shall be attached to the Tender. The name and position held by each person signing the authorization must be typed or printed below the signature. All pages of the Tender where entries or amendments have been made shall be signed or initialed by the person signing the Tender.
- 20.4 In case the Tenderer is a JV, the Tender 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 Tender.

D. Submission and Opening of Tenders

21. Sealing and Marking of Tenders

21.1 The Tenderer shall deliver the Tender in a single, sealed envelope (one-envelope Tendering process). Within the single envelope the Tenderer shall place the following separate, sealed envelopes:

- (a) in an envelope marked "ORIGINAL", all documents comprising the Tender, as described in ITT 11; and
- (b) in an envelope marked "COPIES", all required copies of the Tender; and,
- (c) if alternative Tenders are permitted in accordance with ITT 13, and if relevant:
 - (i) in an envelope marked "ORIGINAL – ALTERNATIVE TENDER", the alternative Tender; and
 - (ii) in the envelope marked "COPIES – ALTERNATIVE TENDER" all required copies of the alternative Tender.

21.2 The inner and outer envelopes shall:

- (a) bear the name and address of the Tenderer;
- (b) be addressed to the Purchaser in accordance with ITT 22.1;
- (c) bear the specific identification of this Tendering process indicated in ITT 1.1; and
- (d) bear a warning not to open before the time and date for Tender 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 Tender.

22. Deadline for Submission of Tenders

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

22.2 The Purchaser may, at its discretion, extend the deadline for the submission of Tenders by amending the

Tendering document in accordance with ITT 8, in which case all rights and obligations of the Purchaser and Tenderers previously subject to the deadline shall thereafter be subject to the deadline as extended.

- 23. Late Tenders**
- 23.1 The Purchaser shall not consider any Tender that arrives after the deadline for submission of Tenders, in accordance with ITT 22. Any Tender received by the Purchaser after the deadline for submission of Tenders shall be declared late, rejected, and returned unopened to the Tenderer.
- 24. Withdrawal, Substitution, and Modification of Tenders**
- 24.1 A Tenderer may withdraw, substitute, or modify its Tender 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 ITT 20.3, (except that withdrawal notices do not require copies). The corresponding substitution or modification of the Tender must accompany the respective written notice. All notices must be:
- (a) prepared and submitted in accordance with ITT 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 Tenders, in accordance with ITT 22.1.
- 24.2 Tenders requested to be withdrawn in accordance with ITT 24.1 shall be returned unopened to the Tenderers.
- 24.3 No Tender may be withdrawn, substituted, or modified in the interval between the deadline for submission of Tenders and the expiration of the period of Tender validity specified by the Tenderer on the Letter of Tender or any extension thereof.
- 25. Tender Opening**
- 25.1 Except as in the cases specified in ITT 23 and ITT 24.2, the Purchaser shall publicly open and read out in accordance with this ITT all Tenders received by the deadline at the date, time and place specified **in the TDS** in the presence of Tenderers’ designated representatives and anyone who choose to attend. All Tenderers, or their representatives and any interested party may attend a public opening. Any specific electronic Tender opening

procedures required if electronic Tendering is permitted in accordance with ITT 22.1, shall be as specified **in the TDS.**

- 25.2 First, envelopes marked “WITHDRAWAL” shall be opened and read out and the envelope with the corresponding Tender shall not be opened, but returned to the Tenderer. 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 Tenderer, the corresponding Tender will be opened. No Tender withdrawal shall be permitted unless the corresponding withdrawal notice contains a valid authorization to request the withdrawal and is read out at Tender opening.
- 25.3 Next, envelopes marked “SUBSTITUTION” shall be opened and read out and exchanged with the corresponding Tender being substituted, and the substituted Tender shall not be opened, but returned to the Tenderer. No Tender substitution shall be permitted unless the corresponding substitution notice contains a valid authorization to request the substitution and is read out at Tender opening.
- 25.4 Next, envelopes marked “MODIFICATION” shall be opened and read out with the corresponding Tender. No Tender modification shall be permitted unless the corresponding modification notice contains a valid authorization to request the modification and is read out at Tender opening.
- 25.5 Next, all remaining envelopes shall be opened one at a time, reading out: the name of the Tenderer and whether there is a modification; the total Tender Prices, per item or lot (contract) if applicable, including any discounts and alternative Tenders; the presence or absence of a Tender Security/or Tender Securing Declaration, if required; and any other details as the Purchaser may consider appropriate.
- 25.6 Only Tenders, alternative Tenders and discounts that are opened and read out at Tender opening shall be considered further for evaluation. The Letter of Tender and the Price Schedules are to be initialed by representatives of the Purchaser attending Tender opening in the manner specified **in the TDS.**

- 25.7 The Purchaser shall neither discuss the merits of any Tender nor reject any Tender (except for late Tenders, in accordance with ITT 23.1).
- 25.8 The Purchaser shall prepare a record of the Tender opening that shall include, as a minimum:
- (a) the name of the Tenderer and whether there is a withdrawal, substitution, or modification;
 - (b) the Tender Price, per lot (contract) if applicable, including any discounts;
 - (c) any alternative Tenders; and
 - (d) the presence or absence of a Tender Security or Tender Securing Declaration, if one was required.
- 25.9 The Tenderers' representatives who are present shall be requested to sign the record. The omission of a Tenderer'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 Tenderers.

E. Evaluation and Comparison of Tenders

- 26. Confidentiality**
- 26.1 Information relating to the evaluation of Tenders and recommendation of contract award, shall not be disclosed to Tenderers or any other persons not officially concerned with the Tendering process until the Notification of Intention to Award the Contract is transmitted to all Tenderers in accordance with ITT 43.
- 26.2 Any effort by a Tenderer to influence the Purchaser in the evaluation or contract award decisions may result in the rejection of its Tender.
- 26.3 Notwithstanding ITT 26.2, from the time of Tender opening to the time of Contract Award, if any Tenderer wishes to contact the Purchaser on any matter related to the Tendering process, it should do so in writing.
- 27. Clarification of Tenders**
- 27.1 To assist in the examination, evaluation, comparison of the Tenders, and qualification of the Tenderers, the Purchaser may, at its discretion, ask any Tenderer for a clarification of its Tender. Any clarification submitted by a Tenderer in respect to its Tender 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 Tender shall be sought, offered, or permitted, except to confirm the correction of arithmetic errors discovered by the Purchaser in the Evaluation of the Tenders, in accordance with ITT 31.

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

**28. Deviations,
Reservations, and
Omissions**

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

- (a) "Deviation" is a departure from the requirements specified in the Tendering document;
- (b) "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in the Tendering document; and
- (c) "Omission" is the failure to submit part or all of the information or documentation required in the Tendering document.

**29. Determination of
Responsiveness**

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

29.2 A substantially responsive Tender is one that meets the requirements of the Tendering 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 Tendering document, the Purchaser's rights or the Tenderer's obligations under the Contract; or
- (b) if rectified, would unfairly affect the competitive position of other Tenderers presenting substantially responsive Tenders.

29.3 The Purchaser shall examine the technical aspects of the Tender submitted in accordance with ITT 16 and ITT 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 Tender is not substantially responsive to the requirements of Tendering 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 Tender is substantially responsive, the Purchaser may waive any nonconformities in the Tender.

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

30.3 Provided that a Tender is substantially responsive, the Purchaser shall rectify quantifiable nonmaterial nonconformities related to the Tender Price. To this effect, the Tender 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 Tenderers. If the price of the item or component cannot be derived from the price of other substantially responsive Tenders, the Purchaser shall use its best estimate.

**31. Correction of
Arithmetical
Errors**

31.1 Provided that the Tender 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 Tenderers shall be requested to accept correction of arithmetical errors. Failure to accept the correction in accordance with ITT 31.1, shall result in the rejection of the Tender.

32. Conversion to Single Currency

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

33. Margin of Preference

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

34. Evaluation of Tenders

34.1 The Purchaser shall use the criteria and methodologies listed in this ITT 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 Tender. This is the Tender of the Tenderer that meets the qualification criteria and whose Tender has been determined to be:

- (a) substantially responsive to the Tendering document; and
- (b) the lowest evaluated cost.

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

- (a) evaluation will be done for Items or Lots (contracts), as specified **in the TDS**; and the Tender Price as quoted in accordance with ITT 14;
- (b) price adjustment for correction of arithmetic errors in accordance with ITT 31.1;
- (c) price adjustment due to discounts offered in accordance with ITT 14.4;

- (d) converting the amount resulting from applying (a) to (c) above, if relevant, to a single currency in accordance with ITT 32;
 - (e) price adjustment due to quantifiable nonmaterial nonconformities in accordance with ITT 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 Tender evaluation.
- 34.4 If this Tendering document allows Tenderers 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 Tender, is specified in Section III, Evaluation and Qualification Criteria
- 34.5 The Purchaser's evaluation of a Tender 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 Tenderer;
 - (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 Tenderer;
 - (c) any allowance for price adjustment during the period of execution of the contract, if provided in the Tender.
- 34.6 The Purchaser's evaluation of a Tender may require the consideration of other factors, in addition to the Tender Price quoted in accordance with ITT 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 Tenders, unless otherwise specified **in the TDS** from amongst those set out in Section III, Evaluation

and Qualification Criteria. The criteria and methodologies to be used shall be as specified in ITT 34.2 (f).

35. Comparison of Tenders

35.1 The Purchaser shall compare the evaluated costs of all substantially responsive Tenders established in accordance with ITT 34.2 to determine the Tender 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 Recipient'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 Tenders

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

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

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

37. Qualification of the Tenderer

37.1 The Purchaser shall determine to its satisfaction whether the Tenderer that is selected as having submitted the lowest evaluated cost and substantially responsive Tender is eligible and meets the qualifying criteria specified in TDS ITT 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 Tenderer's qualifications submitted by the Tenderer, pursuant to ITT 17. The determination shall not take into consideration the qualifications of other firms such as the Tenderer's subsidiaries, parent entities, affiliates, subcontractors or any other firm(s) different from the Tenderer.
- 37.3 Prior to Contract award, the Purchaser will verify that the successful Tenderer (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 Tenderer. If any proposed subcontractor does not meet the requirement, the Purchaser will require the Tenderer to propose a replacement subcontractor.
- 37.4 An affirmative determination shall be a prerequisite for award of the Contract to the Tenderer. A negative determination shall result in disqualification of the Tender, in which event the Purchaser shall proceed to the Tenderer who offers a substantially responsive Tender with the next lowest evaluated cost to make a similar determination of that Tenderer's qualifications to perform satisfactorily.
- 38. Purchaser's Right to Accept Any Tender, and to Reject Any or All Tenders**
- 38.1 The Purchaser reserves the right to accept or reject any Tender, and to annul the Tendering process and reject all Tenders at any time prior to Contract Award, without thereby incurring any liability to Tenderers. In case of annulment, all Tenders submitted and specifically, tender securities, shall be promptly returned to the Tenderers.
- 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 ITT 44. The Standstill Period commences the day after the date the Purchaser has transmitted to each Tenderer the Notification of Intention to Award the Contract. Where only one Tender 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 Tenderer the Notification of Intention to Award the Contract to the successful

Tenderer. The Notification of Intention to Award shall contain, at a minimum, the following information:

- (a) the name and address of the Tenderer submitting the successful Tender;
- (b) the Contract price of the successful Tender;
- (c) the names of all Tenderers who submitted Tenders, and their Tender prices as readout, and as evaluated;
- (d) a statement of the reason(s) the Tender (of the unsuccessful Tenderer 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 ITT 38, the Purchaser shall award the Contract to the successful Tenderer. This is the Tenderer whose Tender has been determined to be the Most Advantageous Tender. This is the Tender of the Tenderer that meets the qualification criteria and whose Tender has been determined to be: <ul style="list-style-type: none"> (a) substantially responsive to the Tendering 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 TDS , and without any change in the unit prices or other terms and conditions of the Tender and the Tendering document. |
| 43. Notification of Award | 43.1 Prior to the date of expiry of the Tender validity and upon expiry of the Standstill Period, specified in ITT 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 Tenderer, in writing, that its Tender 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 Tenderers that submitted Tenders, and their Tender prices as read out at Tender opening, and as evaluated;
- (d) names of all Tenderers whose Tenders 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 Tenderer, the final total contract price, the contract duration and a summary of its scope; and
- (f) successful Tenderer’s Beneficial Ownership Disclosure Form, if specified in TDS ITT 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 ITT 40.1, an unsuccessful Tenderer 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 Tenderers 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 Tenderers 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 Tenderers may be done in writing or verbally. The Tenderer shall bear their own costs of attending such a debriefing meeting.

