The Federal Democratic Republic of Ethiopia

Note to Public Bodies:

- The information contained within the brackets is in the form of **Hidden text** (Hidden text: Character formatting that allows you to show or hide specified text. Microsoft Word indicates hidden text by underlining it with a dotted line.), and will not print unless the print option is flagged. The hidden text doesn't need to be deleted.
- To view hidden text on the screen, click **Show/Hide** ¶ on the **Standard** toolbar (Toolbar: A bar with buttons and options that you use to carry out commands; or
- To view hidden text click **Options** on the **Tools** menu, click the **View** tab, and then select the **Hidden text** check box under **Formatting marks**.
- To see hidden text in a printed document, click the **Print** on the **File** menu. Under **Print** click **Options** and than select the **Hidden text** check box under **Include with document**
- To omit hidden text in a printed document, click **Options** on the **Tools** menu, click the **Print** tab, and then clear the **Hidden text** check box under **Include with document**.

Standard Bidding Document (SBD)

For Procurement of Health Sector Pharmaceuticals

For International Competitive Biddings (ICB)

Subject of Procurement

Procurement Reference Number

Project Name

Date of Issue of Bidding Document

Addis Ababa, October 2011

The Federal Democratic Republic of Ethiopia

Preface

Pharmaceuticals Fund and Supply PFSA (PFSA) is a public institution established (by proclamation number 553/1999) to procure and supply all categories of pharmaceuticals to health facilities in Ethiopia. The PFSA manages pharmaceuticals that are funded through Revolving Drug Fund as well as Program Pharmaceuticals procured using donors fund.

This Standard Bidding Document (SBD) is customized from the standard bidding document prepared by Federal Procurement and Property Administration taking in to account the real experience of foreign pharmaceuticals procurement with existing bidding document. The situation for amending the already developed document is it lacks comprehensive coverage of all health Pharmaceuticals special characteristics this leads to the development of requirements pertinent to the categories of subject procurement. The document has also accounted the real situation of the country in accordance with the provisions of contact:

Pharmaceuticals and Medical Supplies Tender Management Directorate
Pharmaceuticals Fund and Supply Agency (PFSA)
P.O. Box 21904
Addis Ababa, Ethiopia
TEL. 251-11-2763270/2751770
FAX 251-11-2752555
Email: pfsa@ethionet.et
Addis Ketema, woreda 05
Link to Website: http://www.pfsa.gov.et/

The Federal Democratic Republic of Ethiopia

Bidding Document

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Section I. Instructions to Bidders

A. General

1. Introduction

1.1 The Public Body indicated in the Bid Data Sheet (BDS) is the Contracting Authority for this procurement process and it is bound by the rules governing public procurement in the Federal Democratic Republic of Ethiopia. It has the powers and duties to conclude a Contract for the supply of Pharmaceuticalsand Related Services. Accordingly, this procurement process is being conducted in accordance with the recent editions of the Ethiopian Federal Government Procurement and Property Administration Proclamation and Public Procurement Directive under the procurement method indicated in the BDS.

1.2 By the issue of this Bidding Document the Public Body invites interested Candidates to submit their bids with a view to entering into Contract with the Public Body for the provision of Pharmaceuticals (Medicines, Chemical Reagents and Diagnostics, Medical equipment and Supplies, vaccines, contraceptives or nutritional supplements) and Related Services which general description is provided in the BDS. The Pharmaceuticals and Related Services that are subject of this procurement process are more particularly specified in Section 6, Statement of Requirement upon the basis of the information supplied in and in accordance with this Bidding Document.

1.3 The procurement reference number and number of lots of this Bidding Document are provided in the BDS. If Bids are being invited for individual contracts (lots) the Bidder may submit a Bid for one lot only, several or all of the lots. Each lot will form a separate contract and the quantities indicated for different lots will be indivisible. The Bidder must offer the whole of the quantity or quantities indicated for each lot.

1.4 Each Bidder may only submit one Bid, either individually or as a partner in joint venture. A Bidder who submits or participates in more than one Bid (other than as a subcontractor or in cases of alternatives that have been permitted or requested) will cause all the Bids with the Bidder's participation to be disqualified

1.5 This Section 1, Instructions to Bidders shall not form a part of the Contract. These instructions are intended to assist prospective Bidders in the preparation of their Bids.

1.6 Issuance of this Bidding Document does not in any way obligate the Public Body to award a Contract.

1.7 The Public Body retains ownership of all bids submitted in response to this Bidding Document. Consequently, Bidders have no right to have their bids returned to them except late bids.

1.8 In submitting a bid, the Bidder accepts in full and without restriction this Bidding Document as the sole basis of this procurement procedure, whatever his own conditions of sale may be, which he hereby waives. Bidders are expected to examine carefully and comply with all instructions, forms, contract provisions and specifications contained in this Bidding Document. Failure to submit a bid containing all the required information and documentation within the deadline specified may lead to the rejection of the bid. No account can be taken of any reservation in the bid as regards the Bidding Document; any reservation will result in the immediate rejection of the bid without further evaluation.

1.9 The permitted method of communication shall be in writing. Throughout these Bidding Documents the term "in writing" means communicated in written form and delivered against receipt.

1.10 TIME TABLE

The following is an indicative timetable in relation to the procurement process. The Purchaser will attempt to maintain this schedule, but reserves the right to vary key dates where necessary.

Ser No.	Item	Date
1	Tender Issue Date	June 25,2018
2	Last Date For Inquiries	July 10, 2018
3	Tender Closing Date	July 31, 2018
4	Tender Opening Date	July 31, 2018
5	Completion of Tender Evaluation	Within 01 month after bid opening
6	Completion of Approval Process	Within 15 days after tender completion of tender
7	Notification of Award	Within 2 days after approval
8	Contract Commencement Date	Within 3 weeks from award
9	Letter of Credit opening	Within 30 days from contract commencement

PFSA reserves the right to modify the timeline at any time. In such a case PFSA will inform all potential bidders but it is the responsibility of potential bidders to regularly check the relevant PFSA's procurement pages on its website.

2. Source of Funds

2.1 The Public Body has an approved budget toward the cost of the procurement described in the Section 6, Statement of Requirement. The Public Body intends to use these funds to place a Contract for which these Bidding Documents are issued.

2.2 Payments will be made directly by the Public Body and will be subject in all respects to the terms and conditions of the resulting Contract placed by the Public Body.

3. Fraud, Corruption and Complaints Provisions

3.1 The Government of the Federal Democratic Republic of Ethiopia (herein after called the Government) represented by the Public Procurement and Property Administration Agency (herein after called the Agency) requires Contracting Authorities, as well as bidders to observe the highest standards of ethics during the procurement and the execution of contracts. In pursuance of this policy, the Government:

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

(i) "Corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of any thing of value to influence improperly the action of a public official in the procurement process or in contract execution;

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

(iii) "Collusive practices" is a scheme or arrangement between two or more Bidders, with or without the knowledge of the Public Body, designed to establish prices at artificial, non-competitive levels; and

(iv) "Coercive practices" is harming or threatening to harm, directly or indirectly, persons or their property to influence their participation in a procurement process, or affect the execution of a contract.

(v) Obstructive practice is

- deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede the Federal Ethics and Anticorruption Commission, the Federal Auditor General, and the Public Procurement and Property Administration Agency or their auditors' investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent their from disclosing their knowledge of matters relevant to the investigation or from pursuing the investigation, or
- acts intended to materially impede the exercise of inspection and audit rights provided for under ITB Clause 3.5 below.

(b). Will reject a recommendation for award if it determines that the Bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;

(c). Will debar a Bidder from participation in public procurement for a specified period of time if it at any time determines the Bidder has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract. The List of Debarred Bidders is available on the Agency's Website http//www.ppa.gov.et.

3.2 In pursuit of the policy defined in Sub-Clause 3.1, the Public Body may terminate a contract for Pharmaceuticals if it at any time determines that corrupt or fraudulent practices were engaged in by representatives of the Public Body or of a Bidder during the procurement or the execution of that contract.

3.3 Where it is proved that the bidder has given or has offered to give inducement or bribe to an official or procurement staff of the Public Body to influence the result of the bid in his favor shall be disqualified from the bid, prohibited from participating in any future public procurement and the bid security deposited by them shall be forfeited.

3.4 Bidders are required to indicate their acceptance of the provisions on fraud and corruption, as defined in this clause through the statement in the Bid Submission Sheet.

3.5 The Agency will have the right to require to inspect the Supplier accounts and records relating to the performance of the contract and to have them audited by auditors appointed by the Agency.

3.6 Subject to the recent editions of the Public Procurement Proclamation and Procurement Directive, a candidate or a bidder aggrieved or is likely to be aggrieved on account of the Public

Body inviting a bid not complying with the provisions of the Proclamation or Procurement Directive in conducting a bid proceeding may present complaint to the head of the Public Body to have the bid proceeding reviewed or investigated. Any complaint must be submitted in writing to the head of the Public Body, within five working days from the date the Bidder knew, or should have known, of the circumstances giving rise to the complaint. If the head of the Public Body does not issue a decision within ten working days after submission of complaint, or the candidate or the Bidder is not satisfied with the decision, it may submit a complaint to the Board within five working days from the date on which the decision has been or should have been communicated to the candidate or the Bidder by the Public Body. The Board's decision is binding for both parties.

4. Eligible Bidders

4.1 A Bidder may be a natural person, private, public or government-owned legal entity, subject to ITB Sub-Clause 4.5, or any combination of them with a formal intent to enter into an agreement or under an existing agreement in the form of a Joint Venture (JV), consortium, or association. In the case of a Joint Venture, consortium, or association:

(a). All parties to the Joint Venture, consortium or association shall be jointly and severally liable, unless otherwise specified in the BDS; and

(b). A Joint Venture, consortium or association shall nominate a Representative who shall have the authority to conduct all businesses for and on behalf of any and all the parties of the Joint Venture, consortium or association during the bidding process and, in the event the Joint Venture, consortium or association is awarded the Contract, during contract execution.

4.2 This Invitation for Bids is open to all Bidders (including all members of a joint venture, sub-contractors and personnel) from eligible source countries as defined in Section 5, Eligible Countries. A Bidder shall be deemed to have the nationality of a country if the Bidder is a citizen or is constituted, incorporated, or registered and operates in conformity with the provisions of the laws of that country. This criterion shall also apply to the determination of the nationality of proposed subcontractors for any part of the Contract including related services.

4.3 A Bidder shall not have a conflict of interest. All Bidders found to have a conflict of interest shall be disqualified. A Bidder may be considered to have a conflict of interest with one or more parties in this bidding process, if they:

(a). Are or have been associated in the past, directly or indirectly, with a firm or any of its affiliates which have been engaged by the Public Body to provide consulting services for the preparation of the Specification, and any other documents to be used for the procurement of the Pharmaceuticals and Related Services to be purchased under this Bidding Document;

(b). Have a relationship with each other, directly or through common third parties, that puts them in a position to have access to information about or influence on the bid of another Bidder, or influence the decisions of the Public Body regarding this bidding process; or

(c). Submit more than one bid in this bidding process.

4.4 A Bidder that has been debarred from participating in public procurement in accordance with ITB Clause 3.1 (c), at the date of the deadline for bid submission or thereafter, shall be disqualified.

4.5 Government-owned enterprises shall be eligible if they can establish that they are legally and financially autonomous and operate under commercial law and that they are not a dependent

agency of the Public Body.

4.6 Unless otherwise specified in the BDS, Bidders shall provide such evidence of their eligibility satisfactory to the Public Body, to verify that the Bidder:

(a). Is not insolvent, in receivership, bankrupt or being wound up, not have had their business activities suspended and not be the subject of legal proceedings for any of the foregoing

(b). Appropriate documentary evidence demonstrating its compliance, which shall include:

(i) Valid business license indicating the stream of business in which the Bidder is engaged,

(ii) VAT registration certificate issued by the tax authority (only domestic Bidders in case of contract value as specified in BDS),

(iii) Valid Tax clearance certificate issued by the tax authority (domestic Bidders only);

(iv) Relevant professional practice certificates, if required in BDS.

(c). Foreign bidders must as appropriate submit business organization registration certificate or trade license issued by the country of establishment.

4.7 To participate in this public procurement process, being registered in the suppliers list is a prerequisite (mandatory for domestic Bidders only).

4.8 Bidders shall provide such evidence of their continued eligibility satisfactory to the Public Body, as the Public Body shall reasonably request in BDS.

4.9 If its Bid is accepted the Bidder shall submit the documentary evidence that will proof that Bidder is certified by a competent authority in the country of manufacture according to resolution WHA 28 65 (Annex 2) of the World Health Organization's Certificate Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

5. Eligible Pharmaceuticals and Related Services

5.1 All Pharmaceuticals and related services to be supplied under the Contract shall have as their country of origin an eligible country in accordance with Section 5, Eligible Countries.

5.2 For purposes of this Clause, the term "Pharmaceuticals" includes Medicines, Chemical Reagents and Diagnostics, Medical equipment and Supplies, nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms that are subject of procurement under this Bidding Document and the term "Related Services" includes services such as transportation, commissioning, insurance, installation, training, and initial maintenance.

5.3 The term "country of origin" means the country where the Pharmaceuticals 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 imported components.

5.4 The nationality of the Bidder that produces, assembles, distributes, or sells the Pharmaceuticals shall not determine their origin.

5.5 To establish the eligibility of the Pharmaceuticals and Related Services, in accordance with this ITB Clause, Bidders shall complete the country of origin declarations in the Price Schedule Form, included in Section 4, Bidding Forms that shall be confirmed by a certificate of origin issued at the time of shipment.

5.6 If so required in the BDS, in the case of a Bidder offering to supply Pharmaceuticals, identified in the BDS, that the Bidder did not manufacture or otherwise produce, the Bidder shall demonstrate that it has been duly authorized by the manufacturer or producer of such Pharmaceuticals to supply the Pharmaceuticals indicated in its bid in the Federal Democratic Republic of Ethiopia by obtaining Manufacturer Authorization Letter using the form furnished in Section 4, Bidding Forms.

5.7 Unless otherwise stipulated in the BDS, the Pharmaceuticals to be supplied under the Contract shall be registered with the relevant authority in the Federal Democratic Republic of Ethiopia. A Bidder who has already registered its Pharmaceuticals by the time of bidding should submit a copy of the Registration Certificate with its Bid.

5.8 The Public Body shall at all times cooperate with the successful Bidder to facilitate the registration process within the Federal Democratic Republic of Ethiopia. The agency and contact person able to provide additional information about registration are identified in the BDS.

5.9 If the Pharmaceuticals of the successful Bidder have not been registered in the Federal Democratic Republic of Ethiopia at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained. (NA)

B. Contents of Bidding Document

6. Bidding Document

6.1 The Bidding Document consist of Parts 1, 2, and 3, which include all the Sections indicated below, and should be read in conjunction with any Addenda issued in accordance with ITB Clause 8.

Part 1 Bidding Procedures

- Section 1 Instructions to Bidders (ITB)
- Section 2 Bid Data Sheet (BDS)
- Section 3 Evaluation Methodology and Criteria
- Section 4 Bidding Forms
- Section 5 Eligible Countries

Part 2 Statement of Requirements

- Section 6 Statement of Requirements

Part 3 Contract

- Section 7 General Conditions of Contract (GCC)
- Section 8 Special Conditions of Contract (SCC)
- Section 9 Contract Forms

6.2 The Invitation to Bid is not part of the Bidding Document. In case of discrepancies between the Invitation to Bid and the Bidding Documents listed in ITB Clause 6.1 above, said Bidding Documents will take precedence.

6.3 The Public Body is not responsible for the incompleteness of the Bidding Documents and their addenda, if they were not obtained directly from the Public Body. Bidders who did not obtain the Bidding Document directly from the Public Body will be rejected during evaluation. Where a Bidding Document is obtained from the Public Body on a Bidder's behalf, the Bidder's name must be registered with the Public Body at the time of sale and issue.

6.4 The Bidder is expected to examine all instructions, forms, terms, and specifications in the Bidding Documents. Failure to furnish all information or documentation required by the Bidding Documents may result in the rejection of the bid.

7. Written Questions / Clarification of Bidding Documents

7.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the Public Body in writing at the Public Body's address indicated in the BDS. The Public Body will respond in writing to any request for clarification, provided that such request is received no later than twenty one (21) days prior to the deadline for submission of bids. The Public Body shall forward copies of its response to all Bidders who have acquired the Bidding Documents directly from it, including a description of the inquiry but without reference to the identity of the prospective Bidder initiating the request. Should the Public Body deem it necessary to amend the Bidding Documents as a result of a clarification, it shall do so following the procedure under ITB Clause 8 and Sub-Clause 26.2.

7.2 Only the written responses will be considered official and carry weight in this procurement process and subsequent evaluation. Any answers received outside the official channels, whether received verbally or in writing, from employees or representatives of the Public Body, or any

other party, shall not be considered official responses to questions regarding this Bidding Document.

8. Modification to Bidding Documents

8.1 Where Public Body finds it necessary to introduce modification to the Bidding Document on its initiative or on the basis of request for clarification by prospective Bidder, the Public Body may modify the Bidding Document at any time prior to the deadline for submission of bids.

8.2 Any alteration to the content of the Bidding Document shall at the same time be communicated in the form of an amendment to all prospective Bidders who purchased the bidding document and will be binding on them. Bidders are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the amendment will have been taken into account by the Bidder in its Bid.

8.3 The Public Body may, at its discretion, extend the closing date for submission of bids where it modifies a bidding document as per Clause 8.1 above, if it is assumed that the time remaining before the closing date is not sufficient for bidders to prepare adjusted Bid Documents on the basis of such modification.

9. Pre-Bid Conference

9.1 If the Public Body deems it to be appropriate, it may hold a Pre-Bid Conference for prospective bidders who purchased a Bidding Document for clarification and discussion on the Bidding Document or modification thereto.

9.2 The Public Body shall give written notice to all bidders who purchased a bidding document to attend the Pre-Bid Conference, Notice will include time, date, and address where Pre-Bid Conference will be held.

9.3 The Public Body shall welcome all prospective bidders to attend this Pre-Bid Conference. To give all prospective bidders the opportunity to participate in the pre-bid conference, prospective bidders are limited to sending two representatives to this conference. All the costs of attending this conference will be borne by the prospective bidders.

9.4 The Public Body invites all prospective bidders to submit their questions / request for clarification by time and date and to the address indicated in BDS.

9.5 The Pre-Bid Conference shall be minuted. Copies of the minute shall be delivered to all prospective bidders who purchased the Bidding Document to enable them prepare their bid documents by incorporating the content of clarification or modification.

C. Preparation of Bids

10. Cost of Bidding

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

11. Language of Bid

11.1 The Bid, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Public Body, shall be written in English.

11.2 Bids and supporting documents of Bidders prepared in a language other than language of bid shall have to be translated by a legally competent interpreter into language of bid and a copy of the translation has to be submitted together with the original documents, especially where such

documents pertain to the fundamental elements of the bid.