45. Signing of Contract

45.1 The Purchaser shall send to the successful Tenderer the Letter of Acceptance including the Contract Agreement, and, if specified in the TDS, 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 Tenderer shall sign, date and return to the Purchaser, the Contract Agreement within twenty-eight (28) days of its receipt.

45.3 .Notwithstanding ITT 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 Tenderer shall not be bound by its Tender, always provided however, that the Tenderer 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 Tenderer 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 Tenderer, 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 Tenderer is in the form of a bond, it shall be issued by a bonding or insurance company that has been determined by the successful Tenderer 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 Tenderer 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 Tender Security. In that event the Purchaser may award the Contract to the Tenderer with the next Most Advantageous Tender.

47. Procurement Related Complaint

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

Section II - Tender Data Sheet (TDS)

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

ITT Reference	A. General										
	<p>The reference number of the Request for Tenders (RFT) is _HSRP/PMU/PRO/G/MS/S/14</p> <p>The Purchaser is: The Secretary, Ministry of Health, Sri Lanka</p> <p>Purchaser's Representative: Project Director, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP under Ministry of Health</p> <p>The name of the RFT is: Procurement of Cochlear Implants and Accessories</p>										
ITT 1.1	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Item No</th> <th style="width: 15%;">SR No</th> <th style="width: 55%;">Item</th> <th style="width: 10%;">Unit</th> <th style="width: 10%;">Quantity</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">13201301</td> <td>Cochlear Implants with Accessories.</td> <td style="text-align: center;">Nos</td> <td style="text-align: center;">150</td> </tr> </tbody> </table> <p>The number and identification of lots comprising this RFT is: None</p>	Item No	SR No	Item	Unit	Quantity	1	13201301	Cochlear Implants with Accessories.	Nos	150
Item No	SR No	Item	Unit	Quantity							
1	13201301	Cochlear Implants with Accessories.	Nos	150							
ITT 1.1	National Competitive Tendering (NCT)										
ITT 1.2(a)	<p>Electronic –Procurement System</p> <p>Not Applicable</p> <p>For clarification purposes following e-mail address shall be used hsrp.pmu.aiib@gmail.com. This should not be used for tender submission purposes.</p>										
ITT 2.1	<p>The Recipient is: The Government of Democratic Socialist Republic of Sri Lanka</p> <p>Loan Agreement amount: USD 100 Million</p> <p>The name of the Project is: Emergency Health Components of the: (i) Support to Colombo Urban Regeneration Project (SCURP) - Loan No. L0081A; and (ii) Reduction of Landslide Vulnerability by Mitigation Measures Project (RLVMMMP) – Loan No. L0124A funded by Asian Infrastructure Investment Bank</p>										
ITT 4.1	<p>Tenderer also means a supplier/ local agent or any other entity submitting a tender on behalf of manufacturer.</p> <p>Maximum number of members in the Joint Venture (JV) shall be: two (2)</p>										
ITT 4.5	A list of debarred firms and individuals is available on the Bank's external website: https://www.aiib.org/en/about-aiib/who-we-are/debarment-list/index.html										
	B. Contents of Tendering Document										
ITT 7.1	For <u>Clarification of Tender purposes</u> only, the Purchaser's address is:										

	<p>Attention: Senior Procurement Officer, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP under Ministry of Health</p> <p>Address: No. 81/4, Rosmead Place, Colombo 07</p> <p>City: Colombo</p> <p>ZIP Code: 007</p> <p>Country: Sri Lanka</p> <p>Electronic mail address: hsrp.pmu.aiib@gmail.com</p> <p>Requests for clarification should be received by the Purchaser no later than 10 Business Days before the deadline for submission of tender.</p> <p>Web page: https://www.hsep.lk/index.php/aiib/projects-tenders/tenders</p>
	<p>C. Preparation of Tenders</p>
<p>ITT 10.1</p>	<p>The language of the Tender is: English.</p> <p>All correspondence exchange shall be in English language.</p> <p>Language for translation of supporting documents and printed literature is English</p>
<p>ITT 11.1</p>	<p>Documentary evidence of the Tenderer's qualifications to perform the Contract if its Tender is accepted:</p> <p>(i) that, in the case of a Tenderer offering to supply Goods under the Contract that the Tenderer manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Tenderer:</p> <ul style="list-style-type: none"> (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 Tendering document, for at least two (2) years, and for similar Goods for at least five (5) 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), and has demonstrated compliance with the quality standards during the past two years prior to Tender submission; e) A valid certificate of Registration from National Medicines Regulatory Authority (NMRA) of Sri Lanka or a valid request for renewal along with the certified copy of the payment receipt of the NMRA registration for the proposed product. (f) Certificate from an Accredited Laboratory accepted by the purchaser <p>(ii) that, in the case of a Tenderer offering to supply Goods under the Contract that the Tenderer does not manufacture or otherwise produce,</p>

	<p>(a) that the Tenderer has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Sri Lanka; and</p> <p>The Tenderer shall also submit the following additional information:</p> <p>(a) a statement of installed manufacturing capacity;</p> <p>(b) copies of its audited financial statements for the past three fiscal years;</p> <p>(c) details of on-site quality control laboratory facilities and services and range of tests conducted;</p> <p>(d) list of major supply contracts conducted within the last five years.</p> <p>(e) Certificate of Registration issued by the Registrar of Contracts in Sri Lanka and the successful tenderer shall be registered with the Registrar of Contracts in Sri Lanka prior to the award of contract, in accordance with Public Contract Act No. 3 of 1987 of the Government of Sri Lanka, subsequent gazette notification as applicable.</p> <p>All the documents relating to sub clause 11.1 shall be endorsed as either “Certified Original” or “Certified True Copy” by an official Notary Public.</p>
<p>ITT 11.1 (j)</p> <p>11.1 (f)</p>	<p>The Tenderer shall submit the following additional documents in its Tender:</p> <p>Tenderers 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, Surgical Consumables & Laboratory Items or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling, and quality testing. The Tenderer shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Goods offered.</p> <p>Documentary evidence of the Tenderer qualifications to perform the Contract if its Tender is accepted:</p> <p>(i) (a) has a Good Distribution Practice (GDP) Certificate where appropriate.</p> <p>The Tenderer will submit the following additional information:</p> <p>(b) list of Surgical Consumables being manufactured by the Tender with product registration/license number and date.</p> <p>(c) a Certificate of Surgical Consumables Product as recommended by the WHO for each item offered.</p>
<p>ITT 13.1</p>	<p>Alternative Tenders shall not be allowed.</p>
<p>ITT 14.5</p>	<p>The price quoted by the Tenderer shall not be subject to adjustment during the performance of the Contract.</p>
<p>ITT 14.6</p>	<p>Prices quoted for each item(s) under each lot (if applicable) shall correspond to 100% of quantities specified for the particular item in the schedule of Requirements.</p>

ITT 14.7	Not Applicable
ITB 14.8 (a) and (c)	Not Applicable
ITT 14.8 (b)(i)	<p>For Goods offered from outside the purchaser's country, the tenderer shall quote prices using the following Incoterms.</p> <p>CIP to Colombo Port/ Airport with CIP to delivery location (Medical Supplies Division, Ministry of Health, No. 357, Ven. Baddegama Vimalawansa Thero Mawatha, Colombo 10, Sri Lanka as provided in the Delivery Schedule.</p>
ITT 14.8 (b)(ii)	Inland Transportations to specified destination, Insurance and other services such as documents required to clear the cargo from Colombo Port / Airport and all other related services. Purchaser shall pay only the charges specified in Custom Declaration. Purchaser shall not pay any demurrage charges arising from a delay from the supplier.
ITT 15.1	The Tenderer is required to quote in Sri Lanka Rupees (LKR) of the portion of the Tender price that corresponds to expenditures incurred in Sri Lanka.
ITT 15.2	The Tenderer shall express the tender price in Sri Lanka Rupees (LKR) or United States Dollars (USD)
ITT 16.3 (b)	<p>Documentation requirements for eligibility of Goods. In addition to the documents stated in ITT 16.1, 16.2, and 16.3 (a), the following documents should be included with the Tender</p> <p>The pharmaceuticals offered should meet the specified pharmacopoeia 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 tenderer will provide testing protocols and alternative reference standards.</p>
ITT 16.4	The Purchaser's Country does require registration of Goods with the National Medicines Regulatory Authority (NMRA) of Sri Lanka and shall submit the valid NMRA registration certificate or evidence of submission of extension to an existing NMRA registration with the tender.
ITT 16.4 (b)	<p>By the time of Contract signing, the successful Tenderer shall have a valid NMRA Registration. (Only for those who submitted evidence of extension to an existing NMRA registration with the tender). Failure to meet the above requirement may result in cancellation of the award.</p> <p>NMRA registration shall be valid up to six months beyond the final delivery date subject to the clearance of Medical Supplies Division.</p> <p>The Documents required for the registration is available with NMRA website. as www.nmra.gov.lk</p>