11.3 If the Public Body detects discrepancy between language of the original document and the translated version, it shall reject the documents unless such discrepancy constitutes minor deviation from the requirement stated in the Bidding Document.

12. Bid Prices and Discounts

12.1 The prices and discounts quoted by the Bidder in the Bid Submission Sheet and in the Price Schedule (forms furnished in Section 4, Bidding Forms) shall conform to the requirements specified below.

12.2 All items in the Section 6, Statement of Requirements must be listed and priced separately in the Price Schedule. If a Price Schedule shows items listed but not priced, their prices shall be assumed to be included in the prices of other items. Items not listed in the Price Schedule shall be assumed to be not included in the Bid, and provided that the Bid is substantially responsive, the corresponding adjustment shall be applied in accordance with ITB Sub-Clause 33.3.

12.3 The price to be quoted in the Bid Submission Sheet shall be the total price of the Bid including taxes, excluding any conditional discounts offered.

12.4 The Bidder offering conditional discounts shall indicate the methodology for their application in the Bid Submission Sheet.

12.5 The terms DDP, EXW, CIF, 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, at the date of the Invitation for Bids or as specified in the BDS.

12.6 Prices proposed on the Price Schedule Forms for Pharmaceuticals and Related Services, shall be disaggregated, when appropriate as indicated in this sub-clause. This disaggregating shall be solely for the purpose of facilitating the comparison of bids by the Public Body. This shall not in any way limit the Public Body's right to contract on any of the terms offered:

(a). For Pharmaceuticals:

(i) The price of the Pharmaceuticals quoted EXW, FOB, excluding any customs duties and sales and other taxes already paid or payable;

(ii) The price for carriage and insurance of Pharmaceuticals supplied from outside the Federal Democratic Republic of Ethiopia, in accordance with the Incoterms specified in the Special Conditions of Contract;

(iii) The price for inland transportation, insurance, and other local services required to convey the Pharmaceuticals to their final destination if specified in the BDS, and

(iv) All Ethiopian customs duties, VAT, and other taxes already paid or payable on the Pharmaceuticals or on the components and raw material used in the manufacture or assembly if the contract is awarded to the Bidder.

(b). For related services:

(i) The price of the related services; and

(ii) All Ethiopian customs duties and sales and other taxes already paid or payable on the related services if the contract is awarded to the Bidder.

12.7 Prices quoted by the Bidder shall be fixed during the validity period of the Bid and throughout the Bidder's performance of the Contract and not subject to variation on any account. Bids submitted that are subject to price adjustment will be rejected.

12.8 If so indicated in BDS Sub-Clause 1.3, bids are being invited for individual contracts (lots) or for any combination of contracts (packages). Unless otherwise indicated in the BDS, prices quoted shall correspond to 100 % of the items specified for each lot and to 100% of the quantities specified for each item of a lot. Bidders wishing to offer any price reduction for the award of more than one Contract shall specify in their bid the price reductions applicable to each package or, alternatively, to individual Contracts within the package. Price reductions shall be submitted in accordance with ITB Sub-Clause 12.4 and clearly indicated for each lot in such a way that it can be announced during the public Bid opening session.

12.9 Where a foreign Bidder uses local inputs to satisfy the required object of procurement under the contract, the portion of the total contract price representing such local expenditure shall be expressed in ETB in the Price Schedule of the Bidder.

13. Currencies of Bid and Payment

13.1 For Pharmaceuticals that the Bidder will supply from inside Ethiopia the prices shall be quoted in the Ethiopian Birr, unless otherwise specified in the BDS.

13.2 For Pharmaceuticals and Related Services that the Bidder will supply from outside Ethiopia prices shall be expressed in the freely convertible currency. If the Bidder wishes to be paid in a combination of amounts in different currencies, it may quote its price accordingly but use no more than three currencies different from Ethiopian Birr.

14. Professional Qualifications and Capability of the Bidder

14.1 If required, in order to proof their professional qualifications and capability Bidders must provide relevant information for the period specified in the BDS by completing relevant tables in the form entitled Bidders Certification of Compliance furnished in Section 4, Bidding Forms.

15. Financial Standing of the Bidder

15.1 If required in BDS, in order to proof that it has adequate financial resources to manage this Contract the bidder must present its financial data by completing relevant table in the form entitled Bidders Certification of Compliance that is furnished in Section 4, Bidding Forms.

15.2 Along with the proof referred to in Clause 15.1 the documents that are required as proof of the bidder's financial standing are the following:

(a). Financial statements certified by an independent auditor;

(b). Other documents as stated in the BDS.

16. Technical Qualifications, Competence, and Experience of the Bidder

16.1 The Bidder must present a description of its company and organization, with appropriate reference to any parent company and subsidiaries. The Bidder shall also include details demonstrating the Bidder’s experience and ability in selling and servicing the Pharmaceuticals and Related Services listed in Section 6, Statement of Requirements. Also, each Bidder shall include a description of how it plans to manage the work included in this Bidding Document in addition to its other ongoing projects.

16.2 This information shall be included in a separate form entitled Bidders Certification of Compliance that is furnished in Section 4, Bidding Forms.

16.3 As a proof of satisfactory execution of contracts the Bidder must provide Certificates of satisfactory execution of contracts, provided by the other contracting party to the contracts concerned in number and within the period specified in the BDS for similar sized/type contracts with a budget of at least that of this contract, unless otherwise specified in the BDS including

contact information for verification and inspection so as to provide due diligence. Contact information should include, at a minimum: name, function, address, e-mail, and phone number. Each reference provided should be the client's responsible project administrator or a senior official of the client who is familiar with the Bidder's performance and with the Bidder's system capabilities, and who may be contacted by the Public Body during the evaluation process.

16.4 The Certificate of satisfactory execution of contracts shall include the following data:

(a). The name and place of establishment of the contracting parties,

(b). The subject-matter of the contract,

(c). The value of the contract

(d). The time and place of performance of the contract,

(e). A statement concerning the satisfactory execution of contracts.

16.5 If, for objective reasons, such a certificate cannot be obtained from a contracting party, a statement issued by the bidder concerning satisfactory execution of contracts may also be valid, on presentation of proof that the certificate was requested.

16.6 If the Bidder(s) propose a joint venture all of the information listed above must be provided for all of the joint venture members. This information shall be in separate sections, one section per joint venture member. In addition, the Bid shall provide the agreements that support the relationships between joint venture members.

16.7 Unless otherwise specified in the BDS, the Public Body reserves the right to undertake physical checking of current Bidder's technical qualifications and competence in order to make sure that the Bidder has adequate qualifications to manage this Contract.

17. Documentary Technical Evidence

17.1 To establish the conformity of the Pharmaceuticals and Related Services to the Bidding Documents and to support details provided in the Section 6, Technical Specification and Compliance Sheet the Bidder shall furnish as part of its bid the documentary technical evidence, unless otherwise specified in the BDS.

17.2 The documentary evidence may be in the form of literature, illustrations, drawings brochures, or data, and shall consist of a detailed description of the essential technical and performance characteristics of the Pharmaceuticals and Related Services, demonstrating substantial responsiveness of the Pharmaceuticals and Related Services to those requirements, If the Pharmaceuticals offered do not meet the specified pharmaceutical standards as stated in the Statement of Requirements, the Bidder will provide statement of deviations and exceptions to the provisions of the Statement of Requirements and corresponding testing protocols and alternative reference standards.

17.3 Standards for workmanship, process, material, and equipment, as well as references to brand names or catalogue numbers specified by the Public Body in the Statement of Requirements, are intended to be descriptive only and not restrictive. The Bidder may offer other standards of quality, brand names, and/or catalogue numbers, provided that it demonstrates, to the Public Body's satisfaction, that the substitutions ensure substantial equivalence or are superior to those specified in the Section 6, Statement of Requirement.

17.4 Bidders who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce pharmaceuticals

or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling, and quality testing. The Bidder shall furnish a certificate from the competent National Control Authority (NCA) that the manufacturer is licensed to manufacture the Pharmaceuticals offered.

17.5 The Vaccines to be supplied under the Contract must be licensed both in the country of manufacture and in the Federal Democratic Republic of Ethiopia by the time of Contract signing by Ethiopian Food, Medicine and Health Care Administration and Control Authority http://www.daca.gov.et. The Ethiopian Food, Medicine and Health Care Administration and Control Authority is an organization that performs all six critical functions for control of biological products as defined by the World Health Organization, namely: licensing based on published set of requirements; surveillance of vaccine field performance; system of lot release for vaccines; use of laboratory when needed; regular inspections for good manufacturing practice and evaluation of clinical performance. The license from country of manufacture must state that the Bidder is licensed to manufacture the Pharmaceuticals by the National Control Authority (NCA) in the manufacturing country. Documentary evidence in the form of a certified copy of the license shall accompany the bid. A copy of the vaccine license/registration that the offered vaccine has been licensed by the Ethiopian Food, Medicine and Health Care Administration and Control Authority must be submitted by Contract signing.

17.6 The Bidder will submit the following additional documentary evidence and information:

(a). Good Distribution Practice (GDP) Certificate, where appropriate;

(b). List of pharmaceuticals being manufactured by the Bidder with product registration/license number and date;

(c). A Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

18. Presentation of Samples

18.1 The Public Body reserves the right to request production and presentation of samples representing any or all Pharmaceuticals proposed in response to this Bidding Document. If Bidder fails to provide such Pharmaceuticals for presentation, the Bidder's Proposal may be rejected by the Public Body in its sole discretion. The Bidder warrants that if awarded a Contract the Pharmaceuticals and Related Services delivered under such Contract shall meet or exceed the quality of the Pharmaceuticals presented. Samples of the quoted products, when requested in BDS, must be furnished free of charge and in a timely manner. Bidders should not submit unsolicited samples.

18.2 If the Public Body decide to request production and presentation of samples representing any or all Pharmaceuticals all Bidders will be informed in writing on the place where the samples are to be delivered and the time when and the place where the samples will be openly shown.

18.3 The Public Body shall handle and examine carefully, samples supplied by Bidders; however Bidders shall not be paid compensation for samples lost or destroyed in the examination process because of their nature. Samples that are not lost or destroyed shall be returned to unsuccessful bidders. If samples are not claimed by unsuccessful bidders within 6 months, they shall be forfeited to the Government.

18.4 Unless the Public Body decides otherwise, a sample supplied by the successful bidder shall stay with the Public Body until the completion of the procurement process to be used for checking conformity during delivery.

19. Joint Venture or Consortium

19.1 If bidder is a joint venture or consortium of two or more entities, the bid must be single with the

object of securing a single contract; authorized person must sign the bid and will be jointly and severally liable for the bid and any contract. Those entities must designate one of their members to act as leader with authority to bind the joint venture or consortium. The composition of the joint venture or consortium must not be altered without the prior consent in writing of the Public Body.

19.2 The bid may be signed by the representative of the joint venture or consortium only if he has been expressly so authorized in writing by the members of the joint venture or consortium, and the authorizing contract, notarial act or deed must be submitted to the Public Body. All signatures to the authorizing instrument must be certified in accordance with the national laws and regulations of each party comprising the joint venture or consortium together with the powers of attorney establishing, in writing, that the signatories to the bid are empowered to enter into commitments on behalf of the members of the joint venture or consortium. Each member of such joint venture or consortium must prove to the satisfaction of the Public Body that they comply with the necessary legal, technical and financial requirements and have the wherewithal to carry out the contract effectively.

20. Alternative Bids

20.1 Unless otherwise indicated in the BDS, alternative Bids shall not be considered.

20.2 If permitted in BDS, the Public Body may consider alternative systems or products prior to the notification of the successful Bidder provided that the Bidder:

(a). Has submitted Bid in accordance with the Bidding Document as issued; and

(b). Has submitted Bid based on alternative(s) to the Bidding Document as issued;

(c). Has included with the Bid a demonstration of the advantages of the alternative solution over the initial solution, including a quantifiable justification of any economic and/or technical advantages; and

(d). Has included with the Bid sufficient descriptive information for a complete evaluation of the proposed alternative(s) by the Public Body, including calculations, technical specifications, breakdown of prices, proposed work methods and other relevant details.

20.3 Only the technical alternative(s), if any, of the lowest evaluated Bidder conforming to the basic technical requirements shall be considered by the Public Body.

20.4 In evaluating a Bid containing an alternative process or product the Public Body may use any evaluation/award criteria as indicated in the BDS and Section 3, Evaluation Methodology and Criteria.

20.5 Alternative Bids not requested by the Public Body shall be rejected.

21. Period of Validity of Bids

21.1 Bids shall remain valid for the period specified in the BDS after the bid submission deadline prescribed by the Public Body. A bid valid for a shorter period may be rejected by the Public Body as non-responsive.

21.2 In exceptional circumstances, prior to expiry of the bid validity period, the Public Body may request Bidders to extend the period of validity of their bids. The request and the responses shall be made in writing.

21.3 Bidders who are not willing to extend their bid validity period for what ever reason shall be disqualified from the bid without having forfeited their bid security.

21.4 Bidders agreeing to the Public Body's request for extension of their bid validity period have to

express in writing their agreement to such request. Similarly, they have to amend the validity period of their bid security on the basis of the extension of the bid validity period they have agreed to, or alternatively, furnish new bid security to cover the extended period.

21.5 A bidder not agreeing to extend the validity period of his/its bid security shall be treated as a bidder refusing the Public Body's request for extension of bid validity period, and as such, shall be disqualified from further bid proceeding.

22. Bid Security

22.1 Unless otherwise specified in the BDS, the Bidder shall furnish as part of its bid, a bid security in original form and in the amount and currency specified in the BDS. A copy of bid security, if submitted without original form, shall not be accepted.

22.2 The bid security shall be, at the Bidder's option, in any of the following forms:

(a). An unconditional Bank Guarantee;

(b). An irrevocable Letter of Credit;

(c). Cash, check certified by a reputable bank or financial institution;

all from a reputable source from any eligible country. Securities issued by foreign banks or financial institutions shall be counter-guaranteed by an Ethiopian bank. The bid security shall be submitted either using the Bid Security Form included in Section 4, Bidding Forms, or in another substantially similar format approved by the Public Body. In either case, the form must include the complete name of the Bidder. The bid security shall be valid for twenty-eight days (28) beyond the end of the validity period of the bid. This shall also apply if the period for bid validity is extended.

22.3 The Bid Security of a Joint Venture shall be issued in the name of the Joint Venture submitting the bid provided the Joint Venture has legally been constituted, or else it shall be issued in the name of all partners proposed for the Joint Venture in the bid. Sanctions due to a breach of the terms of a Bid Security pursuant to ITB Clause 22.7 will apply to all partners to the Joint Venture.

22.4 Any bid not accompanied by a substantially responsive bid security, if one is required in accordance with ITB Sub-Clause 22.1, shall be rejected by the Public Body as non responsive.

22.5 The bid security of unsuccessful Bidders shall be returned as promptly as possible upon the successful Bidder's furnishing of the performance security pursuant to ITB Clause 47.

22.6 The bid security of the successful Bidder shall be returned as promptly as possible once the successful Bidder has signed the Contract and furnished the required performance security.

22.7 The bid security may be forfeited:

(a). If a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bid Submission Sheet, except as provided in ITB Sub-Clause 21.2; or

(b). If the successful Bidder fails to:

(i) Sign the Contract in accordance with ITB 45;

(ii) Furnish a performance security in accordance with ITB Clause 47; or

22.8 The bid security furnished by foreign bidders from a bank outside of Ethiopia has to be unconditional and counter guaranteed by local banks.

23. Documents Comprising the Bid

23.1 All bids submitted must comply with the requirements in the Bidding Document and comprise the following:

23.2 Mandatory documentary evidence establishing the Bidder's qualification is the following:

(a). Bid Submission Sheet (form furnished in Section 4, Bidding Forms) including the following mandatory attachments:

- (i) VAT registration certificate issued by the tax authority (only domestic Bidders in case of contract value as specified in BDS Clause 4.6(b)(ii));
- (ii) A valid tax clearance certificate issued by the tax authority (domestic Bidders only);
- (iii) Business organization registration certificate or trade license issued by the country of establishment (foreign Bidders only);
- (iv) Relevant professional practice certificates, as appropriate.

(b). Bidder Certification of Compliance (form furnished in Section 4, Bidding Forms) including the following mandatory attachments:

- (i) Written statement by a power of attorney (or notary statement, etc.) proving that the person, who signed the bid on behalf of the company/joint venture/consortium, is duly authorized to do so, as stipulated in ITB Clause 24.2;
- (ii) Documents required in the BDS Clause 15.2 as proof of the bidder's financial standing;
- (iii) Certificates of satisfactory execution of contracts provided by contracting parties to the contracts successfully completed in the course of the period as specified in the BDS with a budget of at least that of this contract; unless otherwise specified in the BDS Clause 16.3.
- (iv) Good Distribution Practice (GDP) Certificate, where appropriate;
- (v) List of pharmaceuticals being manufactured by the Bidder with product registration/license number and date;
- (vi) A Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

(c). Technical Specification + Technical Offer + Compliance Sheet (it should be presented as per template furnished in Section 6, Statement of Requirements) with detailed description of the proposed Pharmaceuticals and Related Services in compliance with the minimum technical requirements, including, if necessary, separate sheets or documentation for details. Technical Specification + Technical Offer + Compliance Sheet Form must include the following mandatory attachments;

- (i) Descriptive technical literature in accordance with ITB Clause 17;
- (ii) Description of the organization of the warranty offered in accordance with the conditions laid down in GCC Clause 23;
- (iii) Manufacturer Authorization Letter in accordance with ITB Clause 5.5;
- (iv) Certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Pharmaceuticals offered in accordance with ITB Clause 17.4 (only Bidders who are not primary manufacturers).

(d). Delivery and Completion Schedule;

(e). Bid Security, in accordance with ITB Clause 22;

(f). Alternative bids, if permissible, in accordance with ITB Clause 20.

(g). Domestic Bidders, individually or in joint ventures, applying for eligibility for a 15-percent margin of domestic preference shall supply all information required to satisfy the criteria for eligibility as described in ITB 35.

(h). In the case of a bid submitted by a joint venture (JV), the Form Data on Joint Ventures, the Agreement governing the formation of joint venture, or letter of intent to form JV, including a draft agreement, in accordance with ITB Clause 4.1

(i). Price Schedule for the Pharmaceuticals and Related Services offered (it should be presented as per template furnished in Section 4, Bidding Forms) and if necessary completed by separate sheets for the details.

(j). Any other document or information required to be completed and submitted by Bidders, as specified in the BDS

24. Format and Signing of Bid

24.1 The Bidder shall prepare one original of the documents comprising the bid as described in ITB Clause 23 and clearly mark it "ORIGINAL." Alternative bids, if permitted in accordance with ITB 20, shall be clearly marked ―ALTERNATIVE. In addition, the Bidder shall submit copies of the bid, in the number specified in the BDS and clearly mark each of them "COPY." In the event of any discrepancy between the original and the copies, the original shall prevail. If required in BDS, Bidders shall be required to submit bid documents in two envelopes containing the technical and financial proposals separately.

24.2 The original and all copies of the bid shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Bidder. This authorization shall consist of a written statement by a power of attorney (or notary statement, etc.) proving that the person, who signed the bid on behalf of the company/joint venture/consortium is duly authorized to do so and it shall be attached to the bid. The name and position held by each person signing the authorization must be typed or printed below the signature. All pages of the bid, except for non-amended printed literature, shall be signed or initialled by the person signing the bid.

24.3 Any interlineations, erasures, or overwriting shall be valid only if they are signed or initialled by the person signing the bid.

D. Submission and Opening of Bids

25. Sealing and Marking of Bids

25.1 The Bidder shall enclose the original and each copy of the bid, including alternative bids, if permitted in accordance with ITB Clause 20, in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." These envelopes containing the original and the copies shall then be enclosed in one single envelope.

25.2 The inner and outer envelopes shall:

(a). Be addressed to the Public Body in accordance with ITB Sub-Clause 26.1;

(b). Bear the subject of the procurement or the Project name, and procurement reference number indicated in the BDS;

(c). Bear the words **"Not to be opened before the time and date for bid opening".**

25.3 The outer envelopes shall also indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared "late" pursuant to ITB Clause 27.1.

25.4 If all envelopes are not sealed and marked as required, the Public Body shall assume no responsibility for the misplacement or premature opening of the bid.

26. Deadline for Submission of Bids

26.1 Bidders may always submit their bids by registered post or by hand. Bids must be received by the Public Body at the address and no later than the date and time indicated in the BDS.

26.2 The Public Body may, at its discretion, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITB Clause 8, in which case all rights and obligations of the Public Body and Bidders previously subject to the deadline shall thereafter be subject to the deadline as extended.

27. Late Bids

27.1 The Public Body shall not consider any bid that arrives after the deadline for submission of bids, in accordance with ITB Clause 26. Any bid received by the Public Body after the deadline for submission of bids shall be declared late, rejected, and returned unopened to the Bidder.

28. Withdrawal, Substitution, and Modification of Bids

28.1 A Bidder may withdraw, substitute, or modify its bid after it has been submitted by sending a written notice, duly signed by an authorized representative, and shall include a copy of the authorization in accordance with ITB Sub-Clause 24.2, (except that withdrawal notices do not require copies). The corresponding substitution or modification of the bid must accompany the respective written notice. All notices must be:

(a). Submitted in accordance with ITB Clauses 24 and 25 (except that withdrawals notices do not require copies), and in addition, the respective envelopes shall be clearly marked "Withdrawal," "Substitution," "Modification;" and

(b). Received by the Public Body prior to the deadline prescribed for submission of bids, in accordance with ITB Clause 26.

28.2 Bids requested to be withdrawn in accordance with ITB Sub-Clause 28.1 shall be returned unopened to the Bidders. Bid withdrawal notices received after the bid submission deadline will be ignored, and the submitted bid will be deemed to be a validly submitted bid.

28.3 No bid may be withdrawn, substituted, or modified in the interval between the deadline for submission of bids and expiry of the period of bid validity specified by the Bidder on the Bid Submission Sheet or any extension thereof.

29. Bid Opening

29.1 The Public Body shall conduct the bid opening in the presence of Bidders` designated representatives who choose to attend, and at the address, date and time specified in the BDS. The opening of the bid shall not be affected by the absence of the bidders on their own will.

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

"MODIFICATION" shall be opened and read out with the corresponding bid. No bid modification shall be permitted unless the corresponding modification notice contains a valid authorization to request the modification and is read out at bid opening. Only envelopes that are opened and read out at bid opening shall be considered further.

29.3 All other envelopes shall be opened one at a time, reading out: the name of the Bidder and whether there is a modification; the Bid Prices, including any discounts and alternative offers; the presence of a bid security, if required; and any other details as the Public Body may consider appropriate. Only discounts and alternative offers read out at bid opening shall be considered for evaluation. No bid shall be rejected at bid opening except for late bids, in accordance with ITB Sub-Clause 27.1.

29.4 The Public Body shall prepare a record of the bid opening that shall include, as a minimum: the name of the Bidder and whether there is a withdrawal, substitution, or modification; the Bid Price, per lot if applicable, including any discounts and alternative offers; and the presence or absence of a bid security, if one was required. The Bidders' representatives who are present shall be requested to sign the record. The omission of a Bidder's signature on the record shall not invalidate the contents and effect of the record. A copy of the record shall be distributed to all Bidders.

29.5 Any bid document not opened and read out during the bid opening proceeding shall not be considered for further evaluation.

E. Evaluation and Comparison of Bids

30. Confidentiality

30.1 Information relating to the examination, evaluation, clarification, and comparison of bids, and recommendation of contract award, shall not be disclosed to bidders or any other persons not officially concerned with such process until information on Contract award is communicated to all bidders.

30.2 Any effort by a Bidder to influence the Public Body in the examination, evaluation, and comparison of the bids or Contract award decisions may result in the rejection of its bid.

30.3 Notwithstanding ITB Sub-Clause 30.2, from the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Public Body on any matter related to the bidding process, it should do so in writing.

31. Clarification of Bids

31.1 To assist in the examination, evaluation, and comparison of the bids, the Public Body may, at its sole discretion, ask any Bidder for a clarification of its bid. Any clarification submitted by a Bidder that is not in response to a request by the Public Body shall not be considered. The Public Body's request for clarification and the response shall be in writing. No change in the prices or substance of the bid shall be sought, offered, or permitted, except to confirm the correction of arithmetic errors discovered by the Public Body in the evaluation of the bids, in accordance with ITB Clause 34.

31.2 If a Bidder does not provide clarifications of its bid by the date and time set in the Public Body's request for clarification, its bid may be rejected.

32. Responsiveness of Bids

32.1 The Public Body's determination of a bid's responsiveness is to be based on the contents of the

bid itself.

32.2 A substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents 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 or quality of the Pharmaceuticals and Related Services specified in the Contract; or

(ii) Limit in any substantial way, inconsistent with the Bidding Documents, the Public Body's rights or the Bidder's obligations under the Contract; or

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

32.3 If a bid is not substantially responsive to the salient requirements of the Bidding Document it shall be rejected by the Public Body and may not subsequently be made responsive by the Bidder by correction of the material deviation, reservation, or omission.

32.4 Decisions to the effect that a bid is not substantially responsive t must be duly justified in the evaluation minutes.

32.5 If only one Bid meets all salient requirements of the Bidding Document and is not otherwise disqualified, the Public Body may still complete the full evaluation of that Bid and sign contract with that Bidder if the Bid submitted by such bidder is satisfactory to the Public Body and the price offered by the bidder is comparable to or less than the market price of the required object of procurement.

33. Nonconformities and Omissions

33.1 Provided that a bid is substantially responsive, the Public Body may waive any non-conformity or omissions in the bid that does not constitute a material deviation.

33.2 Provided that a bid is substantially responsive, the Public Body may request that the Bidder submit the necessary information or documentation, within a reasonable period of time, to rectify nonmaterial nonconformities or omissions in the bid related to documentation requirements. Requesting information or documentation on such nonconformities shall not be related to any aspect of the price of the bid. Failure of the Bidder to comply with the request may result in the rejection of its bid.

33.3 Provided that a bid is substantially responsive, the Public Body shall rectify nonmaterial nonconformities or omissions. To this effect, the Bid Price shall be adjusted, for comparison purposes only, by the highest price quoted in this bidding process to reflect the price of the missing or non-conforming item or component.

34. Dubious price quotations and errors in calculation

34.1 Provided that the bid is substantially responsive, the Public Body shall correct arithmetical errors on the following basis:

(a). If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail and the total price shall be corrected, unless in the opinion of the Public Body there is an obvious misplacement of the decimal point in the unit price, in which case the total price 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.

34.2 The Public Body shall correct the detected errors in calculation and notify the bidder in writing of the corrections made without any delay, requesting the bidder to confirm that he accepts the correction of the calculation error within the period specified in BDS from the date on which the notice was received. The corrections shall be clearly indicated in the bid.

34.3 If the Bidder that submitted the lowest evaluated bid does not accept the correction of errors, its bid shall be disqualified.

35. Margin of Preference

35.1 Preference shall be granted to locally produced Pharmaceuticals, to small and micro enterprises established under the relevant Proclamation.

35.2 The margin of preference to be so granted for locally produced Pharmaceuticals and applied when comparing prices during evaluation of bids shall be 25 %

35.3 The preference to be granted as per Sub-Clause 35.2 shall be effective where it is certified by a competent auditor that no less than 35% of the total value of such products is added in Ethiopia.

35.4 For the purpose of Sub-Clause 35.3, value added in Ethiopia shall be calculated by deducting from the total value of the product in question, the cost, exclusive of indirect taxes, of imported raw materials and other supplies used in the production of such product as well as services rendered abroad in connection with the production of that product.

35.5 Preference shall be given to small and micro enterprises established under the relevant law by a margin of 3% when such enterprises compete with local bidders.

36. Preliminary Examination of Bids

36.1 The Public Body shall examine the bids to confirm that all documentary evidence establishing the Bidder's qualification requested in ITB Clause 23 have been provided, and to determine whether bid comply with administrative requirements of the Bidding Document.

36.2 From the time the Bids are opened to the time the Contract is awarded, the Bidders should not contact the Public Body on any matter related to its Bid. Any effort by Bidders to influence the Public Body in the examination, evaluation, ranking of Bids, and recommendation for award of Contract may result in the rejection of the Bidders' Bid.

36.3 The Public Body may determine bid as not responsive when:

(a). Bidder has failed to submit Written statement by a power of attorney (or notary statement, etc.) proving that the person, who signed the bid on behalf of the company/joint venture/consortium, is duly authorized to do so (ITB Sub-clause 24.2);

(b). Original and all copies of the bid are not typed or written in indelible ink and signed by a person duly authorized to sign on behalf of the Bidder (ITB Sub-clause 24.2);

(c). All pages of the bid, except for non-amended printed descriptive literature, are not signed or initialled by the person signing the bid (ITB Sub-clause 24.2);

(d). Bid is not written in language specified in the ITB Clause 11.1;

(e). Bidder has failed to submit signed and dated Bid Submission Sheet Form;

(f). Bidder has failed to submit signed and dated Price Schedule Form;

(g). Bidder has failed to submit signed and dated Bidder Certification of Compliance Form;

(h). Bidder has failed to submit signed and dated Technical Specification + Technical Offer+ Compliance Sheet Form;

(i). Bidder has failed to submit signed and dated Delivery and Completion Schedule;

(j). Bidder has failed to submit signed and dated Bid Security;

(k). The Bid Security is not in accordance with ITB Clause 22.

37. Legal, Professional, Technical, and Financial Admissibility of Bids

37.1 After confirming the bids comprise all mandatory documentary evidence establishing the Bidder's qualification, the Public Body will rule on the legal, technical, professional, and financial admissibility of each bid, classifying it as compliant or non-compliant with qualification requirements set forth in the Bidding Document.

37.2 **Legal admissibility**

The Public Body may determine bid as not responsive when:

(a). Bidder does not have nationality in accordance with ITB Sub-Clause 4.2;

(b). Bidder is found to have a conflict of interest as described in ITB Sub-Clause 4.3;

(c). Bidder has failed to submit valid business license indicating the stream of business in which the bidder is engaged in accordance with ITB Clause 4.6(b)(i);

(d). Bidder has failed to register itself in the Public Procurement and Property Administration Agency's suppliers list (mandatory for domestic Bidders only), in accordance with ITB Clause 4.7;

(e). Domestic Bidder has failed to submit VAT registration certificate issued by the tax authority (in case of contract value specified in BDS Clause 4.6(b)(ii), in accordance with ITB Clause 4. 6(b)(ii);

(f). Domestic Bidder has failed to submit a valid tax clearance certificate issued by the tax authority, in accordance with ITB Clause 4.6(b)(iii);

(g). Foreign Bidder has failed to submit business organization registration certificate or valid trade license issued by the country of establishment, in accordance with ITB Clause 4.6(c);

(h). Bidder has been debarred by a decision of the Public Procurement and Property Administration Agency from participating in public procurements for breach of its obligation under previous contracts, in accordance with ITB Clause 4.4.

(i). In the case of a bid submitted by a joint venture (JV), the Bidder has failed to submit the Form Data on Joint Ventures, the Agreement governing the formation of joint venture, or letter of intent to form JV, including a draft agreement, in accordance with ITB Clause 4.1.

37.3 **Professional admissibility**

The Public Body may determine bid as not responsive when:

(a). Bidder has failed to submit relevant professional practice certificates, if required in BDS Clause 4.6(b)(iv);

(b). Bidder has failed to provide in the Bidder Certification of Compliance Form information related to its professional qualification and capability for the period specified in the BDS Clause 14.1;

37.4 **Technical admissibility**

The Public Body may determine bid as not responsive when:

(a). Bidder has failed to provide in the Bid Submission Sheet Form the Statement attesting the origin of the Pharmaceuticals and Related Services offered;

(b). Bidder has failed to provide in the Bidder Certification of Compliance Form information about major relevant contracts successfully completed in the number and period specified in the BDS;

(c). Bidder has failed to submit Certificates of satisfactory execution of contracts provided by contracting parties to the contracts successfully completed in the period and budget as specified in the BDS Clause 16.3;

(d). Bidder has failed to complete its Technical Specification + Technical Offer+ Compliance Sheet Form in accordance with technical specification presented as per template in Section 6, Statement of Requirements and to submit the following mandatory attachments:

(i) Bidder has failed to submit Descriptive technical literature in accordance with ITB Clause 17;

(ii) Bidder has failed to submit Description of the organization of the warranty offered in accordance with the conditions laid down in GCC Clause 23;

(iii) Bidder has failed to submit Manufacturer Authorization Letter in accordance with ITB Clause 5.6;

(iv) Bidder has failed to submit Certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Pharmaceuticalsoffered in accordance with ITB Clause 17.4 (only Bidders who are not primary manufacturers).

(v) Bidder has failed to submit Good Distribution Practice (GDP) Certificate where appropriate in accordance with ITB Clause 17.6;

(vi) Bidder has failed to submit List of pharmaceuticals being manufactured by the Bidder with product registration/license number and date in accordance with ITB Clause 17.6;

(vii) Bidder has failed to submit a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered in accordance with ITB Clause 17.6.

(e). Bidder has failed to submit signed and dated Delivery and Completion Schedule presented as per template in Section 6, Statement of Requirements.

37.5 **Financial admissibility**

The Public Body may reject any bid when:

(a). Bidder has failed to submit financial statements certified by an independent auditor as required in ITB Clause 15.2(a) for the period specified in Section 3, Evaluation Methodology and Criteria

(b). Bidder has failed to submit other documents proofing its financial standing, as required in the BDS Clause 15.2(b);

(c). The average annual turnover for the period specified in Section 3, Evaluation Methodology and Criteria does not exceed the amount of the financial proposal of the Bid in value specified in the BDS.

(d). Bidder has failed to calculate Bid Prices for the Pharmaceuticals and Related Services offered as prescribed in ITB Clause 12; and

(e). Bidder has failed to quote prices in currency specified in the BDS in accordance with ITB Clause 13.

38. Evaluation of Bids

38.1 The Public Body shall evaluate each bid that has been determined, up to this stage of the

evaluation, to be substantially responsive.

38.2 For evaluation and comparison purposes, the Public Body shall convert all bid prices expressed in the amounts in various currencies into a single currency indicated in BDS, using the selling exchange rate established by the National Bank of Ethiopia and on the date of the Bid opening

38.3 To evaluate a bid, the Public Body shall only use all the criteria and methodologies defined in this Clause and in Section 3, Evaluation Methodology and Criteria. No other criteria or methodology shall be permitted.

38.4 To evaluate a bid, the Public Body shall consider the following:

(a). The bid price;

(b). Price adjustment for correction of arithmetic errors in accordance with ITB Sub-Clause 34;

(c). Price adjustment due to discounts offered in accordance with ITB Sub-Clause 12.4;

(d). Converting the amount resulting from applying (a) to (c) above, if relevant, to a single currency in accordance with ITB Sub-Clause 38.2;

(e). Adjustment for nonconformities and omissions in accordance with ITB Sub-Clause 33;

(f). Application of all the evaluation factors, if indicated in Section 3, Evaluation Methodology and Criteria.

(g). Adjustments due to the application of a margin of preference, in accordance with ITB Clause 35.

38.5 The Public Body's cost evaluation of a bid may require the consideration of other factors, in addition to the Bid Price quoted in accordance with ITB Clause 12. These factors may be related to the characteristics, performance, and terms and conditions of purchase of the Pharmaceuticals and Related Services. The factors to be used, if any, and the methodology of application shall be indicated in Section 3, Evaluation Methodology and Criteria.

38.6 If these Bidding Documents allow Bidders to submit a Bid for different lots, and the award to a single Bidder of multiple lots, the methodology of evaluation to determine the lowest evaluated lot combinations, including any discounts offered in the Bid Submission Sheet, is specified in the BDS and detailed in Section 3 Evaluation Methodology and Criteria.

39. Comparison of Bids

39.1 The Public Body shall compare all substantially responsive bids to determine the lowest evaluated bid as specified in Section 3: Evaluation Methodology and Criteria.

40. Post-qualification Evaluation

40.1 After identifying the successful bidder by evaluating the bid documents against the criteria set forth in this Bidding Document the Public Body shall conduct post qualification evaluation to establish the current qualification of the successful bidder where it feels that it has to be ascertained.

40.2 Such post qualification evaluation of the successful bidder may relate to submission of the documentary evidence specified in ITB Clause 37, unless satisfactory documents are already included in the Bid, concerning its current legal, professional, technical, and financial standing and conformity to the requirements stated in this Bidding Document.

40.3 If the successful bidder fails to provide this documentary proof within 15 calendar days following the Public Body's request or if the successful bidder is found to have provided false

information its Bid shall be disqualified, in which event the Public Body shall proceed to the next lowest evaluated bid to make a similar determination of that Bidder's capabilities to perform satisfactorily.

41. Acceptance or Rejection of Bids

41.1 The Public Body reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to Bidders.

42. Re-advertising bids

42.1 The Public Body may issue invitation to bid for a second time under the following circumstances:

(a). Where the Invitation to Bid has been unsuccessful, namely where no qualitatively or financially worthwhile Bids have been received.

(b). Where the best price offered by a bidder is significantly higher than the market price estimate of the object of procurement made by the Public Body prior to the issuance of the invitation to bid.

(c). Where it is concluded that non compliance with the rules and procedures governing bids prescribed by the Proclamation and Procurement Directive led to the failure of the invitation to bid to attract more than one bidder, or where it is believed that modifying the bidding document could attract adequate number of bidders.

(d). Circumstances of Force Majeure render normal implementation of the Contract impossible.

F. Award of Contract

43. Award Criteria

43.1 The Public Body shall award the Contract to the Bidder whose bid has been determined to be the lowest evaluated bid and is substantially responsive to the Bidding Documents, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily.

43.2 If Bids are being invited for individual contracts (lots) Contracts will be awarded lot by lot, but the Public Body may select the most favorable overall solution after taking account of any discounts offered.