ITT 16.5	For the purpose of obtaining additional information about the requirements for registration, Tenderers may visit NMRA website (link: www.nmra.gov.lk)
ITT 18.1	The Tender shall be valid until: 120 days from the date of closing of Tenders
ITT 18.3 (a)	The Tender price shall be adjusted by the following factor(s): Foreign currency component shall be adjusted by 1% Local Currency component shall be adjusted by 12 %
ITT 19.1	A Tender Security shall be required in an amount of LKR. 4,000,000.00 or equivalent USD
ITT 19.3 (a)	The Tender Security shall be an Unconditional on Demand Bank Guarantee issued by a commercial Bank registered with the Central Bank of Sri Lanka. If the unconditional guarantee is issued by a commercial bank located outside the Sri Lanka, the issuing bank shall have a correspondent commercial bank in Sri Lanka registered with the Central Bank of Sri Lanka to make it enforceable. Other forms of securities are not acceptable. Noncompliance shall lead to rejection of such Tender. Tender security shall be valid for 148 days from the date of closing of tenders.
ITT 19.9	Not Applicable
ITT 20.1	In addition to the original of the Tender, the number of copies is: one copy (01)
ITT 20.3	The written confirmation of authorization to sign on behalf of the Tenderer shall consist of: The written confirmation of authorization to sign on behalf of the Tenderer shall consist of: An organizational document board resolution or its equivalent, or power of attorney specifying the representative's authority to sign the Tender on behalf of, and to legally binding, the Tenderer. If the Tenderer is an intended or an existing Joint Venture, the power of attorney should be signed by all partners and specify the authority of the named representative of the Joint Venture to sign on behalf of, and legally binding, the intended or existing Joint Venture partner. If the Joint Venture has not been formed, also included evidence from all proposed Joint Venture partner of their intent to enter into a Joint Venture in the event of a contract award following ITB 11.2
D. Submission and Opening of Tenders	
ITT 22.1	For <u>Tender submission purposes</u> only, the Purchaser's address is: Project Director, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP under Ministry of Health Street Address: No. 81/4, Rosmead Place, Colombo 07, Sri Lanka

	<p>City: Colombo</p> <p>ZIP Code: 007</p> <p>Country: Sri Lanka</p> <p>The deadline for Tender submission is:</p> <p>Date: 18.11.2024</p> <p>Time: 10.00 am</p> <p>Tenderers Shall not have the option of submitting their Tenders electronically.</p>
ITT 25.1	<p>The Tender opening shall take place at:</p> <p>Location: Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP under Ministry of Health</p> <p>Street Address: No. 81/4, Rosmead Place, Colombo 07, Sri Lanka</p> <p>City: Colombo</p> <p>ZIP Code: 007</p> <p>Country: Sri Lanka</p> <p>Date: 18.11.2024</p> <p>Time: 10.00 am</p>
ITT 25.1	The Electronic Tender opening procedures shall not be applicable:
ITT 25.6	The Letter of Tender and Price Schedules shall be initialed by 3 members of the Tender Opening Committee (TOC)
E. Evaluation and Comparison of Tenders	
ITT 32.1	<p>The currency that shall be used for Tender evaluation and comparison purposes to convert (at the selling exchange rate) all Tender prices expressed in various currencies into a single currency is: Sri Lanka Rupees (LKR)</p> <p>The source of exchange rate shall be: Central Bank of Sri Lanka</p> <p>The date for the exchange rate shall be: Date of opening of Tenders</p>
ITT 33.1	A margin of domestic preference shall not apply.
ITT 34.2 (a)	Evaluation will be done as lot wise
ITT 34.6	<p>The adjustments shall be determined using the following criteria, from amongst those set out in Section III, Evaluation and Qualification Criteria:</p> <p>(a) Deviation in Delivery schedule: Not Allowed</p> <p>(b) Deviation in payment schedule: Not Allowed</p>
F. Award of Contract	
ITT 42	The maximum percentage by which quantities may be increased is Twenty five Percent (25%)

	The maximum percentage by which quantities may be decreased is Twenty Five Percent (25%)
ITT 45.1	The successful Tenderer shall submit the Beneficial Ownership Disclosure Form.
ITT 47.1	<p>The procedures for making a Procurement-related Complaint are detailed in the (Annex III) of AiIB Directive on Procurement Instructions for Recipients (July 26, 2024). If a Tenderer wishes to make a Procurement-related Complaint, the Tenderer should submit its complaint following these procedures, in writing (by the quickest means available, that is either by email), to:</p> <p>For the attention: Dr. S.A.R Dissnayake,</p> <p>Title/position: Project Director, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP under Ministry of Health</p> <p>Purchaser: Secretary, Ministry of Health</p> <p>Email address: hsrp.pmu.aiib@gmail.com</p> <p>In summary, a Procurement-related Complaint may challenge any of the following:</p> <ol style="list-style-type: none"> 1. the terms of the Tendering Documents; and 2. the Purchaser’s decision to award the contract.

Section III - Evaluation and Qualification Criteria

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

Contents

1. Most Advantageous Tender	48
2. Evaluation (ITT 34)	48
3. Qualification (ITT 37).....	48

1. Most Advantageous Tender

Most Advantageous Tender

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

- (a) substantially responsive to the Tendering document, and
- (b) the lowest evaluated cost.

2. Evaluation (ITT 34)

2.1. Evaluation Criteria (ITT 34.6)

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

- (a) Delivery schedule (as per Incoterms specified in the TDS) ****not allowed****
- (b) Deviation in payment schedule. ****not allowed****
- (c) Specific additional criteria ****none****

2.2. Multiple Contracts (ITT 34.4)

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

2.3. Alternative Tenders (ITT 13.1) ****not allowed****

3. Qualification (ITT 37)

The Tenderer shall demonstrate that it continues to meet the prequalification criteria. The Tenderer 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
No.	Subject	Requirement	Single Entity	Joint Venture (existing or intended)			Submission Requirements
				All Members Combined	Each Member	One Member	
1. Eligibility							
1.1	Nationality	Nationality in accordance with ITT 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 ITT 4.2	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Tender Submission Letter
1.3	Bank Eligibility	Not having been declared ineligible by the Bank, as described in ITT 4.5 and 5.1	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Tender Submission Letter
1.4	State-owned enterprise of the Recipient country	Meet conditions of ITT 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 Recipient's country law	Not having been excluded as a result of prohibition in the Recipient's country laws or official regulations against commercial relations with the Tenderer's country, or by an act of compliance with UN Security Council resolution, both in accordance with ITT 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							

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	
2.1	History of Non-Performing Contracts	Non-performance of a contract ¹ did not occur as a result of Supplier's default since 1 st January 2018	Must meet requirement ²	Must meet requirements	Must meet requirement ²	N/A	Form PER-1
2.2	Suspension Based on Execution of Tender/Proposal Securing Declaration by the Purchaser	Not under suspension based on execution of a Tender/Proposal Securing Declaration pursuant to ITT 4.7.	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Tender Submission Letter
2.3	Pending Litigation	Tenderer'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 Tenderer	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 Tenderer since 1 st January 2018	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Form PER-1
3. Financial Situation and Performance							
3.1	Financial	The audited balance sheets or, if	Must meet	N/A	Must meet	N/A	

¹ Nonperformance, as decided by the Purchaser, shall include all contracts where (a) nonperformance 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. Nonperformance shall not include contracts where Purchaser's decision was overruled by the dispute resolution mechanism. Nonperformance 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 Tenderer have been exhausted.

² This requirement also applies to contracts executed by the Tenderer as JV member.

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	
	Capabilities	not required by the laws of the Tenderer's country, other financial statements acceptable to the Purchaser, for the last three (3) years (2020/2021, 2021/2022 and 2022/2023) shall be submitted and must demonstrate the current soundness of the Tenderer's financial position and indicate its prospective long-term profitability.	requirement		requirement		
3.2	Average Annual Turnover	Average annual turnover (Average Annual Sales Revenue) from supply of Health Sector Goods LKR 156 Mn or equivalent in USD calculated as total certified payments received for contracts in progress and/or completed during the last three years. (2020/2021, 2021/2022 and 2022/2023)	Must meet requirement	Must meet requirement	N/A	N/A	Form FIN – 3.2
3.3	Current Commitments	The Tenderer 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					Form CON -1

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	
		future contract commitments.					
4. Experience							
4.1	General Experience	Experience in supply of Health Sector Goods for at least the last three years (2019-2023)	Must meet requirement	N/A	Must meet requirement	N/A	Form EXP –1
4.2 (a)	Specific Experience	(i) Documentary evidence of the Tenderer’s qualifications to perform the Contract in accordance with 4.2 (b)(i) 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 Must meet requirement Must meet requirement	N/A N/A N/A	Must meet requirement Must meet requirement Must meet requirement	
4.2 (b)	See below for details						

Financial Situation and Performance

The financial situation and performance under 3.2 Average Annual Turnover (from the table above), shall be LKR. 156.00 Mn

Specific Experience Requirements

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

4.2 (b)(i) Documentary evidence of the Tenderer's qualifications to perform the Contract in accordance with TDS ITT 11.1

- i. Certificate of Origin of goods
- ii. License of the regulatory authority in the country of manufacture of the good.
- iii. Documentary evidence for specific goods have manufactured and marketed for at least two (2) years, and similar Goods for at least three (3) years; in the relevant country of origin.
- iv. GMP inspection certificate
- v. NMRA Registration certificate or valid request for renewal along with a certified copy of the payment receipt.
- vi. Certificate from an Accredited Laboratory
- vii. Manufacture's Authorization
- viii. Statement of installed manufacturing capacity
- ix. Details of on-site quality control laboratory facilities and services and range of tests conducted
- x. List of major supply contracts conducted within the last five years
- xi. Details of the Quality Standards
- xii. Good Distribution Practice (GDP) Certificate
- xiii. List of Surgical Consumables being manufactured by the Tender with product registration/license number and date
- xiv. Certificate of Surgical Consumables Product as recommended by the WHO for each item offered

4.2(b)(ii) Technical and Production Capability

The Tenderer/ Manufacturer 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 **two contracts for supply of 100 nos of Hearing Aid, Cochlear type implant with accessories** to those requested under ITT 1.1 **within the last five years supported by Goods Received Noted or Acceptance Certificates**. Similar contracts are those of approximately the same size and that includes comparable products, e.g., The goods may have been supplied by the Tenderer 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 **per item/lot specified in the schedule of requirement** during the last three years as below.

Item No	Item	Unit	Quantity
1	Cochlear Implants with Accessories.	Nos	150

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

The Tenderer should provide proof of experience with and knowledge of modes of packing, distribution, and transportation of Surgical Consumables similar to those subject to Tendering under logistical and climatic conditions similar to the ones in the purchaser's country. It should provide names of countries to which the Tenderer has supplied (including packaged, distributed, and transported) products worth at least the amount **2.0 million LKR or equivalent within the past three years.**

4.2 (b)(iv) Contractual Experience

Successfully completed or substantially completed, as main supplier, within the last five years of at least **one contract of valued mention below**, with nature and complexity similar to the Part B – Product Specification (Section VII - Schedule of Requirements)

Item No.	Description	Value of similar nature contract (LKR)
1	Cochlear Implants with Accessories.	94,000,000.00

Section IV - Tendering Forms

Table of Forms

Letter of Tender	56
Tenderer Information Form.....	59
Form ELI -1.1 (continued)	60
Tenderer Information Form.....	60
Tenderer’s JV Members Information Form	62
Financial Situation and Performance	63
Average Annual Turnover (Annual Sales Value)	65
Current Contract Commitments / Contracts in Progress Form	66
Experience	67
Historical Contract Non-Performance, and Pending Litigation and Litigation History 68	
Price Schedule Forms	70
Price Schedule: Goods Manufactured Outside the Purchaser’s Country, to be Imported –.....	74
Form of Tender Security - (Bank guarantee)	72
Manufacturer’s Authorization	74

Letter of Tender

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

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

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

Date of this Tender submission: *[insert date (as day, month and year) of Tender submission]*

Request for Tender No.: HSRP/PMU/PRO/G//MS/S/14 (2024)

Alternative No.: *[insert identification No if this is a Tender for an alternative]*

To: Ministry of Health

- (a) **No reservation:** We have examined and have no reservations to the Tendering document, including Addenda issued in accordance with Instructions to Tenderers (ITT 8);
- (b) **Eligibility:** We meet the eligibility requirements and have no conflict of interest in accordance with ITT 4;
- (c) We have not been suspended nor declared ineligible by the Purchaser based on execution of a Tender-Securing Declaration or Proposal-Securing Declaration in the Purchaser's Country in accordance with ITT 4.7;

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.]
- (d) **Conformity:** We offer to supply in conformity with the Tendering 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]*;

- (e) **Tender Price:** The total price of our Tender, 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 Tender 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]*;

- (f) **Tender Validity:** Our Tender 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;
- (g) **Performance Security:** If our Tender is accepted, we commit to obtain a Performance Security in accordance with the Tendering document;
- (h) **One Tender per Tenderer:** We are not submitting any other Tender(s) as an individual Tenderer, and we are not participating in any other Tender(s) as a Joint Venture partner or as a subcontractor, and meet the requirements of ITT 4.3, other than alternative Tenders submitted in accordance with ITT 13;
- (i) **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 or any ineligibility imposed or recognized by the Bank. 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;
- (j) **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 ITT 4.6];*
- (k) **Commissions, gratuities, fees:** We have paid, or will pay the following commissions, gratuities, or fees with respect to the Tendering 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.”)