43.3 If the Bidder is awarded more than one lot, a single contract may be concluded covering all those lots.

44. Right to Vary Quantities at Time of Award

44.1 At the time the Contract is awarded, the Public Body reserves the right to increase or decrease the quantity of Pharmaceuticals and scope of Related Services originally specified in Section 6, Statement of Requirement, provided this does not exceed the percentages indicated in the BDS, and without any change in the unit prices or other terms and conditions of the bid and the Bidding Documents.

45. Announcing and Awarding of the Successful Bidder

45.1 Prior to expiry of the period of bid validity, the Public Body shall notify in writing the result of a bid evaluation to all bidders alike at the same time.

45.2 The letter of notification to be disclosed to the unsuccessful bidders on the technical evaluation shall state the reason why they did not succeed in their bid and the identity of the successful bidder.

45.3 A letter of award to be sent by the Public Body to a successful bidder shall not constitute a contract between him and the Public Body. A contract shall be deemed to have been concluded between the Public Body and the successful bidder only where a contract containing detailed provisions governing the execution of the procurement in issue is signed.

45.4 A letter of contract award to be sent to a successful bidder may contain the following information:

(a). That the Public Body has accepted his bid;

(b). The total contract price;

(c). The list of items and their respective unit price;

(d). The amount of the performance security the successful bidder is required to furnish and the deadline for providing such security.

46. Signing of Contract

46.1 Promptly after notification of the proposed contract award the Public Body shall send the successful Bidder the Contract.

46.2 Within fifteen (15) days of receipt of the notification of award, the successful Bidder shall sign, date, and return it to the Public Body the Contract

46.3 The Public Body shall not sign a contract before seven working days from the date bidders are notified of the result of their bid or of any complaint against the bid proceeding.

47. Performance Security

47.1 Within fifteen (15) days from signing the Contract the successful Bidder shall furnish the performance security in accordance with the GCC, using for that purpose the Performance Security Form included in Section 9, Contract Forms, or another form acceptable to the Public Body.

47.2 Failure of the successful Bidder to submit the above-mentioned Performance Security or sign the Contract shall constitute sufficient grounds for annulment of the award and forfeiture of the bid security.

47.3 Small and micro enterprises shall be required to submit a letter of guarantee written by a competent body organizing and overseeing them in lieu of bid security, performance security or advance payment guarantee.

47.4 Where the successful bidder can not or is unwilling to sign a contract or submit the above-mentioned Performance Security, the Public Body may either declare the bidder submitting the second lowest evaluated bid the successful bidder or invite such bidder to sign a contract or advertise the bid afresh by assessing the benefit of the two options.

Section 2. Bid Data Sheet

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Section 2. Bid Data Sheet (BDS)

Instructions for Bidders (ITB) reference	Data relevant to ITB
A. Introduction	
ITB 1.1	The Public Body is: Registered Address: Addis Ketema, Woreda 05] Pharmaceuticals Fund and Supply Agency(PFSA) Floor and Room No.: Floor 1, Room number 101 City: Addis Ababa P.O.Box: 21904 Country: Ethiopia Telephone: +251-11-275 1770 / *27763270/ 2763266* Facsimilenumber:*+251-11-2752555*, *Website:-www.pfsa.gov.et*
ITB 1.1	The Bidding Document is issued under Procurement Method:
ITB 1.2 and 25.2(b)	The Project name is: General description of Pharmaceuticals that are subject of the procurement is:
ITB 1.3 and 25.2(b)	The Procurement Reference Number is:
ITB 1.3	The number and identification of Lots in this Bidding Document is:The evaluation will be conducted on item basis
ITB 4.1(a)	The individuals or firms in a joint venture, consortium or association jointly and severally liable.
ITB 4.6(b)(ii)	Domestic Bidders shall provide VAT registration certificate issued by the tax authority in case of contract value of and above. (NA)
ITB 4.6(b)(iv)	Relevant professional practice certificate required (based on relevance of commodities under procurement).
ITB 4.8	A Bidder shall amend the evidence of its continued eligibility with the following documents:
ITB 5.6	The Bidder required to include with its bid, documentation from the Manufacturer of the Health Sector Pharmaceuticals, that it has been duly authorized to supply, in Ethiopia, the Pharmaceuticals indicated in its bid.

<table>
<tr><th>Instructions for Bidders (ITB) reference</th><th>Data relevant to ITB</th></tr>
<tr><td>ITB 5.7</td><td>The Applicable Law of the Federal Democratic Republic of Ethiopia registration of the Pharmaceuticals to be supplied under the Contract</td></tr>
<tr><td>ITB 5.7(b)</td><td>By the time of Contract signing, the successful Bidder shall have complied with the following documentary requirements in order to register the Pharmaceuticals to be supplied under the Contract: . (NA)</td></tr>
<tr><td>ITB 5.8</td><td>For the purpose of obtaining additional information about the requirements for registration, Bidders may contact</td></tr>
<tr><td colspan="2"><h2>B. Bidding Documents</h2></td></tr>
<tr><td>ITB 7.1 and 9.4</td><td>For questions and/or <u>clarification purposes</u> only, the Public Body’s address is:
<table>
<tr><td>Public Body:</td><td></td></tr>
<tr><td>Attention:</td><td></td></tr>
<tr><td>Floor/Room number:</td><td></td></tr>
<tr><td>P.O. Box:</td><td></td></tr>
<tr><td>Street Address:</td><td></td></tr>
<tr><td>Town/City:</td><td></td></tr>
<tr><td>Post Code:</td><td></td></tr>
<tr><td>Country:</td><td>Ethiopia</td></tr>
<tr><td>Telephone:</td><td></td></tr>
<tr><td>Facsimile:</td><td></td></tr>
<tr><td>E-mail address</td><td></td></tr>
</table></td></tr>
<tr><td>ITB 7.2 and 9.4</td><td>The deadline for submission of questions and/or clarifications is:
Date:
Time:</td></tr>
<tr><td colspan="2"><h2>C. Preparation of Bids</h2></td></tr>
<tr><td>ITB 12.5</td><td>The Incoterms edition is:</td></tr>
<tr><td>ITB 12.6(iii)</td><td>Bidders be required to quote the price for inland transportation of the Pharmaceuticals to their final destination.</td></tr>
<tr><td>ITB 12.8</td><td>Prices quoted for each lot shall correspond to at least percent of the items specified for each lot. (If applicable only)
Prices quoted for each item of a lot shall correspond to at least percent of the quantities specified for each item of a lot.(if applicable only)
Prices quoted for each item shall correspond to at least percent of the quantities specified for each item. (If it is item based evaluation)</td></tr>
<tr><td>ITB 13.1</td><td>For Pharmaceuticals and Related Services that the Bidder will supply from inside Ethiopia the prices shall be quoted in .</td></tr>
</table>

Instructions for Bidders (ITB) reference	Data relevant to ITB
ITB 14.1	Bidder must provide in the Bidder Certification of Compliance Form information related to its professional qualification and capability for the current and the previous years in order to proof its professional capacity.
ITB 15.2(b)	As a proof of the bidder's financial standing the following documents need to be furnished: A minimum average annual turnover of two times the bid prices offered over the last five years
ITB 16.3	Bidder must submit at least Certificates of satisfactory execution of contracts provided by contracting parties to the contracts successfully completed in the course of the past years with a budget of at least . (NA for new bidders entering the market)
ITB 16.7	The Public Body undertake physical checking of current Bidder's technical qualifications and competence.
ITB 17.1	Bidder furnish as part of its bid the following documentary technical evidence: Refer Evaluation Methodology and Criteria Under Section 3
ITB 18.1	Samples of the quoted products be requested. If requested officially, the following samples must be submitted: a) For Tablet and Capsule Dosage forms…… 2 packs b). Ointments presented in Kilogram ……. 2 units c). Ointments presented in collapsible tubes…… 2 tubes d). Solution (Emulsions, Suspension …….. 2 Unit Pack e). Parenteral: Injectable in ampoules …… 2 unit pack f). Lyophilized preparations or powder for injections …… 2 Unit Pack g). Solutions … 3 bags/each type h). Instrument sets ---------- 2 pieces i). Diagnostics and reagents ---------- 2 sets j.) Supplies and consumables ----------2 pieces k.) Other capital and Non capital Equipment ----------1 set
ITB 20.1	Alternative Bids be considered].
ITB 20.4	If alternative bids are permitted under BDS Clause 20.1 they must meet the following criteria:
ITB 21.1	The bid validity period shall be: days.
ITB 22.1	A bid security required. If a bid security is required, the amount of the bid security shall be [ETB or Equivalent convertible currency, insert the amount and currency required ranging from 0.5% to 2% of the total estimated contract price]. Bid Security=0.5% *estimated budgeted price not exceeding ETB 500,000.

<table>
<tr><th>Instructions for Bidders (ITB) reference</th><th>Data relevant to ITB</th></tr>
<tr><td>ITB 24.1</td><td>In addition to the original of the bid, the number of copies required is: .</td></tr>
<tr><td>ITB 24.1</td><td>Bidders required to submit bid documents in two envelopes containing the technical and financial proposals separately.
• Technical proposal shall be consisted of mandatory documentary evidence listed in the ITB Clause 23.2 (a) to (e);
• Financial proposal shall be consisted of Price Schedule for the Pharmaceuticals and Related Services offered, as stated in the ITB Clause 23.2 (f).</td></tr>
<tr><td colspan="2">D. Submission and Opening of Bids</td></tr>
<tr><td>ITB 26.1</td><td>For <u>bid submission purposes</u> only, the Public Body’s address is:
<table>
<tr><td>Public Body:</td><td></td></tr>
<tr><td>Attention:</td><td></td></tr>
<tr><td>Floor/Room number:</td><td></td></tr>
<tr><td>P.O. Box:</td><td></td></tr>
<tr><td>Street Address:</td><td></td></tr>
<tr><td>Town/City:</td><td></td></tr>
<tr><td>Post Code:</td><td></td></tr>
<tr><td>Country:</td><td>Ethiopia</td></tr>
</table>
The deadline for bid submission is:
Date:
Time:</td></tr>
<tr><td>ITB 29.1</td><td>The bid opening shall take place at:
<table>
<tr><td>Public Body:</td><td></td></tr>
<tr><td>Floor/Room number:</td><td></td></tr>
<tr><td>Street Address:</td><td></td></tr>
<tr><td>Town/City:</td><td></td></tr>
<tr><td>Post Code:</td><td></td></tr>
<tr><td>Country:</td><td>Ethiopia</td></tr>
<tr><td>Date:</td><td></td></tr>
<tr><td>Time:</td><td></td></tr>
</table></td></tr>
<tr><td colspan="2">E. Evaluation, and Comparison of Bids</td></tr>
<tr><td>ITB 34.2</td><td>Bidder has to confirm that he accepts the correction of the calculation error within the period</td></tr>
<tr><td>ITB 37.4(b)</td><td>Bidder must provide in the Bidder Certification of Compliance Form information about major relevant contracts successfully completed in the course of the past years. (NA for new manufacturers)</td></tr>
<tr><td>ITB 37.5(c)</td><td>The average annual turnover for the last business year of the Bidder must exceed times the amount of the financial proposal of the Bid.</td></tr>
<tr><td>ITB 38.2</td><td>The currency that shall be used for bid evaluation and comparison purposes to convert all bid prices expressed in various currencies into a single currency is:</td></tr>
</table>

Instructions for Bidders (ITB) reference	Data relevant to ITB
ITB 38.6	Multiple award to one Bidder be permitted. The evaluation methodology to determine the lowest-evaluated combination of lots shall be detailed in Section 3 Evaluation Methodology and Criteria.
F. Award of Contract	
ITB 44.1	The percentage by which quantities may be increased is: . The percentage by which quantities may be decreased is: .

Section 3. Evaluation Methodology and Criteria

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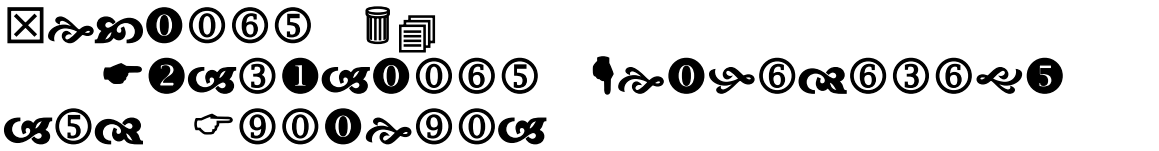

This section, read in conjunction with Section 1, Instructions to Bidders and Section 2, Bid Data Sheet, contains all the factors, methods and criteria that the Public Body shall use to evaluate a bid and determine whether a bidder has the required qualifications. No other factors, methods or criteria shall be used.

1. Preliminary, Technical, and Financial Qualification Criteria

The following qualification criteria will be applied to Bidders. In the case of bids submitted by a consortium, these qualification criteria will be applied to the consortium as a whole :

1.1 Preliminary Qualifications and Capability of the Bidder (ITB Clause 14)

A. Originality of Bidding Document

The bid offered to the purchaser shall be original, signed by authorized body and duly stamped.
B. the Bid price validity period:-
The bid price that the bidders offered shall remain valid for 120 days from the bid opening date.
C. Bid security and validity period:-
The bid security value that the bidder shall submit is as per ITB 22.1
which shall be expected to be valid at least for 28 days beyond the bid validity period.
D. Manufacturer Authorization Letter:-
Written confirmation of authorization to commit a Bid from the manufacturer/Supplier is required to accept that bidder as legal entity for bidding.
E. Delivery time or period:-
Bidders shall deliver their awardees within 60-90 days from Letter of Credit Opening or CAD reservation.
F. Power of attorney:-
The quotation from the bidders shall be signed by an authorized body delegated to sign.

G. Product Certification:-

The Bidder shall be submit a product certificate for the offered model

H. Dully filled-in form of the bid and price schedule, in accordance with the forms indicate in section IV.

I. Written letter of authorization for local agent for the participation of the bid.

J. Unconditional bid security with acceptable validity period.

K. Renewed trade license, VAT registered certificate and professional license (for local manufacturers and representatives).

L. Local agent should be registered in FDRE public procurement and property administration agency website in the suppliers list if any.

1.2 Technical Qualifications, Competence, and Experience of the Bidder (ITB Clause 16)

(a). ☐ The Bidder has successfully completed at least contracts with a budget of at least that of this contract in the past years;

Technical Evaluation Criteria for Diagnostic Reagent

Manufacturing license (All categories)

b. FMHACA Product Registration certificate (Except for some Lab commodities)

c. Good Distribution Practice (GDP) (All)

d. GMP Inspection report from an authorized body (All)

e. SRA/FDA/WHO inspection report (All)

. Valid COPP certificates (Medicines)

i. Valid FSC/MA certificate (Medicines)

j. GMP inspection report by EFMHACA

k. GMP inspection by the regulatory body of the country of origin

WHO prequalification list (Latest version)

n. Global fund Quality assurance policy list (Latest Version)

o. For HIV RDT the product should be in the current country algorithm(EPHI Pass certificate)

p. Certification document by EPHI that it is a closed system.

Only for medical Equipment

1) In addition to the above criteria's for Medical Refrigerator the manufacturer and the product quoted shall have WHO PQS pre qualified must be submitted along with the quotation. Failure to do so will result in the rejection of the Bid.

2) The supplier must provide installation, training and warranty when indicated in the **technical specification section as per the price schedule provided.** This will be added to the cost of the tender to arrive at the lowest bid.

3) Bidders must provide the price for consumables and essential accessories and maintenance contract after warranty with price breakdown for each year, etc. of the machines for five years.

4) Only original manufacturer catalogues (Data sheet) with detailed specification are accepted (including website). The model should be stated in your compliance sheet (quotation) and the model described in the quotation must be similar to the model described with the attached catalogue (Data sheet) and the manual attached. Any mismatch will result in the rejection of the bid. Copy and paste of PFSA specification will result in the rejection of the bid.

5) Bidders must clearly indicate the system configuration of the indicated item/machine in the price schedule

6) Bidders must provide list of important spare parts and accessories with their part number and costing for five years along with the quotation.

7) All instrument sets especially used for surgery must be made of Medical Surgical Grade Stainless steel have a permanent, laser marked, that shows manufacturer, model and others markings such as SRA.

Moreover, bidders must submit user manual, installation manual and/or maintenance manual in Soft Copy.

Privilege is given for bidders who submit valid ----------,---------- certificates before Closing date and time of the tender

In case if all bidders fails to meet the first criteria, bidders who submit ----------,---------- certificates will be given second criteria

1.3 **Financial Evaluation of the Bidder (ITB Clause 15)**

(a). ☐ The average annual turnover calculated as total certified payments received for contracts in progress or completed within the last years must exceed times the amount of the financial proposal of the Bid;

(b). ☐ .

(c). ☐

2. Determining the Successful Bid

According to the methodology defined in the Public Procurement Proclamation and Directive the Public Body shall select the successful bid by applying the following method:

A. ☒ The bid that is found to be substantially responsive to the professional, technical, and financial qualification requirements, technically compliant in relation to the technical specifications, and with the lowest price.

B. ☐ The bid that is found to be substantially responsive to the professional, technical, and financial qualification requirements, technically compliant in relation to the technical specifications, and with the lowest evaluated bid The lowest evaluated bid shall be the bid offering better economic advantage ascertained on the basis of factors affecting the economic value of the bid.

A. The Bid with the Lowest Price

2.1 The bids shall be examined to confirm that all documentary evidence establishing the Bidders' qualifications requested in ITB Clause 23 have been provided;

2.2 After confirming the bids comprise all mandatory documentary evidence establishing the Bidder's qualification the Public Body will rule on the legal, technical, professional, and financial admissibility of each bid, classifying it as compliant or non-compliant with qualification requirements set forth in the Bidding Document;

2.3 The Public Body will then analyze the bids' technical conformity in relation to the technical specifications, classifying them technically compliant or non-compliant.

2.4 The Public Body shall continue evaluation of bids that have been determined to be substantially responsive with rectification of nonconformities and omissions in bids, if any.

2.5 The Public Body shall examine all bids to ascertain whether there are any arithmetic errors in computation and summation. The Public Body shall notify bidders on adjusted calculation errors and request bidders to confirm that they accept the correction of the calculation error within the time limit of three days from the receiving of the notification.

2.6 After evaluation of legal, professional, technical, and financial admissibility of bids the Public Body shall award of the contract the bidder whose bid has been determined to be substantially responsive to the Bidding Documents and with the lowest price.