- (l) **Binding Contract:** We understand that this Tender, 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;
- (m) **Purchaser Not Bound to Accept:** We understand that you are not bound to accept the lowest evaluated cost Tender, the Most Advantageous Tender or any other Tender that you may receive;
- (n) **Prohibited Practice:** 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 Prohibited Practice; and
- (o) **Inspection and Audit:** We agree to permit the Bank or its representative to inspect our accounts and records and other documents relating to the tender submission and to have them audited by auditors appointed by the Bank.

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

Name of the person duly authorized to sign the Tender on behalf of the Tenderer:

*******[insert complete name of person duly authorized to sign the Tender]*

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

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 Tender submitted by a Joint Venture specify the name of the Joint Venture as Tenderer.

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

Tenderer Information Form

[The Tenderer 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 Tender submission]*

RFT No.: *[insert number of Tendering process]*

Alternative No.: *[insert identification No if this is a Tender for an alternative]*

Page _____ of _____ pages

1. Tenderer's Name <i>[insert Tenderer's legal name]</i>
2. In case of JV, legal name of each member: <i>[insert legal name of each member in JV]</i>
3. Tenderer's actual or intended country of registration: <i>[insert actual or intended country of registration]</i>
4. Tenderer's year of registration: <i>[insert Tenderer's year of registration]</i>
5. Tenderer's Address in country of registration: <i>[insert Tenderer's legal address in country of registration]</i>
6. Tenderer's Authorized Representative Information Name: <i>[insert Authorized Representative's name]</i> Address: <i>[insert Authorized Representative's Address]</i> Telephone/Fax numbers: <i>[insert Authorized Representative's telephone/fax numbers]</i> Email Address: <i>[insert Authorized Representative's email address]</i>
7. Attached are copies of original documents of <i>[check the box(es) of the attached original documents]</i> <input type="checkbox"/> Articles of Incorporation (or equivalent documents of constitution or association), and/or documents of registration of the legal entity named above, in accordance with ITT 4.4. <input type="checkbox"/> In case of JV, letter of intent to form JV or JV agreement, in accordance with ITT 4.1. <input type="checkbox"/> In case of state-owned enterprise or institution, in accordance with ITT 4.6 documents establishing: <ul style="list-style-type: none"> • Legal and financial autonomy • Operation under commercial law • Establishing that the Tenderer is not under the supervision of the Purchaser
8. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership. <i>[If required under TDS ITT 45.1, the successful Tenderer shall provide additional information on beneficial ownership, using the Beneficial Ownership Disclosure Form.]</i>

Form ELI -1.1 (continued)

Tenderer Information Form

Date: *[insert day, month, year]*

RFT No. and title: *[insert RFT number and title]*

Page *[insert page number]* of *[insert total number]* pages

1. Tenderer'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

Tenderer's JV Members Information Form

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

Date: *[insert date (as day, month and year) of Tender submission]*

RFT No.: *[insert number of Tendering processes]*

Alternative No.: *[insert identification No if this is a Tender for an alternative]*

Page _____ of _____ pages

1. Tenderer's Name: <i>[insert Tenderer's legal name]</i>
2. Tenderer's JV Member's name: <i>[insert JV's Member legal name]</i>
3. Tenderer's JV Member's country of registration: <i>[insert JV's Member country of registration]</i>
4. Tenderer's JV Member's year of registration: <i>[insert JV's Member year of registration]</i>
5. Tenderer's JV Member's legal address in country of registration: <i>[insert JV's Member legal address in country of registration]</i>
6. Tenderer's JV Member's authorized representative information Name: <i>[insert name of JV's Member authorized representative]</i> Address: <i>[insert address of JV's Member authorized representative]</i> Telephone/Fax numbers: <i>[insert telephone/fax numbers of JV's Member authorized representative]</i> Email Address: <i>[insert email address of JV's Member authorized representative]</i>
7. Attached are copies of original documents of <i>[check the box(es) of the attached original documents]</i> <input type="checkbox"/> Articles of Incorporation (or equivalent documents of constitution or association), and/or registration documents of the legal entity named above, in accordance with ITT4.4. <input type="checkbox"/> 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 ITT4.6.
8. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership. <i>[If required under TDS ITT 45.1, the successful Tenderer shall provide additional information on beneficial ownership for each JV member using the Beneficial Ownership Disclosure Form.]</i>

Form FIN – 3.1

Financial Situation and Performance

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

Tenderer's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]*

RFT No. and title: *[insert RFT number and title]*

Page *[insert page number]* of *[insert total number]* pages

1. Financial data

Type of Financial information in (currency)	Historic information for previous _ <i>[insert number]</i> years, <i>[insert in words]</i> (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 Tenderer and its parties shall provide copies of financial statements for 3 years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

- (a) reflect the financial situation of the Tenderer 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 statements³ 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 tendering, 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 Tenderer and for each member of a Joint Venture]

Tenderer's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]*

RFT No. and title: *[insert RFT number and title]*

Page *[insert page number]* of *[insert total number]* pages

Annual turnover data			
Year	Amount Currency	Exchange rate	USD equivalent
<i>[indicate calendar year]</i>	<i>[insert amount and indicate currency]</i>		
		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 <i>[insert address, telephone, fax, e-mail address]</i>
3. Value of outstanding contracts <i>[current US\$ equivalent]</i>
4. Estimated delivery date
5. Average monthly invoices over the last six months (US\$/mon.)

Form- EXP-1 Experience

Contracts over <i>[insert amount]</i> 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 Tenderer and for each member of a Joint Venture]

Tenderer's Name: [insert full name]

Date: [insert day, month, year]

Joint Venture Member Name: [insert full name]

RFT No. and title: [insert RFT number and title]

Page [insert page number] of [insert total number] pages

Non-Performed Contracts in accordance with Section III, Evaluation and Qualification Criteria (<i>In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document</i>)			
<input type="checkbox"/> Contract non-performance did not occur since 1 st January [insert year]		<input type="checkbox"/> Contract(s) not performed since 1 st 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 (<i>In case of prequalification, in accordance with Section III, Qualification Criteria and Requirements of the Prequalification document</i>)			
<input type="checkbox"/> No pending litigation <input type="checkbox"/> Pending litigation as indicated below.			
Year of dispute	Amount in dispute (currency)	Contract Identification	Total Contract Amount (currency), USD

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

Price Schedule Forms

*[The Tenderer 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.]*

Form of Tender 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]*

RFT No.: *[Purchaser to insert reference number for the Request for Tenders]*

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

Date: *[Insert date of issue]*

TENDER SECURITY 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 Tenderer, 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 Tender (hereinafter called "the Tender") for the execution of _____ under Request for Tenders No. _____ ("the RFT").

Furthermore, we understand that, according to the Beneficiary's conditions, Tenders must be supported by a Tender 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 Tender prior to the Tender validity expiry date set forth in the Applicant's Letter of Tender, or any extended date provided by the Applicant; or
- (b) having been notified of the acceptance of its Tender by the Beneficiary prior to the expiry date of the Tender 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 Tenderers (“ITT”) of the Beneficiary’s Tendering document.

This guarantee will expire: (a) if the Applicant is the successful Tenderer, 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 Tenderer, upon the earlier of (i) our receipt of a copy of the Beneficiary’s notification to the Applicant of the results of the Tendering process; or (ii) twenty-eight days after the expiry date of the Tender 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.

Manufacturer's Authorization

[The Tenderer 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 Tenderer shall include it in its Tender, if so indicated in the TDS.]

Date: *[insert date (as day, month and year) of Tender submission]*

RFT No.: *[insert number of Tendering processes]*

Alternative No.: *[insert identification No if this is a Tender 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 Tenderer]* to submit a Tender 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 Product¹

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 ingredients² 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 products license⁷ 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 ITT 4.8 and 5.1, for the information of the Tenderers, at the present time firms, goods and services from the following countries are excluded from this Tendering process:

Under ITT 4.8(a) and 5.1: None Refer www.aiib.org
Under ITT 4.8(b) and 5.1: None Refer www.aiib.org

Section VI –Prohibited Practices

(Section VI shall not be modified)

1. The Bank requires that the Recipient (and all other beneficiaries of the Bank financing), as well as tenderers, suppliers, contractors, concessionaires and consultants under Bank-financed contracts for the Project, observe the highest standard of transparency and integrity during the procurement, execution and implementation of such contracts.
2. Definitions. In pursuance of this policy, the Bank defines the terms set forth below as Prohibited Practices:
 - (a) **“Coercive practice”** means impairing or harming or threatening to impair or harm, directly or indirectly, any party or the property of a party to influence improperly the actions of a party.
 - (b) **“Collusive practice”** means an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party.
 - (c) **“Corrupt practice”** means the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party.
 - (d) **“Fraudulent practice”** means any act or omission, including a misrepresentation, that knowingly or recklessly misleads or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation.
 - (e) **“Misuse of resources”** means improper use of the Bank’s resources, carried out either intentionally or through reckless disregard.
 - (f) **“Obstructive practice”** means any of the following practices: (i) deliberately destroying, falsifying, altering or concealing of evidence material to a Bank investigation; (ii) making false statements to investigators in order to materially impede a Bank investigation into allegations of a Prohibited Practice; (iii) failing to comply with requests to provide information, documents or records in connection with a Bank investigation; (iv) threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to a Bank investigation or from pursuing the investigation; or (v) materially impeding the exercise of the Bank’s contractual rights of audit or inspection or access to information.
 - (g) **“Theft”** means the misappropriation of property belonging to another party.
3. Any occurrence, or suspected occurrence, of a Prohibited Practice in the procurement, award or implementation of a Bank-financed contract is dealt with in accordance with the provisions of the Bank’s Policy on Prohibited Practices. Suppliers, contractors, service providers and consultants selected pursuant to the provisions of Section II and

concessionaires selected pursuant to paragraph 14.3 of the Bank's Procurement Instructions for Recipients, as well as the Recipient shall fully cooperate with the Bank (or a co-financier undertaking an investigation pursuant to paragraph 6.1 of the Bank's Procurement Instructions for Recipients) in any investigation into an alleged Prohibited Practice to be carried out pursuant to the Policy on Prohibited Practices, and permit the Bank or its representative (including such co-financier) to inspect such of their accounts and records as may be relevant for such investigation and to have such records and accounts audited by the auditors appointed by the Bank.

4. Provisions to this effect are included in the Legal Agreements and the procurement contracts with such entities.
5. If the Project is financed by a sovereign-backed loan, the Bank (or, where relevant, a co-financier having undertaken an investigation pursuant to paragraph 6.1 of the Bank's Procurement Instructions for Recipients):
6.
 - (a) may take any of the following additional actions in connection with a Prohibited Practice under the Project:
 - (i) reject a proposal for award if it determines that the tenderer recommended for award, or any of its personnel, or its agents, or its subconsultants, subcontractors, service providers, suppliers or their employees, has, directly or indirectly, engaged in a prohibited practice in competing for the contract in question; and
 - (ii) cancel the undisbursed portion of the loan allocated to a contract (and require reimbursement of the disbursed portion of the loan allocated to the contract) if it determines at any time that representatives of the Recipient or of a recipient of any part of the proceeds of the loan engaged in a prohibited practice during the procurement, administration or implementation of the contract in question; and
 - (b) requires that a clause be included in tender documents and in contracts financed by the Bank loan, requiring tenderers, suppliers and contractors and their subcontractors, agents, personnel, consultants, service providers or suppliers, to permit the Bank (and a co-financier undertaking an investigation pursuant to paragraph 6.1 of the Bank's Procurement Instructions for Recipients) to inspect all accounts, records and other documents relating to the submission of tenders and contract performance, and to have them audited by auditors appointed by the Bank.

PART 2 – Supply Requirements

Section VII - Schedule of Requirements

Contents

Notes for Preparing the Schedule of Requirements.....	84
1. List of Goods and Delivery Schedule.....	85
2. Technical Specifications.....	86
3. Inspections and Tests.....	109

Notes for Preparing the Schedule of Requirements

The Schedule of Requirements shall be included in the Tendering document by the Purchaser, and shall cover, at a minimum, a description of the goods and services to be supplied and the delivery schedule.

The objective of the Schedule of Requirements is to provide sufficient information to enable Tenderers to prepare their Tenders efficiently and accurately, in particular, the Price Schedule, for which a form is provided in Section IV. In addition, the Schedule of Requirements, together with the Price Schedule, should serve as a basis in the event of quantity variation at the time of award of contract pursuant to ITT 42.1.

The date or period for delivery should be carefully specified, taking into account (a) the implications of delivery terms stipulated in the Instructions to Tenderers pursuant to the *Incoterms* rules (i.e., EXW, or CIP, FOB, FCA terms—that “delivery” takes place when goods are delivered **to the carriers**), and (b) the date prescribed herein from which the Tenderer’s delivery obligations start (i.e., notice of award, contract signature, opening or confirmation of the letter of credit).

1. List of Goods and Delivery Schedule					
Item No.	Description of Goods	Quantity	Physical Unit	Delivery Date	
				Required Delivery Dates (Before 21.02.2025 after signing of the contract agreement or as per specific delivery schedule of MSD)	Tenderer's offered Delivery date [to be provided by the Tenderer]
1	Cochlear Implants with Accessories.	150	Nos		

Notes

*1 Final Destination as specified in TDS = Medical Supplies Division, No. 357, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

*2 Upon MSD approval, split deliveries may be allowed by the Purchaser at the time of awarding the contract.

2. Technical Specifications

Surgical Items

Part A - General Requirement/ Specification

Part B - Product Specification

Part A - General Requirement/ Specification

Conditions of Supply

1. The consignments supplied in respect of an order concerned, shall exactly match with the reference sample submitted and the product information (item descriptions, shelf life/warranty where applicable, manufacturer's name, country of manufacture, country of origin, etc.) provided in the Tender Document by the supplier, which has been accepted by the Purchaser.
2. All items shall be supplied, sourcing from the manufacturer and country of manufacturer, stated in the Tender submitted by the Tenderer 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), &/ import license / manufacture licensing at NMRA, is a pre-requisite for the supply of surgical, pharmaceutical and relevant laboratory items. Hence all suppliers shall produce relevant valid registration certificates/licenses, when requested by the Purchaser/ MSD.
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 Purchaser / MSD decides to accept a part or full consignment, with deviations from accepted 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 Purchaser/ 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 higher .

All possible tender deviations which regard to 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 the above shall be considered as tender deviations, to apply surcharge. (as in the item no. 46 of these General Requirement/ Specifications).

6. The specifications of the products 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 accepted**, when there are product/s offered in compliance with the tender specification.

Shelf life & Warrantees

7. Freshly manufactured stocks of the product shall be supplied; thereby the residual shelf life (shelf life remaining at the time of delivery of goods at the MSD stores/Sri Lanka) of the product, shall be 85% of the product shelf life specified in the Tender Document or as indicated in the NMRA registration Certificates.
- (a) When the shelf life is not specified in the Tender Document /item spec; the requested shelf life shall be considered as, 36 months for consumable surgical items (shelf life is not applicable for surgical non-consumables) and 24 months for Pharma. / Laboratory items. The difference of the residual and requested product shelf life shall not exceed 1/6th (one sixth) of the original product shelf life.
- (b) In the deviation of the above tender condition, Purchaser/ 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 in the item no. 46 of General Requirement/ Specification)

Standards & Quality

8. 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.
9. As per the product registration dossier approved by NMRA, the product information leaflet (PIL) for the pharmaceutical items and the user manual / instruction pamphlet for surgical items, with information to users regarding the; storage conditions, maintenance, and other product compatibilities, shall be provided with the product, for acceptance of goods by MSD.

Any product deficient of or incompatible with, its sub-components / accessories, not at the specified quality standards or all its components not unitized appropriately in packaging (as a set), shall be treated as non- responsive and rejected without further evaluation.

10. The storage conditions and the packing requirements of the product shall conform to the information given by the manufacturer and accepted by NMRA for the product registration. (refer item no. 24 of these General Requirement/ Specifications)

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

11. Immediately after delivery at MSD, the consignments shall be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory. (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.

12. Consignments supplied to MSD deviating 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.

Pack size, Labeling & Packaging

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

14. In respect of bulk packs of all Pharmaceuticals (not applicable for blister/strip packs), “DHS” mark shall be;

- (a). embossed or printed in case of tablets
- (b). printed in case of capsules

Above condition can be waved off, if the purchase order quantity is less than 100000 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.

- 15.** 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 "STATE 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 "Year & Month" or "No Exp."), in the innermost pack and supplier's invoice.

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

- 17.** All outer most cartons (shipping packages) shall bear the Contract Reference No., SR No, Batch No, and Date of Expiry in size 1.5cm letters / figures in prominently visible manner. This may be printed, stenciled or label properly affixed.

- 18.** Batch Number of the product shall be separately Barcoded (in Code 128 or 2D formats) and Barcode shall be printed on the labels at all levels of packing as described below, conforming to the industry standards in Barcode printing and pasting.
Format shall be according to Code 128 or 2D standards.
Maximum barcode size shall be 5.0cm (length) x 2.5cm (width).

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

If the local agent does not follow suit as above, such extra expenses incurred to MSD shall be recovered from the supplier and refund to MSD.

Storage Conditions & Temperature

20. If the storage temperature & conditions are not specified in the item specification, NMRA accepted product storage conditions, shall conform to Sri Lankan ambient storage conditions in the ranges of 30⁰c +/- 2⁰c temperature and 75% +/-5% relative humidity. The product storage conditions shall be clearly indicated at all levels of labels/packages/boxes.
21. Maintenance of Cold Chain;
- a. In case of cold storage items, cold chain monitors (temperature recording devices) shall be included for each carton and the cold chain shall be maintained according to the manufacturer's instructions during storage, transport and delivery.
 - b. Supplier shall use suitable prominently visible identification marks of international standard, with appropriate colors 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 MSD 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 **invoices or copy of the delivery documents**. In such an event, the MSD shall arrange necessary cold storage for the consignment until 'observed cold chain break' is investigated leading to acceptance / total rejection of consignment and the expenses born by MSD in arranging the cold storage shall be recovered from the supplier.
 - d. The vehicles transporting cold cargo to MSD shall be equipped with temperature monitoring devices and the vehicle shall have NMRA approval for transport of pharmaceuticals.
 - e. The suppliers shall dispatch consignments of the items, which require cold chain maintenance, to arrive in Sri Lanka during Monday to Thursday to avoid additional demurrage & storage charges during weekends, during which MSD stores is closed. In case of non-compliance of this condition, any additional expenses incurred to MSD, to Custom clear/store/receive such consignments shall be recovered from the supplier.
22. In respect of the products requiring controlled temperature storage (Eg. < 25⁰c, 2-25⁰c, 15-20⁰c/30⁰c, 2-8⁰c etc.), supplier shall provide MSD with latest product stability study reports with the invoice of the consignment. (Report shall include studies; at 30⁰c +/- 2⁰c & 75% +/- 5% RH for **AC**

stored items and at 25⁰c +/- 2⁰c & 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 item no. 12 of these General Requirement/ Specifications)

Delivery Requirements

- 23.** All consignments shall be delivered at Medical Supplies Division or an alternate receiving point as directed. However, sending consignments **to reach Sri Lanka from 15th December to 10th January** shall be avoided, unless otherwise prior approval has been granted by MSD for such deliveries. Please note that NMRA Registration shall be valid for six months from the date of acceptance.
- 24.** Defaulted consignments with respect to delivery schedule shall only be considered for acceptance, subject to a penalty imposed for the delay due to suppliers' fault, allowing a grace period up to two weeks. Consignments delivered after that grace period shall be considered for acceptance subject to a penalty to the supplier as described in the GCC Clause no 27, SCC Clause No. 27.1 & 27.2
- (b). When the delay exceeds 60days purchase order will be considered as automatically cancelled, on defaulted performance. In such a situation, PE 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.
- 25.** If a delivery defaulted (deviating delivery schedule in the Tender Document) supplier/his local agent, who participate in an urgent local purchase tender of the purchaser 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 main order. In deviation of the same, the cost difference will be set off from the payments to the supplier of the corresponding main order of the purchaser.
- 26.** In the event of failure to meet this deadline due to supplier's fault (eg. In delivery; time, product, document, etc.) goods shall be accepted on the following working day, such date shall be counted for working out penalties as per item no. 27 of these General Requirement/ Specification and GCC Clause 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 additional expenses (i.e. staff OT, forklift charge, etc.) of MSD, by the supplier.

27. The extension of L/C's overstepping delivery schedules in the Tender or its' amendments, shall not in any way affect the recovery of late delivery charges, as per GCC Cl. No. 27 (regarding defaulted consignments) and any other direct or indirect additional costs, relating/consequent to extension of L/C.
28. When adequate storage space is not available at MSD, to accept a delivery defaulted consignment (deviating from the delivery schedule in the Tender or its' amendments) under the item no.27 of these General Requirement/ Specification and GCC Clause No. 27, any additional expenses caused to MSD in arranging temporary external storage and other expenses (eg. demurrage, detention, container storage, re-handling cum transport, etc.) shall be borne by the supplier.