B. Determining the Lowest Evaluated Bid Offering the Best Economic Advantage

2.7 Provided all mandatory legal, professional, technical, and financial requirements have been met all technically compliant Bids shall be evaluated and scored using the two-stage bid evaluation and scoring method. In accordance with ITB Clause 38.4(f), the Public Body's evaluation of the Bid will take into account, in addition to the bid price, the following additional evaluation criteria in order of their importance and their proportional weight in the total system of evaluation, as specified below:

(a). The additional evaluation criteria and their weighting factor that indicate their level of importance are determined, as follows:

Priority	Name of criteria	Proportional value in %
1.	Criterion I	
2.	Criterion II	
3.	Criterion III	
4.	Criterion IV	
I	Total Additional Criteria (1+2+3+4)	
II	Bid Price	
III	Sum Total (I+II)	100

(b). The Public Body will evaluate any additional criterion using the following scoring scale:

SCORING		DESCRIPTION
10	Excellent	Exceeds the requirements of the criteria significantly and in beneficial ways/very desirable
9	Very Good	Exceeds the requirements of the criteria in ways which are beneficial to our needs
7-8	Good	Fully meets the requirement of the criteria
5-6	Average	Adequately meets most of the requirements of the criteria. May be lacking in some areas that are not critical.
3-4	Poor	Addresses all of the requirements of the criterion to the minimum acceptable level.
1-2	Very Poor	Minimally addresses some, but not all, of the requirements of the criteria or lacking in critical areas.
0	Unsatisfactory	Does not satisfy the requirements of the criteria in any manner.

2.8 Individual weighted scores for all technical criteria shall be weighted according to the set proportional weighting factors. The weighted result shall be calculated by multiplying the score by the proportional weighting factor of the individual criterion. The total score for the Bid determined through this method will be the basis for ranking Bids.

2.9 Where two bidders get equal merit points in the evaluation, preference shall be given to local products or services.

2.10 The Public Body may require bidders scoring equal merit points in the evaluation to submit further proposals on certain aspects of the bid with a view to identifying the successful bidder.

2.11 Where by reason of the bidders scoring equal merit points not submitting final proposals they are invited to submit, or by reason of the evaluation result of the final proposals submitted by the bidders being still equal, the successful bidder can not be singled out, the successful bidder shall be determined by casting lot in the presence, as far as possible, of the bidders concerned.

3. Domestic Preference

3.1 If the ITB Clause 35 so specifies, the Public Body will grant a margin of preference to Pharmaceuticals manufactured in the Federal democratic Republic of Ethiopia for the purpose of bid comparison, in accordance with the procedures outlined in subsequent paragraphs Responsive Bids shall be classified into the following groups:

(a). Group A: Bids offering locally produced Pharmaceuticals meeting the criteria of ITB Sub-Clause 35.3; and

(b). Group B: all other Bids.

3.2 For the purpose of further evaluation and comparison of Bids only, an amount equal to 25% percent of the evaluated Bid prices determined in accordance with ITB Sub-Clause 35.3 shall be added to all Bids classified in Group B.

4. Evaluation of Multiple Contracts

Since in accordance with ITB Sub-Clause 38.6 the Public Body be allowed to award one or multiple lots to more than one Bidder, the following methodology shall be used for award of multiple contracts:

To determine the lowest-evaluated lot combinations, the Public Body shall:

(a). evaluate only lots or contracts that include at least the percentages of items per lot and quantity per item as specified in ITB 12.8;

(b). take into account:

(i) the lowest-evaluated bid for each lot that meets the requirement of evaluation criteria;

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

(iii) the contract-award sequence that provides the optimum economic combination, taking into account any limitations due to constraints in supply or execution capacity.

5. Alternative Bids

Alternative Bids, if permitted under BDS Clause 20.1, will be evaluated as follows:

The Public Body shall only apply the following criteria for evaluation of Alternative Bids:

Section 4. Bidding Forms

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A. Bid Submission Sheet

Place and Date
Procurement Reference Number:

To:

Addis Ababa
Ethiopia

SUBMITTED BY[1]:

	Complete Legal Name and Address of the Seat of the Bidder	Nationality[2]
Leader[3]		
Member		
Etc …		

In response to your Bidding Document for the above Procurement Number:, we, the undersigned, hereby declare that:

(a) We have examined and accept in full the content of the Bidding Document for the, Procurement Number: We hereby accept its provisions in their entirety, without reservation or restriction.

(b) We offer to supply in conformity with the Bidding Documents and in accordance with the delivery schedule specified in the Statement of Requirements the following Pharmaceuticals and Related Services: ;

(c) Warranty period for offered Pharmaceuticals and Related Services is .

(d) The total price of our Bid, excluding any discounts offered in item (d) below is: ;

(e) The discounts offered and the methodology for their application are:

Unconditional Discounts: If our bid is accepted, the following discounts shall apply. .
Methodology of Application of the Discounts: The discounts shall be applied using the following method: ;
Conditional Discounts: If our bid(s) are accepted, the following discounts shall apply. .
Methodology of Application of the Discounts: The discounts shall be applied using the following method: ;

(f) Our bid shall be valid for a period of days from the date fixed for the bid submission deadline in accordance with the Bidding Documents, and it shall remain binding upon us and may be accepted at any time before expiry of that period;

[1] One signed original Bid Submission Form must be supplied together with the number of copies specified in the Instruction to Bidders.
[2] Country in which the legal entity is registered.
[3] Add/delete additional lines for members as appropriate. Note that a subcontractor is not considered to be a member for the purposes of this bidding procedure. If this bid is being submitted by an individual bidder, the name of the bidder should be entered as "leader" and all other lines should be deleted.

(g) The prices in this bid have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other bidder or competitor relating to:

i. Those prices;
ii. The intention to submit a bid; or
iii. The methods or factors used to calculate the prices offered.

(h) The prices in this bid have not been and will not be knowingly disclosed by the , directly or indirectly, to any other bidder or competitor before bid opening.

(i) We, including any subcontractors for any part of the contract resulting from this procurement process, are eligible to participate in public procurement in accordance with ITB Clause 4.1 and have not been debarred by a decision of the Public Procurement and Property Administration Agency from participating in public procurements for breach of our obligation under previous contract ;

(j) We are not insolvent, in receivership, bankrupt or being wound up, not have had our business activities suspended and not be the subject of legal proceedings for any of the foregoing;

(k) We have fulfilled our obligations to pay taxes according to Ethiopian Tax laws

(l) We have read and understood the provisions on fraud and corruption in GCC Clause 5 and confirm and assure to the Public Body that we will not engage ourselves into these evil practices during the procurement process and the execution of any resulting contract;

(m) We have not committed an act of embezzlement, fraud or connivance with other bidders.

(n) We have not given or have been offered to give inducement or bribe to an official or procurement staff of the Public Body to influence the result of the bid in our favor.

(o) We are not participating, as Bidders, in more than one bid in this bidding process, other than alternative bids in accordance with the Bidding Document;

(p) We do not have any conflict of interest and have not participated in the preparation of the original Statement of Requirements for the Public Body;

(q) If our bid is accepted, we commit to submit a performance security in accordance with the GCC Clause 47 of the Bidding Documents, in the amount of for the due performance of the Contract;

(r) We, including any subcontractors or suppliers for any part of the Contract, have nationalities from eligible countries];

(s) Offered Pharmaceuticals and Related Services do not originate in a country in respect of which the Government of the Federal Democratic Republic of Ethiopia has imposed trade ban;

(t) Offered Pharmaceuticals and Related Services do not originate in a country under trade embargo of the Security Counsel of the United Nations in which transacting with any business organization or individual who is the national of that country is prohibited;

(u) We will inform the Public Body immediately if there is any change in the above circumstances at any stage during the implementation of the contract. We also fully recognize and accept that any inaccurate or incomplete information deliberately provided in this bid may result in our exclusion from this and other contracts funded by the Government of the Federal Democratic Republic of Ethiopia.

(v) We understand that this bid, together with your written acceptance thereof included in your notification of award, shall not constitute a binding contract between us, until a formal contract is prepared and executed.

(w) We understand that you reserve the right to reject any or all bids that you may receive.

Name
In the capacity of .

Signed

Duly authorized to sign the bid for and on behalf of .

Dated on [insert day] day of], 20

Attachments:

1. Valid trade license indicating the stream of business in which the is engaged;
2. VAT registration certificate issued by the tax authority
3. A valid tax clearance certificate issued by the tax authority ;
4. Business organization registration certificate or trade license issued by the country of establishment ;
5. Relevant professional practice certificates.
6. Bid Security; and
7. Other documents requested by the Public Body.

B. Price Schedule for pharmaceuticals manufactured outside the country

Name of Bidder _____. IFB Number _____.

1	2	3	4	5	6	7			8	9	10		11	12	13	14	15
						Unit prices											
Item No.	Description	Dosage form	Unit	Qty. offered	Country of origin	[a] Unit price FOB	[b] C+F Sea Djibouti	[c] C+F Air Addis Ababa	Total FOB price	Total C+F Sea Djibouti price	Total C+F Air Addis Ababa price	Payment Term	Validity	Shelf life	Port of Shipment	Name of the manufacturer	Pharma-copoeial standard

Total FOB Price:

Total Freight

Total C+F Offer in foreign currency in figures & words:

Signed: _____

Dated: _____

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

C. Bidder Certification of Compliance[4]

Place and Date
Procurement Reference Number:
To:

Addis Ababa
Ethiopia

1. General Information About the Bidder

Bidder's Legal Name:	
In case of Joint Venture, legal name of each party:	
Place of Registration:	
Legal Address in Country of Registration:	
Authorized Representative Information	Name: Position: Address: Telephone/Fax: E-mail address:
Attached copies of original documents of:	☐ In case of JV, letter of intent to form JV including a draft agreement, or agreement governing formation of JV, in accordance with ITB Sub-Clause 4.1
	☐ Form Data on Joint Ventures
	☐ In case of government owned entity from the Public Body's country, documents establishing legal and financial autonomy and compliance with the principles of commercial law, in accordance with ITB Sub-Clause 4.4.

We have attached an official written statement by a power of attorney (or notary statement, etc.) proving that the above person, who signed the bid on behalf of the company/joint venture/consortium, is duly authorized to do so.

2. Financial Standing

has adequate financial resources to manage this Contract as established by our financial statements, audited by an independent auditor, submitted in this Bid. The following table contains our financial data. These data are based on our annual audited accounts. Figures in all columns have been provided on the same basis to allow a direct, year-on-year comparison to be made.

[4] One signed original Bidder Certification of Compliance Form must be supplied together with the number of copies specified in the Instruction to Bidders. If this bid is being submitted by a joint venture/consortium, the data in the tables below must be the sum of the data provided by the joint venture/consortium members.

FINANCIAL DATA	Historic Information for Previous Years in				
	Year 2	Year 1	Last Year	Current Year	Average
A. Information from Balance Sheet					
1.Total Assets					
2. Total Liabilities					
I. Net Value (1-2)					
3. Current Assets					
4. Short-term debts					
II. Working Capital (3-4)					
B. Information from Income Statement					
1. Total Revenue					
2. Pre-tax Profits					
3. Losses					

Along with financial data we provided above we have attached the following documents as proof of our financial standing, as required in the BDS:

(a).

(b). .

Attached documents comply with the following conditions:

- Documents reflect the financial situation of the Bidder or partner to a Joint Venture, and not sister or parent companies;
- Historic financial statements are audited by a certified accountant;
- Historic financial statements are complete, including all notes to the financial statements;
- Historic financial statements correspond to accounting periods already completed and audited.

Annual Turnover Data	
Year	Amount and Currency
Average Annual Turnover*	

*Average annual turnover calculated as total certified payments received for contracts in progress or completed over the number of years specified in Section 3, Evaluation and Qualification Criteria, Sub-Factor 1.3(a), divided by that same number of years.

3. Technical Qualifications, Competence, and Experience in the Procurement Object

As proof of the technical and professional ability in selling and servicing the Pharmaceuticals and Related Services listed in our Bid the tables below summarizes the major relevant contracts successfully completed in the course of the past years with a budget of .
Each partner of a Joint Venture should separately provide details of its own relevant contracts.

.

	Name of Bidder or partner in a Joint Venture:	
1.	**Name of Contract**	
	Country	

	Name of Bidder or partner in a Joint Venture:	
2.	**Name of client**	
	Address of client	
	Name of contact person	
	Function of contact person	
	Telephone number	
	E-mail address	
4.	**Nature of Pharmaceuticals and Related Services relevant to the contract for which the Bidding Documents are issued**	
5.	**Contract role (check one)**	☐ Prime Contractor: ☐ Subcontractor; ☐ Partner in a Joint Venture
6.	**Overall supply value in**	
7.	**Date of award/completion**	
8.	**Final acceptance issued (check one)**	**Yes:** ☐ **Not Yet** ☐ **No:** ☐
9.	**Number of staff provided**	
10	**Indicate the approximate percent of total contract value of Pharmaceuticals and Related Services undertaken by subcontract, if any, and the nature of such Non-Consultancy services**	
11	**Other relevant information**	

The Clients' Certificate concerning the satisfactory execution of contract is attached to this document

4. Professional Qualifications and Capabilities

In order to proof our professional qualifications and capability the following table contains personnel statistics for the current and the two previous years.

Average manpower	Year before last		Last year		This year	
	Overall	Specialists in Technical Area	Overall	Specialists in Technical Area	Overall	Specialists in Technical Area
Permanent						
Temporary						
TOTAL						

5. Quality Assurance / Managerial and Control Procedures

6. Equipment and Facilities

7. Bidder's Audit Agency

8. Organization of Firm

9. Bank Account Number and Bank Address

The bank account into which payment should be made is the following:

Name
In the capacity of .

Signed

Duly authorized to sign the bid for and on behalf of .

Dated on [insert day] day of], 20
Attachments:

1. Statement issued by a power of attorney authorizing the signatory of the Bid;
2. Audited financial statements;
3. Documents required as proof of the bidder's financial standing, as required in the BDS.
4. Certificates of satisfactory execution of contracts provided by contracting parties to the contracts successfully completed in the course of the past years, as required in the BDS.
5. Good Distribution Practice (GDP) Certificate, where appropriate
6. List of pharmaceuticals being manufactured by the Bidder with product registration/license number and date.
7. A Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

D. Form - Data on Joint Venture/Consortium

Date:
Procurement Reference Number:
Alternative No:

1.	**Name of Joint Venture/Consortium**	
2.	**Managing Board's Address**	
	P.O. Box:	
	Street Address:	
	Town/City:	
	Post Code:	
	Country:	
	Telephone:	
	Facsimile:	
	E-mail address	
3.	**Agency in the Federal Democratic Republic of Ethiopia, if any (in the case of a joint venture/consortium with a foreign lead member)**	
	P.O. Box:	
	Street Address:	
	Town/City:	
	Post Code:	
	Telephone:	
	Facsimile:	
	E-mail address	
4.	**Names of Members**	
	Member 1	
	Member 2	
	Etc.	
5.	Name of Lead member	
6.	**Agreement governing the formation of the joint venture/consortium**	
	Date of signature	
	Place	
7.	Proposed proportion of responsibilities between members (in %) with indication of the type of the works to be performed by each	

Name
In the capacity of .
Signed
Duly authorized to sign the bid for and on behalf of .
Dated on [insert day] day of], 20

Note to Bidders: This Bid Security should be on the letterhead of the issuing Financial Institution and should be signed by a person with the proper authority to sign the Bid Security. It should be included by the Bidder in its bid.

E. Bid Security

Date:

Procurement Reference Number:

Alternative No:

To:

Whereas (hereinafter "the Bidder") has submitted its bid dated for Procurement reference Number for the supply of , hereinafter called "the Bid."

KNOW ALL PEOPLE by these presents that WE , of having our registered office at (hereinafter "the Guarantor"), are bound unto (hereinafter "the Public Body") in the sum of , for which payment well and truly to be made to the aforementioned Public Body, the Guarantor binds itself, its successors or assignees by these presents. Sealed with the Common Seal of this Guarantor this] day of , .

THE CONDITIONS of this obligation are the following:

1. If the Bidder withdraws its bid during the period of bid validity specified by the Bidder in the Bid Submission Sheet, except as provided in ITB Sub-Clause 21.2; or
2. If the Bidder, having been notified of the acceptance of its bid by the Public Body, during the period of bid validity, fails or refuses to:
   (a) Execute the Contract; or
   (b) Furnish the Performance Security, in accordance with the ITB Clause 47; or

We undertake to pay the Public Body up to the above amount upon receipt of its first written demand, without the Public Body having to substantiate its demand, provided that in its demand the Public Body states that the amount claimed by it is due to it, owing to the occurrence of one or more of the above conditions, specifying the occurred conditions.

This security shall remain in force up to and including twenty-eight (28) days after the period of bid validity, and any demand in respect thereof should be received by the Guarantor no later than the above date.

Name:
In the capacity of
Signed:
Duly authorized to sign the bid for and on behalf of:
Dated on [insert day] day of], 20

F. Manufacturer's Authorization

Date: .

Procurement Reference Number:

Alternative No:

To:

WHEREAS , who are official manufacturers of , having factories at , do hereby authorize to submit a bid in relation to the Invitation for Bids indicated above, the purpose of which is to provide the following Pharmaceuticals, manufactured by us , and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 23 of the General Conditions of Contract, with respect to the Pharmaceuticals offered by the above firm in reply to this Invitation for Bids

Name:
In the capacity of

Signed:

Dated on [insert day] day of], 20

Section 5. Eligible Countries

A. Eligible Countries

Procurement Reference Number:

All countries are eligible except countries subject to the following provisions.

A country shall not be eligible if:

(c). As a matter of law or official regulation, the Government of the Federal Democratic Republic of Ethiopia prohibits commercial relations with that country, provided that the Government of the Federal Democratic Republic of Ethiopia is satisfied that such exclusion does not preclude effective competition for the provision of Pharmaceuticals or related services required; or

(d). 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 Government of the Federal Democratic Republic of Ethiopia prohibits any import of Pharmaceuticals from that country or any payments to persons or entities in that country.

Part 2 Statement of Requirement

Section 6. Statement of Requirements

Table of Contents

A. Technical Specification - General Requirements

1. The Technical Specifications describe the minimum requirements for the Pharmaceuticals and Related Services to be supplied and shall be read in conjunction with the other documents forming the Contract. Any ambiguity between the documents forming the Contract shall be referred to the Public Body for clarification in accordance with the provisions of the Contract.

2. The Bidders are requested to complete the Technical Specification template, as follows:

- The second column shows the requested specifications (not to be modified by the Bidder).
- The fifth column to be filled in by the Bidder shows what is offered (the words “compliant” or “yes” are not sufficient).
- The sixth column allows the Bidder to state whether the offered items "comply" or do "not comply" giving details of the areas of non-compliance and to make remarks on his proposed equipment and to indicate references to the documentation supplied.
- The seventh column is to be left empty for the evaluator's remarks.

3. The Bidder is required to furnish as part of its Bid the statement of deviations and exceptions to the provisions of the Statement of Requirement, if applicable.

4. The Bidder may offer other standards of quality, brand names, and/or catalogue numbers, provided that it demonstrates, to the Public Body’s satisfaction, that the substitutions ensure substantial equivalence or are superior to those specified in the Statement of Requirement.

5. The Bidder must submit a description of the organization of the warranty offered, which must be in accordance with the conditions laid down in GCC Clause 23.

6. The Bidder must be clear enough to allow the evaluators to make an easy comparison between the requested specifications and the offered specifications. Bids that do not permit to identify precisely the models and the specifications may be rejected by the evaluation committee.