Documents & Information

29. MSD Order No, Item Description, SR No, Batch No., Date of Manufacture, Date of Expiry and product Storage Condition, shall be indicated in all Supply Invoices and detailed Packing Lists.
30. One of the tender samples of the selected tender shall be forwarded to MSD, for using as a reference sample (can make it; a part of the last consignment or a returnable to supplier) for checking the conformity of the consignments received under the indent/PO. (Applicable for all consumable surgical items and laboratory regular items, except when stated otherwise in the relevant order list).

The product artwork or dimensional detail diagrams, product Catalogs and Catalog No's, as necessary for the surgical items (**not relevant to Pharmaceutical & Laboratory items**), shall be provided with the Tender document, for reference in the; tender evaluation by the Purchaser, 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.

31. The supplier shall submit all shipping documents to (Including Bills of Lading / Draft Air Way Bills etc.) as specified in the SCC Clause No. 13.1 to Purchaser and MSD by e-mail (Please follow instructions in the website www.msd.gov.lk), at least 03 days before the Expected Time of Arrival (ETA) of sea freighted consignments & 02 days before the ETA of Air freighted consignments.

32. After establishing the L/C, the latest logistical position of manufacturing & supply, shall be updated biweekly through e-mails to Purchaser 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 item 27 of these General Requirement/ Specification will not be applicable.

Submission of Samples

33. Purchaser may request from the responsive supplier/s to supply a sample within one week of such request. Failure to submit an acceptable sample meeting the technical specifications of the product in both quality and standards within the designated period shall result in rejection of the Tender without considering for further evaluation. If past suppliers and current suppliers are willing to submit the same item with the same brand, will be excluded from submitting samples.

34. If the substantially responsive tenderer is a new tenderer who is registered in NMRA, but not supplied to Ministry of Health previously, shall submit a sample along with a recognized national or international laboratory accreditation report upon requisition of the procurement entity. Depending on the Purchaser's discretion samples may be subjected to be verified by a subject specialist or an end user

35. Upon request of the Purchaser, representative samples in respect of items offered should be submitted to **Chairman. Project Procurement Committee, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP - No. 81/4, Rosmead Place, Colombo 07, Sri Lanka.** clearly indicating the word "sample", the tender reference number/package number, SR No. name of the supplier, closing date & time on the outer pack / envelope.

36. All responsive Suppliers are advised to submit their samples through their Local Agents if any to ensure compliance with this request. Even past suppliers other, than the present supplier is liable to submit representative samples as specified therein.

37. If the Supplier does not have a Local Agent, then samples should be sent to The **Chairman - Project Procurement Committee, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP - No.81/4, Rosmead Place, Colombo 7, Sri Lanka.** With the outer pack marked with

Tender Reference, closing date and time indicating the words 'Sample'. A No-Commercial Value Invoice (indicating nominal value for custom's purpose only) together with Analytical Certificates should be attached to the consignee's copy of Air Way bill and a copy should also be sent direct to the Chairman - **Project Procurement Committee, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP - No.81/4, Rosmead Place, Colombo 7, Sri Lanka**. All these documents and all sample packs should bear the Tender Reference (without which the customs will not permit clearance).

- 38.** All samples (except bulk drugs or raw materials) must be in their original trade containers properly labeled in the English Language and should be according to labeling conditions of these General Requirement/ Specification.
- 39.** Samples should not be included in the envelope carrying the Tender. Samples should be sent separately to the Chairman - **Project Procurement Committee, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP - No.3/19, Kynsey Road, Colombo 8, Sri Lanka**
- 40.** 1 No of Sample is required (should be in their original trade containers Except for Raw Materials or Chemicals).
- 41.** In case of quality failure reports / complaints samples are sent to NMQAL / ITI, for further analysis.

Common conditions

- 42.** 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 Purchaser, 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.
- 43.** Administrative surcharge of 25% (on the value of goods), will be applied for tender condition deviations that cause deficiencies in supply with respect to; quality, standards & specifications, short packing & short supply or delayed delivery as per the cabinet decision.

Abbreviations: *NMRA; National Medicines Regulatory Authority/Sri Lanka, MSD; Medical Supplies Division/Ministry of Health-Sri Lanka. LOA; Letter of Acceptance, MSMIS; Medical Supplies Information Management System. NMQAL; National Medicine Quality Assurance Laboratory, ITI; Industrial Technology Institute*

(b) Part B - Special Order Conditions (SOC) of Supply

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

All anesthetic products should strictly comply the labeling requirement specified in Tender Document.

Part B - Product Specific Specifications

Cochlear Implants with Accessories (SR No. – 13201301)

S/N	Description	Priority	Tenderer's Offer		
			Conformity		Remarks/ Variations if any
			Yes	No	
1	The Device shall consist of the external component (Speech processor) and the internal component (Receiver)	C			
2	The device shall have valid US FDA or EU approval	C			
Internal component (Receiver)					
3	There shall be 10 years of comprehensive warranty for the internal component.	C			
4	Should contain not less than 12 number of intra cochlear stimulation channels/ electrodes.	C			

5	Shall be compatible with MRI without magnet.	C			
6	Shall be able to remove and reinsert magnet for MRI imaging	C			
7	Shall have Intra operative monitoring facility.	C			
8	Shall be compatible with future improvements of the Speech processors	C			
9	<p>Fresh Stock and Shelf Life Supplies should be from fresh stocks manufactured recently conforming to the stipulated specifications and shelf line. Residual shelf life should be minimum of 36 months. However, shelf life remaining at the time of receipt of goods at Medical Supplies Division, Sri Lanka should be at least 85% out of the total shelf life of the product.</p> <p>Note: Purchaser reserves the right to call for free replacement of goods supplied with inadequate residual shelf life, or reject such consignment and refrain from its clearance from the port.</p>	C			
External component (Speech processor)					
10	<p>External Component BTE – Processor Unit – 05 years after delivery Coil – 2 years after delivery Coil Cable – 2 years after delivery Battery Pack – 2 years after delivery BTE Controller – 02 years after delivery OTE – Single Unit Processor – 05 years after delivery</p>	C			

11	external component shall be BTE type or off-the-ear single unit sound processor	C			
12	Shall have Two Microphones or if single microphone, the microphone should be omni directional	C			
13	Minimum of two rechargeable batteries should be supplied with the quoted model	C			
14	Interchangeable magnets of varying strength should be available with the tenderer and should be replaced free of charge on request within the warranty period.	C			
15	Should have Remote control facility for user for easy manual ability.				
16	Should have Dry Box to absorb moisture of external processor if recommended	C			
17	Should provide loaner machine immediately if the repair cannot be completed within two weeks.	C			
18	Fresh Stock and Shelf Life Supplies should be from fresh stocks manufactured recently conforming to the stipulated specifications and shelf line. Residual shelf life should be minimum of 36 months. However, shelf life remaining at the time of receipt of goods at Medical Supplies Division, Sri Lanka should be at least 85% out of the total shelf life of the product.	C			

	Note: Purchaser reserves the right to call for free replacement of goods supplied with inadequate residual shelf life, or reject such consignment and refrain from its clearance from the port.				
General Specifications					
19	Country of origin of the device	C			
20	Country of manufacture of the speech processor	C			
21	Country of manufacture of the receiver	C			
22	The length of the electrode				
23	<p>Eligible Goods and Registration</p> <p><i>With the National Medicines Regulatory Authority (NMRA)</i></p> <p>(a) All surgical & specified laboratory products imported to Sri Lanka should be registered with the National Medicines Regulatory Authority of Sri Lanka. Therefore, all prospective tenderers should advise their local representatives to attend to such registration.</p>	C			
	The selected tenderer must submit a certified copy of the NMRA registration certificate / Waiver of Registration certified by the Attorney-at-Law,	C			

	<p>Commissioner of Oaths or Justice of Peace on or before signing the contract.</p> <p><i>* Considering the urgent nature of this procurement, waiving off of the NMRA registration may be considered as an exception.</i></p>				
24	<p>Testing and Batch Samples</p> <p>In the case of distribution to Hospitals / State Institutions random batch samples and random post-marketing samples of all goods supplied will be tested at the NMQAL or Quality Assurance & Research Laboratory of the State Pharmaceuticals Corporation and reports on its suitability issued. The findings of the reports will be final and binding. Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an administrative cost within 30 dates from the date of intimation.</p>				
25	<p>Quality Certificate</p> <p>The purchaser reserves the right to nominate independent competent authorities for the issue pre-shipment certification (certificate of quality, quantity and loading). In such an event, the cost of such certification must be borne by the supplier and should be included in the bid.</p>	C			

	<p>The, Secretary, Ministry of Health, Sri Lanka reserves the right to nominate suitable persons to inspect the production and quality control facilities of tenderers and manufacturers and their records. Tenderers, who refuse permission to our nominees to carry out such an audit will be automatically disqualified</p> <p>The expenses involved in the inspections hod be borne by the manufacturer/ supplier.</p>				
26	<p>Product Liability In the event of an order being placed, the supplier should indemnify the purchaser against all product liability claims arising out of the items supplied on his bid. E.g., due to incorrect labelling, deviation from agreed specifications etc.</p>				
27	<p>Patent Rights and Other Third-Party Rights and Royalties The Suppliers shall at all times indemnify and keep the purchaser indemnified against any and all claims arising at any time on Account of Patent rights or other rights, whether from manufacturers or others, from the use of the supplied goods in Sri Lanka.</p>				
28	<p>Packing and Storage Conditions i. Pack size offered should confirm to requirements. Bids for alternative pack sizes may be rejected. Export worthy packing which will prevent damage</p>				

	<p>in transit should be used. Details of nature packing should be given.</p> <p>ii. Packing of all items should be suitable for storage and use under tropical conditions. Final Export packing should indicate the required storage temperature for goods which require Refrigeration / Cool Room / Freezer enabling the cargo handling staff at the Port of Destination to arrange proper storage for such goods immediately on arrival.</p> <p>iii. Containers and closures used should prevent leakage in transit and storage also suitable for safe and easily handling.</p> <p>iv. Final export packing should be in seaworthy cases or cartons, stenciled with blue bands in the form of a cross on each face and in addition carrying the shipping marks, details of which will be provided with the order. Such export packing should be suitable to withstand the long journey and rough handling at ports of loading and unloading. Bag Cargo should be palletized and shrink wrapped.</p> <p>v. Sri Lankan ambient storage conditions are in the ranges of 30°C +/- 2°C temperature and 75% +/- 5% relative humidity.</p>				
--	---	--	--	--	--

	<p>vi. The items which have to be stored between 2°C - 8°C should be sent with cold chain monitors.</p> <p>vii. The recommended storage mentioned on the product label should be maintained at transit also and storage condition should be clearly shown on Bill of Lading / Air way Bill and invoice.</p> <p>viii. All outer carton and inner box (if any) of surgical consumables / imposable items should contain the following information.</p> <p>a) <i>Description of the item</i></p> <p>b) <i>Date of Manufacturer in 1.5cm Font</i></p> <p>c) <i>Date of Expiry in 1.5cm Font</i></p> <p>d) <i>Batch No. in 1.5cm Font</i></p> <p>e) <i>Name and address of the manufacturer</i></p> <p>f) <i>Contract No</i></p> <p>g) <i>Stock Reference No (SR No.)</i></p> <p>ix. It is the responsibility of the manufacturer / supplier to ensure that the containers would be intact and without damage until the items are delivered to final destination.</p> <p>x. In any damage (s) caused due to non-compliance of packing to the above-mentioned conditions, supplier should bear the full cost damages.</p> <p>xi. Contract number, Serial No (SR No.), batch numbers, date of manufacture, date of expiry</p>				
--	--	--	--	--	--