B. Technical Specification + Technical Offer + Compliance Sheet

Place and Date
Procurement Reference No.:
Alternative No.:
To:

Ethiopia

Item No.	International Nonproprietary Name (INN) or Generic Name	Description	Strength in Metric Units	Basic Unit	Quantity	Package Size[5]	No. of Packages	Bidder's Offer		Bidder's Remark on Compliance of Specification Offered	Evaluation Committee's Remark		
								Specification Offered	The Name of the Original Manufacturer		Overall Compliance		Observations
											yes	no	
1	2	3	4	5	6	7	8	9	10	11	12	13	14
											☐	☐	
											☐	☐	
											☐	☐	
											☐	☐	

Name
In the capacity of .
Signed
Duly authorized to sign the bid for and on behalf of .
Dated on [insert day] day of], 20**Attachments:**

1. Documentary technical evidence in accordance with ITB Clause 17 (if required in BDS);
2. Description of the organization of the warranty offered in accordance with the conditions laid down in GCC Clause 23;
3. Copyright Authorization Letter in accordance with ITB Clause 5.6.
4. Certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Pharmaceuticalsoffered (only Bidders who are not primary manufacturers).

[5] Bidder may offer a different (but acceptable) package size representing the same number of basic units.

C. Delivery and Completion Schedule

Place and Date
Procurement Reference No.:
Alternative No.:
To:

Ethiopia

Item No.	International Nonproprietary name (INN) or Generic Name	Description	Strength in Metric Units	Basic Unit	Quantity	Package Size[6]	No. of Packages	Delivery Completion period (days/weeks/months)	Delivery Location/Site
1	2	3	4	5	6	7	8	9	10

Name
In the capacity of .
Signed
Duly authorized to sign the bid for and on behalf of .
Dated on [insert day] day of], 20

[6] Bidder may offer a different (but acceptable) package size representing the same number of basic units.

D. Sample Technical Specifications - Pharmaceuticals

1. Product and Package Specification

1.1 The Pharmaceuticals to be purchased by the Public Body under this Invitation for Bids are included in the current List of Medicines for Ethiopia published by the Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia. The required packing standards and labeling must meet the latest requirements of the World Health Organization (WHO) good manufacturing practices (GMP) standards in all respects. (These standards are contained in "Good Practices in the Manufacture and Quality Control of Drugs.")

1.2 Product specifications indicate dosage form (e.g., tablet, capsules, dry syrup, liquid, ointment, injectable, emulsion, suspension, etc.) and the drug content (exact number of mg or international units [IU] or % v/v, *w/w or v/w* acceptable range). The Pharmaceuticals should conform to standards specified in the following compendia:

1.3 Not only the pharmaceutical item, but also the packaging and labeling components (e.g., bottles, closures, and labeling) should also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the Federal democratic Republic of Ethiopia. All packaging must be properly sealed and tamper-proof and packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national regulatory authority (RA).

1.4 All information required on the label shall be in English and must appear clearly and conspicuously so that it will be read and understood by the ordinary individual under the customary conditions of purchase and use

1.5 Pharmaceuticals requiring refrigeration or freezing or those that should not fall below a certain minimum temperature for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transport.

1.6 Upon award, the successful Bidder shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific Pharmaceuticals the Public Body may request.

2. Labeling Requirements

Package labeling includes package leaflet, label on the immediate container, and outer wrapper or carton

2.1 **General requirements for package labeling**

(a). All information required on the label shall be in English and must appear clearly and conspicuously so that it will be read and understood by the ordinary individual under the customary conditions of purchase and use.

(b). Other information found acceptable may be added, but not at the expense of clarity and legibility or other essential information.

(c). The Bidders are required to provide legible labels. When the available space left for essential information is limited the Bidders are encouraged to provide carton and/or package insert where all the required information can be written. It is possible to use vial labels with a pouch containing a small insert or vial labels with an overlap.

(d). Each label should be affixed/mounted on a separate "81/2X11" sheet of paper so that the entire label (front and back) can be read without taking apart from the paper.

(e). All claims written on the labels must be supported by relevant data.

(f). The titles for batch number, manufacturing and expiry dates should be part of the printing (type written materials, stickers, etc. are not acceptable). If the labeling technology of the manufacturer is such that this information is to be printed on the label on production line using ink jet, laser printing, rubber stamp, etc, a written commitment to show all the required information on the label of the finished product must be submitted.

(g). The Bidder should submit a letter confirming that the labeling materials submitted are identical to the ones used in the country of origin.

2.2 **Package leaflet**

The package leaflet should consist of factual and scientific information and must bear adequate information for use and it should at least include:

(a). The name of the product; brand and generic/INN;

(b). Description, appearance, pharmaceutical form and route of administration;

(c). Qualitative and quantitative composition of active ingredient(s), preservative(s), and other ingredients that require precaution in their use;

(d). Clinical Pharmacology;

(e). Indication(s);

(f). Warnings, precautions, and contraindications;

(g). Adverse reactions/side effects;

(h). Dosage and administration (directions for use.);

(i). Over dosage (signs and symptoms, and treatment); where applicable;

(j). Potential for drug abuse and dependence: when applicable;

(k). Pharmaceutical precautions;

(l). Storage instructions;

(m). How supplied (package quantities);

(n). Name and address of manufacture;

(o). The establishment (license number) of the manufacturer;

(p). Date of preparation or last review of the leaflet.

Note:
If the product does not have an insert, then the particulars required under Sub-Clause 2.2 excluding 2.2(d) should appear on the label of the immediate container.

2.3 **Label of immediate container**

The label of the immediate container should at least include:

The name of the product; brand and generic/INN;

Pharmaceutical form, and route of administration;

Qualitative and quantitative composition of active ingredient(s), preservative(s);

The volume of the contents, and/or the number of doses or quantity in container;

Directions to consult the package insert, or the carton label for complete directions for use;

Handling and storage requirements;

The establishment (license number) of manufacturer;

Batch number;

Manufacturing date;

Expiry date (the actual dates are not required);

Name and address of manufacturer.

Note:
Where the immediate container of the medicament does not, on account its small size (small containers, ampoules, and unit packaging), enable the particulars required under Sub-Clause 2.2 to be displayed, the label on the container shall at least include: 2.3(a), 2.3(c), 2.3(d), 2.3(e), and 2.3(j).
No other statement, design, device or trade name shall overshadow the generic name. The size of the letters of the generic name should not be less than the size of the letters of the trade name.
The preferred format for the date manufacture and/or expiry date is yy/mm (year/month). It is understood that the expiry date corresponds to the last day of the month. Since the expiry date is calculated from the date of the start of the potency testing, the month that is indicated must fall within the total expiry time stipulated in the outline of the production. Example: potency testing started June, 14, 2011, for a product with an expiry dating of 12 months: Expiry date will be "2012/04"

2.4 **Outer wrapper or carton**

The outer wrapper or carton must bear all of the information required to appear on the label of the immediate container itself or else the wording on the label of the immediate container must be legible through the outer wrapper or carton.

3. Standards of Quality Control for Supply

3.1 The successful Bidder will be required to furnish to the Public Body:

(a). With each consignment, and for each item a WHO certificate of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the Pharmaceuticals being supplied and the manufacturer's certificate of analysis.

(b). Assay methodology of any or all tests if requested.

(c). Evidence of bio-availability and/or bio-equivalence for certain critical Pharmaceuticals upon request. This information would be supplied on a strictly confidential basis only.

(d). Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

3.2 The Bidder will also be required to provide the Public Body with access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality control mechanisms.

E. Sample Technical Specifications - Vaccines

1. Product Qualification Requirements

1.1 The Pharmaceuticals to be purchased by the Public Body under this Bidding Document must be produced under the control of a recognized, well-functioning National Control Authority (NCA) for biologicals, which performs all six critical functions as defined by the World Health Organization (WHO):

(a). licensing based on published set of requirements;

(b). surveillance of vaccine field performance;

(c). system of lot release for vaccines;

(d). use of laboratory when needed;

(e). regular inspections for good manufacturing practices (GMP);

(f). evaluation of clinical performance.

1.2 The Pharmaceuticals to be purchased by the Public Body under this Bidding Document must be produced in accordance with the GMP recommendations of WHO for biological products.

1.3 The Pharmaceuticals to be purchased by the Public Body under this Bidding Document must be registered by the Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia.

2. Product Specifications

2.1 Dosage form .
2.2 Type .
2.3 Administration .
2.4 Description of intended use .
2.5 Dosage size (if not restrictive), or expected immunogenic reaction .
2.6 Dose package .
2.7 Filling volume .
2.8 Closures .
2.9 Storage temperature .
2.10 The product should remain stable up to the indicated test expiry date if kept according to the required storage temperature.
2.11 Standards .

3. Labeling Requirements

3.1 All information required on the manufacturer's standard label of each vial or ampoule shall be in English and must appear clearly and conspicuously so that it will be read and understood by the ordinary individual under the customary conditions of purchase and use.

3.2 The label of the immediate container should at least include:

(a). The name of the vaccine; brand and generic/INN;

(b). Pharmaceutical form, and route of administration;

(c). Qualitative and quantitative composition of active ingredient(s), preservative(s);

(d). The volume of the contents, and/or the number of doses or quantity in container;

(e). Directions to consult the package insert, or the carton label for complete directions for use;

(f). Handling and storage requirements;

(g). The establishment (license number) of manufacturer;

(h). Batch number;

(i). Manufacturing date;

(j). Expiry date (the actual dates are not required);

(k). Name and address of manufacturer; and

(l). Any other information that is appropriate.

Note:
Where the immediate container of the medicament does not, on account its small size (small containers, ampoules, and unit packaging), enable the particulars required under Sub-Clause 3.2 to be displayed, the label on the container shall at least include: 3.2(a), 3.2(c), 3.2(d), 3.2(e), and 3.2(j).

No other statement, design, device or trade name shall overshadow the generic name. The size of the letters of the generic name should not be less than the size of the letters of the trade name.
The preferred format for the date manufacture and/or expiry date is yy/mm (year/month). It is understood that the expiry date corresponds to the last day of the month. Since the expiry date is calculated from the date of the start of the potency testing, the month that is indicated must fall within the total expiry time stipulated in the outline of the production. Example: potency testing started June, 14, 2011, for a product with an expiry dating of 12 months: Expiry date will be "2012/04"

3.3 All labeling shall withstand immersion in water and remain intact.

4. Packing Requirements

4.1 **Inner boxes:**

Inner Boxes shall contain not more than individual vials/ampoules and shall be constructed of sturdy white cardboard outfitted with individual segments for protecting and separating each vial/ampoules.

4.2 **Printed materials:**

Each inner box shall contain at least manufacturer's standard package inserts in Amharic if available at no extra charge; otherwise, package insert shall be in English.

4.3 **Overpacking:**

Inner boxes shall be overpacked so that the vaccine remains refrigerated as designated in Sub-Clause 2.9. The overpacking must be suitable for export handling and be in accordance with WHO Expanded Program of Immunization (EPI) Guidelines on International Packaging and Shipping of Vaccines including all measures needed to maintain required temperatures for seventy-two (72) hours. It must have adequate insulation and sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above that designated in Sub-Clause 2.9 when exposed to continuous outside temperature of +43 degrees C, nor fall below that specified of -20 degrees C during transit and for a period of at least twenty-four (24) hours after arrival at the airport destination. Additional cushioning shall be provided sufficient to protect the vials/ampoules from breakage during transit and handling.

4.4 **Exterior shipping cartons:**

Product and printed materials, packaged as described above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1,900 kPa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage. No shipping carton should contain vaccine from more than one lot.

4.5 **Cold chain monitor cards:**

Each insulated shipping container must include appropriate temperature-monitoring devices designated by the Public Body.

(a). At least two suitable cold chain monitor cards, as approved by the Public Body, shall be packed in each transport case of vaccine.

(b). Freeze watch indicators shall be included in each transport case at the direction of Public Body.

5. Marking Requirements

5.1 All containers and invoices must bear the following information:

(a). the name of the vaccine;

(b). expiration date of the vaccine;

(c). appropriate storage temperature.

5.2 **Inner boxes:**

The inner boxes containing vaccine vials or ampoules shall be marked with the following information in a clearly legible manner that is acceptable to the Public Body:

(a). The name of the product; brand and generic/INN;

(b). Pharmaceutical form, and route of administration;

(c). Qualitative and quantitative composition of active ingredient(s), preservative(s);

(d). The volume of the contents, and/or the number of doses or quantity in container;

(e). Directions to consult the package insert, or the carton label for complete directions for use;

(f). Handling and storage requirements;

(g). The establishment (license number) of manufacturer;

(h). Batch number;

(i). Manufacturing date;

(j). Expiry date (the actual dates are not required);

(k). Name and address of manufacturer.

5.3 **Exterior Shipping Cartons:**

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least 30mm high with waterproof ink in a clearly legible manner that is acceptable to the Public Body.

(a). The exterior shipping cartons must bear all of the information required to appear on the label of the immediate container itself or else the wording on the label of the immediate container must be legible through the exterior wrapper or carton; and

(b). Destination and routing;

(c). Consignee's name and address in full;

(d). Consignee contact name and telephone number;

(e). Number of vials or ampoules contained in the carton;

(f). Gross weight of each carton (in kg);

(g). Carton #____ of _____;

(h). Contract number;

6. Quality Control for Supply

6.1 All Pharmaceuticals must:

(a). meet the requirements of manufacturing legislation and regulation of vaccines in the country of origin;

(b). meet internationally recognized standards for safety, efficacy, and quality;

(c). conform to all the specifications and related documents contain herein;

(d). be fit for the purposes expressly made known to the Bidder by the Public Body;

(e). be free from defects in workmanship and materials; and

(f). be certified by the Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia.

6.2 The Bidder will be required to furnish to the Public Body with each consignment;

(a). A certificate of quality control and test results in conformity with the WHO release certificate.

(b). Assay methodology of any or all tests if required.

(c). Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

6.3 **Preshipment inspection and testing:**

The Bidder will be required to provide the Public Body or his representative with access to the product as packed for shipment at the sellers' factory and/or warehouse at a mutually agreeable time prior to shipment of the product.

(a). The Public Body may inspect and sample, or cause to be sampled, such product.

(b). The Public Body may cause independent laboratory testing to be performed as deemed necessary to ensure that the Pharmaceuticals conform to prescribed requirements. The testing laboratory shall be of the Public Body's choice and suitably equipped and qualified to conduct quality control test on biological products.

F. Sample Technical Specifications - Condoms

1. Product and Package Specifications

1.1 The Pharmaceuticals must conform to the manufacturer's current standards for condoms and specified in line with the ISO 4074 Standard for Latex Rubber Condoms.

1.2 The specifications for the Pharmaceuticals shall indicate critical factors, i.e., bursting volume and pressure, freedom from holes, width and length, thickness, lubricant quality, and viscosity.

1.3 The Pharmaceuticals and packaging and labeling components shall meet the standards specified in the latest WHO specification, including batch-by-batch independent quality control laboratory tests.

1.4 Condoms should be shipped in special containers to ensure stability in transit from point of shipment to port/air port of entry and point of destination for CIP deliveries. Any special temperature requirements must be designed to meet the climatic conditions prevailing in the Federal Democratic Republic of Ethiopia, and the Public Body should advise the Bidder of any particular requirements.

2. Labeling Requirements

2.1 The primary pack should be labeled in accordance with the latest WHO specifications and include:

(a). Manufacturer's name;

(b). Batch number (printed at the time of packaging);

(c). Month and year of expiry; and

(d). Any other information as requested by the Public Body.

2.2 The secondary packing, i.e., the inner box, should be labeled in accordance with the latest WHO specifications and include:

(a). Batch number;

(b). Month and year of manufacture (including the words: Date of Manufacture/month/year);

(c). Manufacturer's name and registered address;

(d). Nominal width expressed in millimeters;

(e). Number of condoms in box;

(f). Instructions for storage; and

(g). Month and year of expiry.

3. Packaging Specification

3.1 All exterior shipping cartons and packaging must comply with the latest WHO specification for packaging of condoms.

4. Case Identification

4.1 All cases should predominantly indicate the following:

(a). Batch number;

(b). Month and year of manufacture (including the words: Date of Manufacture/month/year);

(c). Name and address of supplier;

(d). Nominal width expressed in millimeters;

(e). Number contained in the carton;

(f). Instructions for storage and handling; and

(g). Month and year of expiry.

5. Lot Traceability

5.1 All exterior shipping cartons for each batch should be assembled and shipped together to facilitate the monitoring of batch quality during shipping and storage.

5.2 Both codes should be used on exterior shipping cartons, color coded for ease of identification if requested by the Public Body.

6. Unique Identifiers

6.1 The Public Body will have the right to request the Bidder to imprint, provided the quantity justifies it, a logo on the packaging of the condoms. The design and details will be clearly indicated at the time of bidding and shall be provided to the Bidder at the time of contract award

7. Standards of Quality Control for Supply

7.1 The Bidder will be required to provide the Public Body with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms

8. Quality Control Testing

8.1 The Bidder shall be required to carry out testing of a proposed shipment in line with the WHO specification, and the size of sample will be calculated by reference to ISO 2859-1.

8.2 With each consignment the Bidder must provide a certificate of quality control test results in conformity with the WHO specifications and in accordance with the general sampling levels appropriate to each feature as necessary.

Part 3 Contract

Section 7. General Conditions of Contract

Table of Clauses

Section 7 General Conditions of Contract

A. General Provisions

1. Definitions

1.1 The headings and titles of these General Conditions of Contract shall not limit, alter or affect the meaning of the Contract.