	<p>and respective quantity carton number containing same should be indicated in all supply invoices and packing list.</p> <p>All tenderers should indicate in their bids, as to whether above mentioned requirements could be met; which will be taken into consideration at the time of evaluation of the bid.</p>				
29	<p>Labelling</p> <p>1.</p> <p>Il labels should be printed in English language and the labelling requirements should be according to the specifications required for registration at NMRA as follows.</p> <ul style="list-style-type: none"> a) Description of the item b) The brand name c) List of content d) A statement of the net contents (e.g: number of units, weight or volume) e) Any special storage conditions that may necessary f) Warning and precautions that may be necessary g) The date of manufacture, where applicable h) The date of expiry, where applicable i) The batch or lot number assigned by the manufacturer and j) The name and address of the manufacturer 				

	<p>2. Size of the letters of the above (g), (h) and (i) and the SR number on the outer carton should not be less than 1.5cm</p> <p>3. Identification marks The “SR No.” which will be made available to the successful tenderer should be embossed or imprinted in each (item) on the affixed label. These marks should be indelible.</p> <p>4. The name of the manufacturer or identification mark should be imprinted in a permanent manner on surgical consumable items.</p> <p>All tenderers should indicate in their bids, as to whether the above-mentioned requirements could be met; which will be taken into consideration at the time of evaluation of the bid.</p>				
Post Operative Care					
30	Tenderer should have minimum of one auditory rehabilitation facility per province with qualified therapists for mapping and therapy sessions and such information including the names and qualifications of the personal who perform such work be attached in the bid document.	C			

31	Therapists should have minimum qualification of a bachelor degree in speech and hearing from a recognized university and a special training on auditory Verbal Therapy. (Documentary proof in this regard shall be provided by the successful tenderer for at least one therapist in each therapy center with bidding documents.)	C			
32	The successful tenderer should provide Auditory Verbal Therapy (AVT) for at least twelve (12) sessions for the first year and Six (6) sessions for the second year after implant for all recipients free of charge either in government hospital or in the tenderers institute and maintain records to that effect with the facility and the recipient.	C			
33	Tenderer should provide any number of mapping sessions as requested by the surgeon, free of charge by an audiologist specially trained for this purpose for each patient within 5years of implant. (Documentary proof of qualifications shall be provided by the tenderer with the offer).	C			
34	The successful tenderer should translate the owner's manual of the equipment fully, including the graphics to Sinhala and Tamil languages as it appears in the English version and print in color the same and distribute one copy each for all recipients free of cost.	C			

35	The successful tenderer should design a quick user guide extracting the most important user instructions from the manual and print in color the same in Sinhala and Tamil languages and distribute among all the recipients free of cost in addition to the user manual.	C			
36	The successful tenderer should design a review & Progress format in accordance with the format given by the Ministry of Health as an attachment to the translated user manual and distribute to all recipients.	C			
37	The successful tenderer should maintain a hotline with a knowledgeable person of all three languages for the recipients to contact and obtain any information. The hotline details should be provided with the bid document.	C			
Additional Services					
38	Local supplier/agent should supply following details/facilities - a. Name & contact details of the local agent. b. Agency certificate.	C			
39	Intra operative monitoring should be done free of charge	C			
40	The Tenderer should provide the depth gauge, free of charge in case, such device is needed at the time of the surgery.	C			

41	The tenderer should provide the prices of all accessories and spare parts of the equipment in USD yearly for 5 years after the warranty period in USD	C			
42	The successful tenderer shall keep stocks of all required spare parts with him and once ordered shall supply within one week	C			
43	The tenderer or its local agent should be ready to supply a suitable short array back up devices free of charge in the case of difficulty of insertion during implantation surgery.	C			

Supporting documents to be supplied.

1. Product Catalogs of item with catalog number, brand name, model number, country of origin, manufacturer and standard picture/s.
2. Valid authorization/s from the manufacturer.
3. Certified copies of Invoices and Good Receipt Notices to confirm the successful supply
4. Certified copies of valid NMRA Certificate/s OR evidence of NMRA registration renewal
5. Evidence for Production, Packaging & Distribution capabilities

3. Inspections and Tests

The following inspections and tests shall be performed:

Physical check will be conducted on receipt of the goods accordance with the technical specifications

Quality Control Inspections / Conformity Test in detail will be conducted after the delivery according to the item no. 13 of the General Requirement/ Specifications.

PART 3 - Contract

Section VIII - General Conditions of Contract

Table of Clauses

1. Definitions	115
2. Contract Documents.....	116
3. Fraud and Corruption	116
4. Interpretation	116
5. Language.....	117
6. Joint Venture, Consortium or Association	118
7. Eligibility	118
8. Notices.....	118
9. Governing Law	118
10 Settlement of Disputes	119
11. Inspections and Audit by the Bank.....	119
12. Scope of Supply.....	119
13. Delivery and Documents.....	119
14. Supplier's Responsibilities	120
15 Contract Price.....	121
16. Terms of Payment	121
17. Taxes and Duties	121
18. Performance Security	122
19. Certification of Goods in Accordance with Laws of the Purchaser's Country	122
20. Confidential Information	123

21. Subcontracting	123
22. Specifications and Standards	124
23. Packing and Documents	124
24. Insurance	124
25. Transportation and Incidental Services	124
26. Inspections and Tests	125
27. Liquidated Damages	127
28. Warranty.....	127
29. Patent Indemnity	128
30 Limitation of Liability.....	129
31. Change in Laws and Regulations	130
32. Force Majeure	130
34. Extensions of Time	131
35. Termination	132
36. Assignment	133
37. Export Restriction.....	133

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 Asian Infrastructure Investment Bank
- (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 Tender 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 “Prohibited Practices Policy” as set forth in the Appendix to the GCC. Policy on Prohibited Practices.

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 Tendering 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 Recipient’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 Recipient’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 15.3 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.
- 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 indentured labor, bonded labor or similar labor-contracting arrangements.
- 14.4. Trafficking in persons is defined as the recruitment, transportation, transfer, harboring 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 Tender, 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 Tender 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 arbitration 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 Tender. 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 Tender 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 specification's 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 Tender 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 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

(Section VI shall not be modified)

3. The Bank requires that the Recipient (and all other beneficiaries of the Bank financing), as well as tenderers, suppliers, contractors, concessionaires and consultants under Bank-financed contracts for the Project, observe the highest standard of transparency and integrity during the procurement, execution and implementation of such contracts.
4. Definitions. In pursuance of this policy, the Bank defines the terms set forth below as Prohibited Practices:
 - (h) **“Coercive practice”** means impairing or harming or threatening to impair or harm, directly or indirectly, any party or the property of a party to influence improperly the actions of a party.
 - (i) **“Collusive practice”** means an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party.
 - (j) **“Corrupt practice”** means the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party.
 - (k) **“Fraudulent practice”** means any act or omission, including a misrepresentation, that knowingly or recklessly misleads or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation.
 - (l) **“Misuse of resources”** means improper use of the Bank’s resources, carried out either intentionally or through reckless disregard.
 - (m) **“Obstructive practice”** means any of the following practices: (i) deliberately destroying, falsifying, altering or concealing of evidence material to a Bank investigation; (ii) making false statements to investigators in order to materially impede a Bank investigation into allegations of a Prohibited Practice; (iii) failing to comply with requests to provide information, documents or records in connection with a Bank investigation; (iv) threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to a Bank investigation or from pursuing the investigation; or (v) materially impeding the exercise of the Bank’s contractual rights of audit or inspection or access to information.
 - (n) **“Theft”** means the misappropriation of property belonging to another party.
7. Any occurrence, or suspected occurrence, of a Prohibited Practice in the procurement, award or implementation of a Bank-financed contract is dealt with in accordance with the provisions of the Bank’s Policy on Prohibited Practices. Suppliers, contractors,

service providers and consultants selected pursuant to the provisions of Section II and concessionaires selected pursuant to paragraph 14.3 of the Bank's Procurement Instructions for Recipients, as well as the Recipient shall fully cooperate with the Bank (or a co-financier undertaking an investigation pursuant to paragraph 6.1 of the Bank's Procurement Instructions for Recipients) in any investigation into an alleged Prohibited Practice to be carried out pursuant to the Policy on Prohibited Practices, and permit the Bank or its representative (including such co-financier) to inspect such of their accounts and records as may be relevant for such investigation and to have such records and accounts audited by the auditors appointed by the Bank.

8. Provisions to this effect are included in the Legal Agreements and the procurement contracts with such entities.
9. If the Project is financed by a sovereign-backed loan, the Bank (or, where relevant, a co-financier having undertaken an investigation pursuant to paragraph 6.1 of the Bank's Procurement Instructions for Recipients):
 - (b) may take any of the following additional actions in connection with a Prohibited Practice under the Project:
 - (i) reject a proposal for award if it determines that the tenderer recommended for award, or any of its personnel, or its agents, or its subconsultants, subcontractors, service providers, suppliers or their employees, has, directly or indirectly, engaged in a prohibited practice in competing for the contract in question; and
 - (ii) cancel the undisbursed portion of the loan allocated to a contract (and require reimbursement of the disbursed portion of the loan allocated to the contract) if it determines at any time that representatives of the Recipient or of a recipient of any part of the proceeds of the loan engaged in a prohibited practice during the procurement, administration or implementation of the contract in question; and
 - (c) requires that a clause be included in tender documents and in contracts financed by the Bank loan, requiring tenderers, suppliers and contractors and their subcontractors, agents, personnel, consultants, service providers or suppliers, to permit the Bank (and a co-financier undertaking an investigation pursuant to paragraph 6.1 of the Bank's Procurement Instructions for Recipients) to inspect all accounts, records and other documents relating to the submission of tenders and contract performance, and to have them audited by auditors appointed by the Bank.

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.