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

(a). "Authorized Officer"	means a person designated as such by the Public Body from time to time as notified in writing to the Supplier to act as the representative of the Public Body for all purposes connected with the Contract, including any authorized representative of such person;
(b). "Bankrupt"	means with respect to any entity, such entity (i) files a petition or otherwise commences, authorizes or acquiesces in the commencement of a proceeding or cause of action under any bankruptcy, insolvency, reorganization or similar law, or has any such petition filed or commenced against it, (ii) makes an assignment or any general arrangement for the benefit of creditors, (iii) otherwise becomes bankrupt or insolvent (however evidenced), (iv) has a liquidator, administrator, receiver, trustee, conservator or similar official appointed with respect to it or any substantial portion of its property or assets, or (v) is generally unable to pay its debts as they fall due;
(c). "Completion"	means the fulfilment of the Contract by the Supplier in accordance with the terms and conditions set forth in the Contract;
(d). "Contract Documents"	means the documents listed in the GCC, including all attachments, appendices, and all documents incorporated by reference therein, and shall include any amendments thereto;
(e). "Contract Manager"	means a person designated as such by the Supplier from time to time as notified in writing to the Public Body to act as the duly authorized representative of the Supplier for all purposes connected with the Contract, including any authorized representative of such person;
(f). "Contract Price"	means the money payable by the Public Body to the Supplier based on the Contract Agreement and shall include all royalties, license fees or similar expenses in respect of the making, use or exercise by the Supplier of any Intellectual Property or Intellectual Property Rights for the purpose of performing the Contract;
(g). "Contract"	means the binding Contract Agreement entered into between the Public Body and the Supplier, comprising Contract Documents referred to therein, including all attachments, appendices, and all documents incorporated by reference therein,
(h). "Day"	means calendar day;
(i). "Delivery"	means the transfer of the Pharmaceuticals from the Supplier to the Public Body in accordance with the terms and conditions set forth in the Contract;
(j). "Effective Date"	means the date of fulfillment of conditions stated in Sub-Clause 2.1 (Effective Date) of the Contract Agreement, from which the Time

	for Completion shall be counted;
(k). "Eligible Countries"	means the countries and territories eligible as listed in Section 5 of the Bidding Document;
(l). "General Conditions of Contract"	hereinafter referred to as "GCC", means the conditions in this section of the Contract, which shall govern the Contract, except where amended by the SCC or Contract Agreement;
(m). "Good Industry Practice"	means the exercise of that degree of skill, diligence and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the provision of Pharmaceuticals similar to the Pharmaceuticals under the same or similar circumstances as those applicable to the Contract and which are in accordance with any codes of practice published by relevant trade associations;
(n). "Pharmaceuticals"	means all of the pharmaceuticals including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms that the Supplier is required to supply to the Public Body under the Contract
(o). "Government"	means the Government of the Federal Democratic Republic of Ethiopia;
(p). "In writing"	shall be interpreted to include any document which is recorded in manuscript or typescript;
(q). "Liquidated damages"	means the compensation stated in the contract as being payable by Supplier to the Public Body for failure to perform the contract or part thereof within the periods under the contract, or as payable by Supplier to the Public Body for any specific breach identified in the contract;
(r). "Location"	means the location for the delivery of the Pharmaceuticals and Related Services as set out in the Contract or as otherwise agreed in writing between the Public Body and the Supplier;
(s). "Member"	means any of the entities that make up the joint venture / consortium / association; and "Members" means all these entities;
(t). "Party"	means the Public Body or the Supplier and includes their permitted successors and "Parties" means both of them;
(u). "Public Body"	means public body, which is partly or wholly financed by the Federal Government Budget, higher education institutions, and public institutions of like nature which has the powers and duties to conclude a Contract for the supply of Pharmaceuticals and Related Services, as named in the SCC;
(v). "Purchase Order"	or acronym "PO" means an individual order for Pharmaceuticals and Related Services issued by Public Body pursuant to the terms, conditions, and pricing established in a Contract. Each individual Purchase Order is a binding contractual instrument and will refer and incorporate the terms and conditions of this Contract and specify the Pharmaceuticals to be supplied, delivery schedule, and price;
(w). "Related Services"	means the services incidental to the supply of the Pharmaceuticals, such as insurance, installation, training and initial maintenance and other similar obligations of the Supplier under the Contract;
(x). "Special Conditions of Contract"	hereinafter referred to as "SCC", means the conditions attached to the Contract Agreement, which shall govern the Contract and shall prevail over these General Conditions of Contract;

(y). "Subcontractor"	means any natural person, private or government entity, or a combination of the above, including its legal successors or permitted assigns, to whom any part of the Pharmaceuticals to be supplied or execution of any part of the Related Services is subcontracted by the Supplier;
(z). "Supplier"	means a natural or juridical person under contract with a Public Body to supply Pharmaceuticals and Related services, as named in the SCC.

2. Appointment

2.1 The Public Body appoints the Supplier to supply the Pharmaceuticals and Related Services:

(a). Promptly (and in any event within any time targets as may be set out in the Section 6, Statement of Requirements) and in a professional and courteous manner so as to reflect and promote the image of the Public Body;

(b). Strictly in accordance with the Statement of Requirements and all provisions of the Contract; and

(c). In accordance with all applicable laws and regulations of the Federal Democratic Republic of Ethiopia and Good Industry Practice; and

(d). In accordance with the policies, rules, and procedures of the appropriate Authority as amended from time to time.

(e). In accordance with the national drug policy and legislation and standards, directives, and guidelines set by the Ethiopian Medicine and Health Care Administration and Control Authority and applicable WHO standards;

(f). In accordance with the terms and conditions of appointment as provided in this Clause in consideration of the Contract Price.

3. Relationship of the Parties

3.1 The Supplier shall not incur any liabilities on behalf of the Public Body or enter into any contract or obligation on behalf of the Public Body.

3.2 The Supplier shall be an independent contractor performing the Contract. The Contract does not create any agency, partnership, joint venture, or other joint relationship between the parties to the Contract.

3.3 Subject to the provisions of the Contract, the Supplier shall be solely responsible for the manner in which the Contract is performed. All employees, representatives, or Subcontractors engaged by the Supplier in connection with the performance of the Contract shall be under the complete control of the Supplier and shall not be deemed to be employees of the Public Body, and nothing contained in the Contract or in any subcontract awarded by the Supplier shall be construed to create any contractual relationship between any such employees, representatives, or Subcontractors and the Public Body.

4. Due Diligence

4.1 The Supplier acknowledges that it:

(a). Has made and shall make its own enquiries to satisfy itself as to the accuracy and adequacy of any information supplied to it by or on behalf of the Public Body;

(b). Has raised all relevant due diligence questions to the Public Body before the Effective Date;

and

(c). Has entered into this Contract in reliance on its own due diligence alone.

4.2 Any disputes relating to due diligence shall be resolved in accordance with the Ethiopian Law.

5. Fraud and Corruption

5.1 It is the Government of the Federal Democratic Republic of Ethiopia's policy to require that Public Body, as well as bidders/suppliers, to observe the highest standards of ethics during the procurement and the execution of contracts. In pursuance of this policy, the Government of the Federal Democratic Republic of Ethiopia represented by the Public Procurement and Property Administration Agency (herein referred to as the Agency) requires that Contracting Authorities shall include in bidding documents, provisions against corrupt practices.

5.2 The Agency defines, for the purposes of these provisions, the terms set forth below as follows:

(a). "Corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of any thing of value to influence the action of a public official in the procurement process or in contract execution, and

(b). "Fraudulent practice" is any act or omission, including misrepresentation that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation.

(c). "Collusive practices" is a scheme or arrangement between two or more Suppliers, with or without the knowledge of the Public Body, designed to establish prices at artificial, non competitive levels, and

(d). "Coercive practices" is harming or threatening to harm, directly or indirectly, persons or their property to influence their participation in a procurement process, or affect the execution of a contract.

(e). "Obstructive practice" is

(i) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede the Federal Ethics and Anticorruption Commission, the Federal Auditor General and the Public Procurement and Property Administration Agency or their auditors' investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent their from disclosing their knowledge of matters relevant to the investigation or from pursuing the investigation, or

(ii) acts intended to materially impede the exercise of inspection and audit rights provided for under GCC Sub-clause 44.2.

5.3 PFSA will report to PPA in order to debar a Supplier from participation in public procurement if it at any time determines that the Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract.

5.4 The Agency reserves the right, where a Supplier has been found by a national or international entity to have engaged in corrupt or fraudulent practice, to declare that such a Supplier is ineligible, for a stated period of time, to be awarded a Government funded contract. (NA)

5.5 The Agency will have the right to require that, in contracts funded by the Government of Ethiopia, a provision be included requiring suppliers to permit the Agency to inspect their accounts and records relating to the performance of the contract and to have them audited by auditors appointed by the Agency, if the supplier engages in any corrupt practice. (NA)

5.6 Any communications between the Supplier and the Public Body or the Agency related to matters

of alleged fraud or corruption must be made in writing.(NA)

6. Interpretation

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

6.2 In these terms and conditions, words referring any particular gender include all other genders.

6.3 Incoterms

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

(b). DDP, EXW, CIF, 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 at the date of the Invitation for Bids or as specified in the SCC.

6.4 Entire Agreement

The Contract constitutes the entire agreement between the Public Body and the Supplier and supersedes all communications, negotiations and agreements of parties with respect thereto made prior to the date of Contract.

6.5 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.

6.6 Nonwaiver

(a). Subject to GCC Sub-Clause 6.6(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.

6.7 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.

B. The Contract

7. Contract Documents

7.1 The documents forming the Contract shall be interpreted in the following order of precedence in the event of any conflict between the documents comprising this Contract:

(a). Agreement;

(b). The Special Conditions of Contract;

(c). The General Conditions of Contract;

(d). Bid Submission Sheet with Annexes;

(e). Price Schedule;

(f). List of accepted items including their unit price;

(g). Bidder Certification of Compliance with Annexes;

(h). Technical Specification + Technical Offer + Compliance Sheet with Annexes;

(i). Any other document listed in the SCC as forming part of the Contract.

7.2 All documents forming the Contract are intended to be correlative, complementary, and mutually explanatory

7.3 Any action required or permitted to be taken, and any document required or permitted to be provided, under the Contract by the Public Body or the Supplier may be taken or provided by the authorized representatives specified in the SCC.

7.4 The Contract constitutes the entire agreement between the Public Body and the Supplier and supersedes all communications, negotiations and agreements (whether written or oral) of parties with respect thereto made prior to the date of Contract. No agent or representative of either Party has authority to make, and the Parties shall not be bound by or be liable for, any statement, representation, promise or agreement not set forth herein.

8. Governing Law

8.1 The Contract shall be governed by and interpreted in accordance with the laws of the Federal Democratic Republic of Ethiopia, unless otherwise specified in SCC.

9. Language

9.1 The Contract as well as all written and oral communication and documents relating to the Contract exchanged by the Supplier and the Public Body, shall be in English. Supporting documents and printed literature that are part of the Contract may be in another language, but any documents provided in another language must be accompanied by an accurate translation into English. For purposes of interpretation of the Contract, this translation shall govern.

9.2 The Supplier shall bear all costs of translation to the governing language and all risks of the accuracy of such translation.

10. Notices and written communications

10.1 Any notice, request or consent required or permitted to be given or made pursuant to this Contract shall be in writing. The term “in writing” means communicated in written form with proof of receipt.

10.2 Any such notice, request or consent shall be deemed to have been given or made when delivered in person to an authorized representative of the Party to whom the communication is addressed, or when sent to such Party at the address specified in the SCC.

10.3 A Party may change its address for notice hereunder by giving the other Party notice in writing of such change to the address specified in the SCC.

11. Authorized Officers

11.1 Any notice, information or communication given to or made by an Authorized Officer shall be

deemed to have been given or made by the Public Body.

11.2 The Supplier shall decline from supplying the Pharmaceuticals and Related Services to any of the Public Body's staff who are not Authorized Officers.

12. Assignment

12.1 An assignment is a written agreement by which the Supplier transfers its contract or part thereof to a third party.

12.2 The Supplier shall not, without the prior written consent of the Public Body, assign the Contract or any part thereof, or any benefit or interest thereunder, except in the following cases.

(a). A charge, in favor of the Supplier's bankers, of any monies due or to become due under the Contract; or

(b). Assignment to the Supplier's insurers of the Supplier's right to obtain relief against any other person liable in cases where the insurers have discharged the Supplier's loss or liability.

12.3 With the exception of the carriage of Pharmaceuticals to the Location, the Supplier shall not sub-contract the production or supply of any Pharmaceuticals without the previous consent in writing of the Public Body, such consent not to be unreasonably withheld or delayed.

12.4 For the purpose of GCC Clause 12.2 the approval of an assignment by the Public Body shall not relieve the Supplier of its obligations for the part of the Contract already performed or the part not assigned.

12.5 If the Supplier has assigned his Contract without authorization, the Public Body may, without giving formal notice thereof, apply as of right the sanctions for breach of Contract provided for in GCC Clauses 18 and 20.

12.6 Assignees must satisfy the eligibility criteria applicable for the award of the Contract and they can not be in any of the situations excluding them from participating in Contract.

12.7 Every assignment shall be subject to the provisions of this Contract and shall incorporate the terms and conditions of this Contract.

13. Subcontracting

13.1 A sub-contract shall be valid only if it is a written agreement by which the Supplier entrusts performance of a part of the Contract to a third party.

13.2 In the event the Supplier requires the related services of sub-contractors that are not included in the Contract, the Supplier shall obtain the prior written approval and clearance of Public Body for all sub-contractors. The related services to be sub-contracted and the identity of the subcontractors shall be notified to the Public Body. The Public Body shall with due regard to the provisions of GCC Clause 10 within 15 days of receipt of the notification, notify the Supplier of its decision, stating reasons should he withhold such authorization.

13.3 The terms of any sub-contract shall be subject to and conform to the provisions of this Contract.

13.4 The Public Body shall have no contractual relations with the Sub-Contractors.

13.5 Sub-contractors must satisfy the eligibility criteria applicable to the award of the contract and they can not be in any of the situations excluding them from participating in contract.

13.6 The Supplier shall be responsible for the acts, defaults and negligence of his Sub-Contractors and

their agents or employees, as if they were the acts, defaults or negligence of the Supplier, his agents or employees. The approval by the Public Body of the sub-contracting of any part of the contract or of the Sub-Contractor to perform any part of the services shall not relieve the Supplier of any of his obligations under the contract.

13.7 If the Supplier enters into a subcontract without approval, the Public Body may apply, as of right without giving formal notice thereof, the sanctions for breach of contract provided for in GCC Clauses 18 and 20.

13.8 If a Sub-Contractor is found by the Public Body to be incompetent in discharging its duties, the Public Body may request the Supplier forthwith, either to provide a Sub-Contractor with qualifications and experience acceptable to the Public Body as a replacement, or to resume the implementation of the tasks itself.

14. Modifications and Contract Amendments

14.1 The Public Body may at any time request the Supplier through notice in accordance GCC Clause 10, to make changes within the general scope of the Contract in any one or more of the following:

(a). Drawings, designs, or specifications, where Pharmaceuticals to be furnished under the Contract are to be specifically manufactured for the Public Body; (NA)

(b). The method of shipment or packing;

(c). The place of delivery; and

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

14.2 If any such change causes increase or decrease in the time required for the Supplier's performance of any provisions under the Contract an equitable adjustment shall be made 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 Public Body's change order.

14.3 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.

14.4 Any change to the terms of the Contract must be recorded in writing and executed by authorized signatory of the Supplier and the Authorized Officer. Such record of the change in question must address all consequential amendments required to be made to the Contract as a result of such change.

14.5 Changes will take effect as from the date specified in the signed record of change and shall not have retrospective effect unless expressly provided for in such record.

14.6 Each record of change must be dated and sequentially numbered. Each of the Public Body and the Supplier will be entitled to an original executed counterpart of the record of variation.

14.7 Except as provided in any such record of variation, the Contract will continue in full force and effect.

15. Change in Laws and Regulations

15.1 Unless otherwise expressly agreed in the SCC, if, after the deadline for submission of the Bid, any law, regulation, ordinance, order or bylaw having the force of law is enacted, promulgated, abrogated, or changed in the Federal Democratic Republic of Ethiopia 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 Contract Price shall not be correspondingly increased or decreased and/or the Delivery Date shall not be adjusted to the extent that Supplier has thereby been affected in the performance of any of its obligations under the Contract.

16. Taxes and Duties

16.1 For Pharmaceuticals supplied from outside the Federal Democratic Republic of Ethiopia, the Supplier shall bear the costs of all taxes, custom duties, formalities, license fees, and other such levies imposed outside the Federal Democratic Republic of Ethiopia, unless otherwise specified in the SCC.

16.2 For Pharmaceuticals supplied from within the Federal Democratic Republic of Ethiopia, the Supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Pharmaceuticals to the Public Body, unless otherwise specified in the SCC.

17. Force Majeure

17.1 For the purposes of the Contract, "Force Majeure" shall mean an event or events which are beyond the reasonable control of a Supplier, and which makes a Supplier's performance of its obligations hereunder impossible or so impractical as reasonably to be considered impossible in the circumstances, and includes:

(a). An official prohibition preventing the performance of a contract,

(b). A natural catastrophe such as an earthquake, fire, explosion lightening, floods, or other adverse weather conditions, or

(c). International or civil war, or

(d). The death or a serious accident or unexpected serious illness of the supplier, or

(e). Other instances of Force Majeure identified as such by the civil code.

17.2 The following occurrences shall not be deemed to be cases of Force Majeure:

(a). A strike or lock-out taking of a party or affecting the branch of business in which he carries out his activities, or

(b). An increase or reduction in the price of raw materials necessary for the performance of the contract, or

(c). The enactment of new legislation where by the obligations of the debtor becomes more onerous, or

(d). Any event which is caused by the negligence or intentional action of a Supplier or such Supplier's Subcontractors or agents or employees; or

(e). Any event which a diligent Party could reasonably have been expected to both:

(i) Take into account from the effective date of the Contract; and

(ii) Avoid or overcome in the carrying out of its obligations; or

(f). Insufficiency of funds or failure to make any payment required hereunder.

17.3 The failure of a Supplier to fulfill any of its obligations hereunder shall not be considered to be a breach of, or default under, the Contract insofar as such inability arises from an event of Force Majeure, provided that the Supplier affected by such an event has taken all reasonable precautions, due care and reasonable alternative measures, all with the objective of carrying out the terms and conditions of the Contract.

17.4 A Supplier affected by an event of Force Majeure shall take all reasonable measures to

(a). Remove such Supplier's inability to fulfill its obligations hereunder with a minimum of delay; and

(b). Minimize the consequences of any event of Force Majeure.

17.5 A Supplier affected by an event of Force Majeure shall notify the Public Body of such event as soon as possible, and in any event not later than fourteen (14) days following the occurrence of such event, providing evidence of the nature and cause of such event, and shall similarly give notice of the restoration of normal conditions as soon as possible.

17.6 Not later than thirty (30) days after the Supplier, as the result of an event of Force Majeure, has become unable to supply the Pharmaceuticals and Related Services, the Parties shall consult with each other in good faith and use all reasonable endeavors to agree appropriate terms to mitigate the effects of the Force Majeure Event and facilitate the continued performance of the Contract.

18. Breach of Contract

18.1 Either party commits a breach of contract where it fails to discharge any of its obligations under the specific contract.

18.2 Where a breach of contract occurs, the party injured by the breach shall be entitled to the following remedies:

(a). Compensation / Claim for liquidated damages as specified in GCC Clause 25; and/or

(b). Termination of the contract.

18.3 In any case where the Public Body is entitled to damages, it may deduct such Suspension damages from any sums due to the Supplier or call on the appropriate guarantee.

19. Suspension of Assignment

19.1 The Public Body may, by written notice of suspension of the assignment to the Supplier, suspend all payments to the Supplier hereunder if the Supplier fails to perform any of its obligations under the Contract provided that such notice of suspension shall:

(a). Specify the nature of the failure; and

(b). Request the Supplier to remedy such failure within a period not exceeding thirty (30) days after receipt by the Supplier of such notice of suspension.

20. Termination

20.1 Termination shall be without prejudice to any other rights or powers under the contract of the Public Body and the Supplier.