GCC 1.1(i)	The Purchaser's Country is: Democratic Socialist Republic of Sri Lanka
GCC 1.1(j)	The Purchaser is: The Secretary, Ministry of Health
GCC 1.1 (o)	The Final Destination is Medical Supplies Division of the Ministry of Health, No.357, Ven Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka
GCC 1.1 (p)	Not Applicable
GCC 4.2 (a)	The meaning of the trade terms shall be as prescribed by Incoterms and as modified based on the requirements of the Purchaser
GCC 4.2 (b)	Incoterms shall be applicable
GCC 5.1	The language shall be: English Language
GCC 8.1	For notices , the Purchaser's address shall be: Attention: Project Director, Emergency Health Components of: (i) SCURP; and (ii) RLVMMMP Street Address: No. 81/4, Rosmead Place, Colombo 07, Sri Lanka City: <i>Colombo</i> ZIP Code: <i>007</i> Country: <i>Sri Lanka</i> Telephone: (+94) 112 697 173 Facsimile number: (+94) 112 697 163 Electronic mail address: hsrp.pmu.aiib@gmail.com
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:

	<p>GCC 10.2 (a)—Any dispute, controversy or claim arising out of or relating to this Contract, or breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force.</p> <p>(b) Contracts with Supplier national of the Purchaser’s Country:</p> <p>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 Arbitration Act No.3 of 1995 of Sri Lanka.</p>
<p>GCC 13.1</p>	<p><i>For Goods from within the Purchaser’s Country:</i></p> <p>Upon or before delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser:</p> <ul style="list-style-type: none"> (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, air waybill, or multimodal transport document showing Purchaser as <i>[enter correct name of Purchaser for customs purposes]</i> 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 manufacturers 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	<p>GCC 16.1—The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:</p> <p>Payment for Goods and Services supplied from within the Purchaser’s Country:</p> <p>Payment for Goods and Services supplied from within the Purchaser’s Country shall be made in the currency(ies) of the contract as follows:</p> <ol style="list-style-type: none"> i. Advance Payment: Ten (10) percent of the Contract Price shall be paid within thirty (30) days of signing of the Contract against a simple receipt and a bank guarantee for the equivalent amount and in the form provided in the bidding document or another form acceptable to the Purchaser. ii. On Acceptance: The remaining ninety (90) percent of the Contract Price shall be paid to the Supplier within thirty (30) days after the date of the acceptance certificate for the respective delivery issued by the Purchaser.
GCC 16.5	<p>The payment-delay period after which the Purchaser shall pay interest to the supplier shall be sixty days.</p> <p>The interest rate that shall be applied is 1% more than on lending to commercial banks rate declared by the Central Bank of Sri Lanka applicable for the currency of the contract</p>
GCC 18.1	<p>A Performance Security shall be required</p> <p>Performance Security shall be: 10 % of the contract price</p>

GCC 18.3	<p>If required, the Performance Security shall be in the form of: an unconditional on Demand Guarantee issued by a reputable commercial bank registered with the Central Bank of Sri Lanka.</p> <p>If the unconditional demand guarantee is issued by a commercial bank located outside the Sri Lanka, the issuing bank shall have a correspondent commercial bank in Sri Lanka registered with the Central Bank of Sri Lanka to make it enforceable</p> <p>If required, the Performance security shall be denominated in <i>the currencies of payment of the Contract, in accordance with their portions of the Contract Price.</i></p>
GCC 18.4	The Performance Security shall be valid one month beyond the actual goods delivery date to the Medical Supplies Division
GCC19.1	<p>The registration and other certification necessary to prove registration in Purchaser’s Country is NMRA</p> <p>Details of registration and other certification necessary to prove registration is available in the website www.nmra.gov.lk</p>
GCC19.2	<p>The Effective Date of the Contract is: <i>Date of Contract signing.</i></p> <p>the Goods have already been registered at the time of Contracting signing</p>
GCC19.3	The time period shall be 45 Days
GCC 23.2	<p>Packing And Storage Conditions</p> <p>Packing and Storage Conditions shall be fulfilled according to the General Requirement/ Specification</p> <p>Labelling</p> <p>Labelling Conditions shall be fulfilled according to General Requirement/ Specification and/or at the discretion of the Medical Supplies Division.</p>
GCC 24.1	The insurance coverage shall be in: Pursuant to GCC, Subclause 24.1, the Supplier must insure the Goods in an amount equal to 110% of the CIP price of the Goods from “Warehouse” to “Warehouse” on “All Risks” basis, including War Risks and Strikes
GCC 25.1	Obligations for transportation of the Goods shall be in accordance with: Incoterms 2020
GCC 25.2	<p>Incidental services to be provided are:</p> <p>Prepare all the documentation required and payments for all the services to Clearance of goods from Colombo Port/ Airport</p> <p>Transport of goods from Colombo Port/ Airport to MSD warehouse</p> <p>Training of Professional Staff</p>

GCC 26.1	<p>The inspections and tests shall be:</p> <p>Physical check will be conducted on receipt of the goods accordance with the specifications</p> <p>Quality Control Inspections / Conformity Test in detail will be conducted after the delivery</p>
GCC 26.2	<p>Tests and Inspections specified in Section 7 (Schedule of Requirement), shall be carried out at the following times or milestones, and places:</p> <p>Goods: Implant Materials & Miscellaneous Items</p> <p>Time or Milestone: On delivery before accepting</p> <p>Place: As per Schedule of Requirement</p> <p>Address: As per Schedule of Requirement</p> <p>Country: Sri Lanka</p>
GCC 27.1	The liquidated damage shall be: One (1.00) % per week or part thereof.
GCC 27.1	<p>The maximum amount of liquidated damages shall be: Five (5.00) %</p> <p>In the event of partial supplies, LD shall be deducted proportionately.</p>
GCC 28.1	<p>Add the additional provisions as follow;</p> <p>Supplies should be from fresh stocks manufactured recently conforming to the stipulated specifications and shelf line. The shelf life should be minimum of 24 months for pharmaceuticals. However, shelf life remaining at the time of receipt of goods at Medical Supplies Division, Sri Lanka should be at least 85% out of the total shelf life of the product. (Refer No.2 at the Item 3 of Section 6 (Schedule of Supply).</p> <p>The place of final destination shall be: Medical Supplies Division (MSD), Ministry of Health, 357 Ven Baddegama Wimalawansa Mawatha, Colombo 10, Sri Lanka</p>
GCC 28.4	The period for replacement shall be: Thirty (30) days
GCC 35. 1 (a) I	GCC (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, the contract shall be treated as terminated.

GCC 28.6	<p>Add following as the GCC 28.6</p> <p>The Supplier shall correct any defects as follows;</p> <ol style="list-style-type: none">1. Purchaser reserves the right to call for free replacement of goods supplied with inadequate residual shelf life, or reject such consignment and refrain from its clearance from the port. (Refer No.2 at the Item 3 of Section 6 (Schedule of Supply)).2. Purchaser reserves the right to call for free reimbursement in the event of short packing, loss/damage or deterioration of goods supplied within the shelf life, also for packs which cannot be identified due to labels falling off or items with incorrect labelling.3. All quality problems/complaints should be confirmed by the National Medicines Regulatory Authority (NMRA) / Technical Advisory Committee (TAC) of Sri Lanka / State Pharmaceutical Corporation (SPC) Quality Assurance Laboratory or any other Authority as decided by the Ministry of Health of Sri Lanka.4. In the event of receipt of a complaint, samples will be tested by NMQAL and follow the recall procedure approved by the Ministry of Health and will be destroyed according to the section 72 of Drug Regulations.5. In case of withdrawals due to quality failure, suppliers should ensure that the value of entire quantity either the withdrawn batched or product would be total reimbursed with an additional 25% of the total value concerned as an administrative cost. <p>Goods reported as unsuitable and not conforming to the laid down specifications will be rejected and subsequently destroyed. The suppliers should agree to refund its landed cost plus an additional 25% as an administrative cost within 30 dates from the date of intimation. (Refer No.4 & 5 at the Item 3 of Section 6 (Schedule of Supply)).</p>
-----------------	--

Special Conditions of Contract

SURGICAL

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in Tendering document for the procurement of Surgical Consumables

GCC 13.1	<p><i>For Goods supplied from abroad:</i></p> <ul style="list-style-type: none"> (ix) One original of the Certificate of Pharmaceutical/Surgical 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/ Surgical 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.
----------	--

Section X - Contract Forms

Table of Forms

Notification of Intention to Award	144
Letter of Acceptance	150
Contract Agreement.....	151
Performance Security.....	153
Advance Payment Security.....	155

Notification of Intention to Award

[This Notification of Intention to Award shall be sent to each Tenderer that submitted a Tender.]

[Send this Notification to the Tenderer's Authorized Representative named in the Tenderer Information Form]

For the attention of Tenderer'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 Tenderers. The Notification must be sent to all Tenderers 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 : Ministry of Health

Project : Emergency Health Components of: (i) Support to Colombo Urban Regeneration Project (SCURP) – AIB Loan No. L0081A and (ii) Reduction of Landslide Vulnerability by Mitigation Measures Project (RLVMMP) - AIB Loan No. L0124A

Contract : Procurement of Cochlear Implants and Accessories

Country : Sri Lanka

RFT No : HSRP/PMU/PRO/G/MS/S/14

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 Tender, and/or
- b) submit a Procurement-related Complaint in relation to the decision to award the contract.

1. The successful Tenderer

Name:	<i>[insert name of successful Tenderer]</i>
Address:	<i>[insert address of the successful Tenderer]</i>
Contract price:	<i>[insert contract price of the successful Tenderer]</i>

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

Name of Tenderer	Tender price	Evaluated Tender price (if applicable)
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]
[insert name]	[insert Tender price]	[insert evaluated price]

3. Reason/s because your Tender was unsuccessful

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

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 Tender. 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 Tenderer, contact details; and address the request for debriefing as follows:

Attention: Dr. Anil Dissanayake

Title/position: Project Director

Agency: Health System Response Project, No. 81/4, Rosmead Place, Colombo 07, Sri Lanka

Email address: hsrp.pmu.aiib@gmail.com

If your request for a debriefing is received within the three (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 Tenderer, contact details; and address the Procurement-related Complaint as follows:

Attention: Dr. Anil Dissanayake

Title/position: Project Director

Agency: Health System Response Project, No. 81/4, Rosmead Place, Colombo 07, Sri Lanka

Email address: hsrp.pmu.aiib@gmail.com

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 AIB Directive on Procurement Instructions for Recipients (July 26, 2024).

In summary, there are four essential requirements:

1. You must be an 'interested party'. In this case, that means a Tenderer who submitted a Tender in this Tendering 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 Annex III of AIB Directive on Procurement Instructions for Recipients (July 26, 2024).

6. Standstill Period

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

The Standstill Period lasts three (3) 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 TENDERERS: DELETE THIS BOX ONCE YOU HAVE COMPLETED THE FORM

This Beneficial Ownership Disclosure Form (“Form”) is to be completed by the successful Tenderer. In case of joint venture, the Tenderer 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 Tenderer is any natural person who ultimately owns or controls the Tenderer 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 Tenderer*

RFT No.: *[insert number of RFT process]*

Request for Tender 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 Tenderer (Yes / No)
<i>[include full name (last, middle, first), nationality, country of residence]</i>			

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 Tenderer

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 Tenderer 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 Tenderer]"

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

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

Title of the person signing the Tender: [insert complete title of the person signing the Tender]

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 Tender submitted by a Joint Venture specify the name of the Joint Venture as Tenderer. In the event that the Tenderer is a joint venture, each reference to "Tenderer" in the Beneficial Ownership Disclosure Form (including this Introduction thereto) shall be read to refer to the joint venture member.

** Person signing the Tender shall have the power of attorney given by the Tenderer. The power of attorney shall be attached with the Tender 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 Tender 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 Tenderers 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 Forms and (ii) the additional information on beneficial ownership in accordance with TDS ITT 45.1 within eight (8) Business days using the Beneficial Ownership Disclosure Form, included in Section X, - Contract Forms, of the Tendering Document.

Authorized Signature:

Name and Title of Signatory:

Name of Agency:

Attachment: Contract Agreement

Contract Agreement

[The successful Tenderer 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 Tenders for certain Goods and ancillary services, viz., *[insert brief description of Goods and Services]* and has accepted a Tender 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 Tender
 - (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 Tenderer, 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 SECURITY 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.

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*

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.

be 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 SECURITY 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

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.*

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.

.

[signature(s)]

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