20.2 In addition to the grounds for termination defined in these General Conditions, the Public Body may, by not less than thirty days written notice of termination to the Supplier stating the reason for termination of the contract and the date on which such termination becomes effective. (except in the event listed in paragraph (o) below, for which there shall be a written notice of not less than sixty days), such notice to be given after the occurrence of any of the events specified in GCC Sub-Clause 20.2 (a) to (p), terminate the Contract if:

(a). The supplier fails to deliver any or all of the Pharmaceuticals or Related Services within the period specified in the Contract, or within any extension thereof granted by the Public Body pursuant to GCC Clause 59 or if the Pharmaceuticals do not meet the technical specifications

stated in the Contract;

(b). The Supplier fails to remedy a failure in the performance of their obligations as specified in a notice of suspension of assignment pursuant to GCC Clause 19 within thirty days of receipt of such notice of suspension of assignment or within such period other agreed between the Parties in writing;

(c). The Supplier becomes insolvent or bankrupt or enters into any agreements with its creditors for relief of debt or take advantage of any law for the benefit of debtors or go into liquidation or receivership whether compulsory or voluntary, other than for a reconstruction or amalgamation;

(d). The Supplier fails to comply with any final decision reached as a result of direct informal negotiation pursuant to GCC Sub-Clause 24.2 hereof;

(e). The Supplier is unable as the result of Force Majeure, to perform a material portion of the Services for a period of not less than sixty days;

(f). The Supplier assigns the contract or sub-contracts without the authorization of the Public Body;

(g). The Supplier has been guilty of grave professional misconduct proven by any means which the Public Body can justify;

(h). The Supplier has been declared to be in serious breach of contract financed by the Federal Democratic Republic of Ethiopia's budget for failure to comply with its contractual obligations.

(i). The Supplier has been engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

(j). Any organizational modification occurs involving a change in the legal personality, nature or control of the Supplier, unless such modification is recorded in an addendum to the Contract;

(k). Any other legal disability hindering performance of the Contract occurs;

(l). The Supplier fails to provide the required guarantees or insurance, or the person providing the underlying guarantee or insurance is not able to abide by its commitments.

(m). Where the procurement requirement of the Public Body changes for any apparent or obvious reason;

(n). Where it emerges that the gap between the value of the Contract and the prevailing market price is so wide that allowing the implementation of the contract to proceed places the Public Body concerned at a disadvantage;

(o). The Public Body, in its sole discretion and for any reason whatsoever, decides to terminate the Contract.

(p). The accumulated liquidated damage reached its maximum as stated in GCC Clause 25.1(b).

20.3 The Supplier may, by not less than thirty days written notice to the Public Body, of such notice to be given after the occurrence of any of the events specified in GCC Sub-Clause 20.3 (a) to (d) terminate the Contract if:

(a). The Public Body fails to pay any money due to the Supplier pursuant to the Contract and not subject to dispute pursuant to GCC Clause 24, within forty-five days after receiving written notice from the Supplier that such payment is overdue;

(b). The Public Body is in material breach of its obligations pursuant to the Contract and has not remedied the same within forty-five days (or such longer period as the Supplier may have subsequently approved in writing) following the receipt by the Public Body of the Supplier's notice specifying such breach;

(c). The Supplier is unable as the result of Force Majeure, to perform a material portion of the

Services for a period of not less than sixty days; or

(d). The Public Body fails to comply with any final decision reached as a result of settlement of disputes pursuant to GCC Clause 24 hereof.

20.4 If either Party disputes whether an event specified GCC Sub-Clauses 20.2 (a) to (n) or GCC Sub-Clause 20.3 has occurred, such Party may, within forty-five days after receipt of notice of termination from the other Party, refer the matter to settlement of disputes pursuant to GCC Clause 24 and the Contract shall not be terminated on account of such event except in accordance with the terms of any resolution award.

20.5 In the event the Public Body terminates the Contract pursuant to the GCC Sub-Clause 20.2 (a) to (n) the Public Body may procure, upon such terms and in such manner as it deems appropriate, Pharmaceuticals or Related Services similar to those undelivered or not performed, and the Supplier shall be liable to the Public Body for any additional costs for such similar Pharmaceuticals or Related Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

20.6 If the Public Body terminates the Contract in the event specified in GCC Sub-Clause 20.2 (o) the notice of termination shall specify that termination is for the Public Body's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

20.7 If the Public Body terminates the Contract in the event specified in GCC Sub-Clause 20.2 (o) the Pharmaceuticals 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 Public Body at the Contract terms and prices. For the remaining Pharmaceuticals, the Public Body 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 Pharmaceuticals and Related Services and for materials and parts previously procured by the Supplier.

20.8 In the event the Public Body terminates the Contract pursuant to the GCC Sub-Clause 20.2 (c) 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 Public Body.

20.9 In the event of any termination by the Public Body under this Clause, for the avoidance of doubt, the Supplier will not be restricted from making any claim in respect of the Contract Price to the extent the Contract Price is outstanding and due and payable.

21. Arrangements on Termination

21.1 The Public Body and the Supplier agree that termination or expiry of the Contract shall not affect either Party's obligations which the Contract provides shall survive the expiration or termination of the Contract.

21.2 After termination or expiry all data, documents and records (whether stored electronically or otherwise) relating in whole or in part to the supplied Pharmaceuticals and Related Services shall be delivered by the Supplier to the Public Body provided that the Supplier shall be entitled to keep copies thereof to the extent that the information contained therein does not relate solely to the Pharmaceuticals and Related Services or to the extent that the Supplier is required by law to maintain copies thereof or to the extent that the Supplier was possessed of such data documents and records prior to the date of the Contract. In addition, the Supplier shall co-operate fully with

the Public Body during the handover leading to the termination of the Contract. This co-operation shall extend to full access to all documents, reports, summaries and any other information required to achieve an effective transition without disruption to routine operational requirements.

22. Cessation of Rights and Obligations

22.1 Upon termination of the Contract pursuant to GCC Clauses 20, or upon completion of the Contract, all rights and obligations of the Parties hereunder shall cease, except

(a). Such rights and obligations as may have accrued on the date of termination or expiration;

(b). The Supplier's obligation to permit inspection, copying and auditing of their accounts and records set forth in GCC Clause 44; and

(c). Any right which a Party may have under the Governing Law

(d). The warranty right provided for under Clause 23.

23. Warranty

23.1 The Supplier warrants that all the Pharmaceuticals must be of fresh manufacture and must bear the dates of manufacture and expiry.

23.2 Subject to GCC Sub-Clause 49.1, the Supplier further warrants that all Pharmaceuticals supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery for Pharmaceuticals with a shelf life of more than two years and three-fourths (3/4) for Pharmaceuticals with a shelf life of two years or less, unless otherwise specified in the SCC**;** have "overages" within the ranges set forth in the Statement of Requirements, 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 Statement of Requirements and with the conditions laid down in the Contract.

23.3 Unless otherwise specified in the SCC, the warranty shall remain valid for twelve (12) months after the Pharmaceuticals, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the GCC Clause 50.1.

23.4 The Public Body shall give notice to the Supplier stating the nature of any such defects together with all available evidence thereof, promptly following the discovery thereof. The Public Body shall afford all reasonable opportunity for the Supplier to inspect such defects.

23.5 Upon receipt of such notice, the Supplier shall, within the period specified in the SCC, expeditiously replace the defective Pharmaceuticals, at no cost to the Public Body.

23.6 The Supplier will be entitled to remove, at his own risk and cost, the defective Pharmaceuticals once the replacement Pharmaceuticals have been delivered.

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

23.8 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 23.4 above, the Supplier fails to replace the defective Pharmaceuticals within the period specified in the SCC**,** the Public Body 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 Public Body may have against the Supplier under the Contract. The Public Body will also be entitled to claim for storage in respect of the defective Pharmaceuticals for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

23.9 In the event any of the Pharmaceuticals are recalled, the Supplier shall notify the Public Body 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 Pharmaceuticals that fully meet the requirements of the Statement of Requirements and arrange for collection or destruction of any defective Pharmaceuticals. If the Supplier fails to fulfill its recall obligation promptly, the Public Body will, at the Supplier's expense, carry out the recall.

24. Settlement of Disputes

24.1 During any dispute, including a dispute as to the validity of the Contract, it is mutually agreed that the Supplier shall continue its performance of the provisions of the Contract (unless the Public Body requests in writing that the Supplier does not do so).

24.2 The Public Body and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement, controversy or dispute arising between them under or in connection with the Contract or interpretation thereof.

24.3 If a dispute arises between the Public Body and the Supplier in relation to any matter which cannot be resolved by the Authorized Officer and the Supplier Contract Manager either of them may refer such dispute to the procedure described in ITB Sub-Clause 24.4.

24.4 In the second instance each of the Public Body and the Supplier shall appoint more senior representatives than those referred to in Sub-Clause 24.3 to meet solely in order to resolve the matter in dispute. Such meeting(s) shall be minuted and shall be chaired by the Public Body (but the chairman shall not have a casting vote). Such meeting(s) shall be conducted in such manner and at such venue (including a meeting conducted over the telephone) as to promote a consensual resolution of the dispute in question at the discretion of the chairman.

24.5 If the Parties fail to resolve such a dispute or difference amicably within twenty-eight (28) days from the commencement of such procedure, either party may require that the dispute be referred for resolution through the courts in accordance with Ethiopian Law.

24.6 Only those Public Bodies that are allowed by law to proceed to arbitration can do so.

A). The place of Arbitration shall be Addis Ababa, Ethiopia

B). The Language used in arbitrate proceeding shall be Amharic

C). The Award of the Arbitration shall be final and binding

D). The Arbitration cost will be covered by the losing party.

25. Liquidated Damages

25.1 Except as provided under GCC Clause 17, if the Supplier fails to deliver any or all of the Pharmaceuticals or perform the Related Services within the period specified in the Contract, the Public Body may without prejudice to all its other remedies under the Contract, deduct from the Contract Price, as liquidated damages the following:

(a). A penalty of 0.1% or 1/1000 of the value of undelivered item for each day of delay until actual delivery or performance,

(b). The cumulative penalty to be paid by the supplier shall not exceed 10% of the contract price.

25.2 If the delay in performing the contract affects its activities, the Public Body may terminate the contract by giving advance notice to the Supplier pursuant to GCC Clause 20 without any obligation to wait until the penalty reaches 10% of the value of the Contract.

26. Confidentiality

26.1 The Public Body and the Supplier shall keep confidential and shall not disclose 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 if their disclosure would be contrary to law, would impede law enforcement, would not be in public interest, would prejudice legitimate commercial interest of the parties or would inhibit fair competition.. Notwithstanding the above, the Supplier may furnish to its Subcontractor such documents, data, and other information it receives from the Public Body 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 this Clause.

26.2 The Public Body 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 Public Body for any purpose other than supply of the Pharmaceuticals and Related Services required for the performance of the Contract.

26.3 The obligation of a party under this Clause, however, shall not apply to any Confidential Information that:

(a). The Public Body or Supplier need to share with any other institutions participating in the financing of the Contract;

(b). Now or hereafter enters the public domain other than by breach of the Contract or other act or omissions of that Party;

(c). Is obtained by a third party who is lawfully authorized to disclose such information;

(d). 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

(e). Is authorized for release by the prior written consent of the other party.

26.4 The Parties shall not be prevented from using any general knowledge, experience or skills which were in their possession prior to the commencement of the Contract;

26.5 The Supplier authorizes the Public Body to disclose the Confidential Information to such person(s) as may be notified to the Supplier in writing by the Public Body from time to time to the extent only as is necessary for the purposes of auditing and collating information so as to ascertain a realistic market price for the Pharmaceuticals supplied in accordance with the Contract, such exercise being commonly referred to as "benchmarking". The Public Body shall use all reasonable endeavors to ensure that such person(s) keeps the Confidential Information confidential and does not make use of the Confidential Information except for the purpose for which the disclosure is made. The Public Body shall not without good reason claim that the lowest price available in the market is the realistic market price.

26.6 The Supplier agrees that:

(a). Subject to Sub-Clause 26.6 (b), the decision on whether any exemption applies to a request for disclosure of recorded information is a decision solely for the Public Body;

(b). Where the Public Body is managing a request as referred to in Sub-Clause 26.6 (a), the

Supplier shall co-operate with the Public Body making the request and shall respond within five (5) working days of any request by it for assistance in determining how to respond to a request for disclosure.

26.7 The Supplier shall procure that its Subcontractors shall provide the Public Body with a copy of all information in its possession or power in the form that the Public Body requires within five (5) working days (or such other period as the Public Body may specify) of the Public Body requesting that Information.

26.8 The Public Body may consult the Supplier in relation to any request for disclosure of the Supplier's Confidential Information in accordance with all applicable guidance.

26.9 The above provisions of this Clause shall not in any way modify any undertaking of confidentiality given by either of the parties hereto prior to the date of the Contract.

26.10 This Clause 26 shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data. Except as aforesaid and unless otherwise expressly set out in the Contract, this Clause 26 shall remain in force for a period of 3 years after the termination or expiry of this Contract.

26.11 In the event that the Supplier fails to comply with this Clause 26, the Public Body reserves the right to terminate the Contract by notice in writing with immediate effect.

27. Copyright

27.1 The copyright in all drawings, documents, and other materials containing data and information furnished to the Public Body by the Supplier herein shall remain vested in the Supplier, or, if they are furnished to the Public Body directly or through the Supplier by any third party, including suppliers of materials, the copyright in such materials shall remain vested in such third party, unless otherwise specified in the SCC.

28. Miscellaneous

28.1 Any decision, act or thing that the Public Body is required or authorized to take or do under the Contract may be taken or done by any person authorized, either generally or specifically, by the Public Body to take or do that decision, act or thing, provided that upon receipt of a written request the Public Body shall inform the Supplier of the name of any person so authorized.

28.2 The Supplier may from time to time upon the request of the Public Body, execute any additional documents and do any other acts or things which may reasonably be required to implement the provisions of the Contract.

28.3 Any provision of the Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions hereof and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

28.4 The failure by the Public Body and Supplier to insist upon the strict performance of any provision, term or condition of the Contract or to exercise any right or remedy consequent upon the breach thereof shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

28.5 Each Party shall bear its own expenses in relation to the preparation, execution and implementation of the Contract including all costs legal fees and other expenses so incurred.

28.6 The Supplier warrants represents and undertakes to the Public Body that there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier and that there are no material contracts existing to which the Supplier is a party which prevent it from entering into the Contract; and that the Supplier has satisfied itself as to the nature and extent of the risks assumed by it under the Contract and gathered all information necessary to perform its obligations under the Contract and all other obligations assumed by it.

28.7 The rights and remedies provided in the Contract are cumulative and not exclusive of any rights or remedies provided by any other contract or document. In this provision "right" includes any power, privilege, remedy, or proprietary or security interest.

C. Obligations of the Public Body

29. Provision of Assistance

29.1 Unless otherwise indicated in SCC, whenever the supply of Pharmaceuticals and Related Services requires that the Supplier obtain permits, approvals, and import and other licenses from local public authorities, the Public Body shall, if so required by the Supplier, make its best effort to assist the Supplier in complying with such requirements in a timely and expeditious manner.

29.2 The Public Body shall pay all costs involved in the performance of its responsibilities, in accordance with GCC Sub-Clause 29.1.

D. Payment

30. Contract Price

30.1 Prices charged by the Supplier for the Pharmaceuticals delivered and the Related Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid.

30.2 The Contract Price shall be net i.e. after the deduction of all agreed discounts. In the absence of written agreement by the Parties to the contrary, the Contract Price shall include the cost of packaging, packing materials, addressing, labeling, loading and delivery to the Location, and all appropriate tax and duty.

30.3 Except as provided in GCC Sub-Clause 15.1, the Contract price may only be increased above amounts stated in GCC Sub-Clause 30.1 if the Parties have agreed to additional payments in accordance with GCC Clause 14.

31. Price Adjustments

31.1 Contracts Prices shall be fixed throughout the Supplier's performance of the Contract and not subject to adjustment on any account.

31.2 This provision remains in effect for the duration of the contract once it becomes effective.

31.3 Any discount offered by the Supplier under this Contract cannot be reduced during the Term of this Contract without the agreement in writing of the Public Body.

32. Mode of Billing and Terms of Payment

32.1 In consideration of the Supplier's due and proper performance of its obligations under the Contract, the Supplier may charge the Public Body the Contract Price in accordance with this

Clause.

32.2 The payment shall be effected based on the payment term indicated in SCC

32.3 The Supplier's request for payment shall be made to the Public Body or represented banks in writing, accompanied by shipping documents. Shipping documents shall be rendered by the Supplier before delivery of all pharmaceuticals which are the subject of the Purchase Order unless otherwise agreed in writing. Where the Parties agree delivery by installments, the Supplier may render an invoice for each proposed installment.

32.4 An invoice is correctly rendered if:

(a). The invoice is addressed to the Public Body's officer specified in the Purchase Order to receive invoices and identifies the number of relevant Purchase Order and Contract;

(b). The invoice includes date of issuance and its serial number;

(c). The amount claimed in the invoice is due for payment;

(d). The amount specified in the invoice is correctly calculated in accordance with the Contract;

(e). The invoice is set out in a manner that enables the Public Body to ascertain which Pharmaceuticals or Service the invoice covers (description, quantity, and unit of measure) and the respective Price, or Charge payable in respect of that Pharmaceuticals or Service;

(f). The invoice is accompanied by the relevant Certificate of Acceptance signed by the Public Body's official representative certifying that the amount specified in the invoice is in accordance with the Contract and delivered Pharmaceuticals or Services meet all Purchase Order and acceptance criteria requirements;

(g). The invoice includes the name and address of Supplier to whom payment is to be sent;

(h). The invoice includes the name, title, and phone number of person to notify in the event of defective invoice;

(i). The invoice includes Supplier's bank account information, and

(j). The invoice is, where appropriate, certified as sales tax exempt.

Failure to provide such information will entitle the Public Body to delay payment of the Contract Price until such information is provided.

32.5 The Public Body or Representative bank shall pay the Contract Price to the Supplier, up on receipt of complete shipping documents within the period specified in the SCC and upon receipt of the Pharmaceuticals and valid invoice (rendered in accordance with Sub-Clause 32.3.

32.6 All payment to the Supplier under this Contract shall be made in currency specified in the SCC.

32.7 The invoice provided to the Public Body by the Supplier in accordance with this Clause shall show appropriate taxes separately. (Not Applicable for foreign contracts).

32.8 The Public Body shall not be responsible for the payment of any charges for Pharmaceuticals supplied in excess of the Pharmaceuticals required by the Purchase Order or any variation of it unless authorized in writing by a further Purchase Order.

32.9 No payment of or on account of the Contract Price shall constitute any admission by the Public Body as to proper performance by the Supplier of its obligations.

32.10 If the Supplier is local manufacturer and requests an advance payment the advance may be paid by the Public Body in an amount not exceeding 30% of the total contract price.

32.11 As a prerequisite for such advance payment supplier shall submit advance payment security in an amount equal to the advance payment it receives in the form of a certified cheque or unconditional bank guarantee at its option from a reputable bank, together with its request for advance payment

as per the contract.

32.12 Should the advance payment security cease to be valid and the Supplier fails to re-validate it, a deduction equal to the amount of the advance payment may be made by the Public Body from future payments due to the Supplier under the Contract.

32.13 If a Contract is terminated for any reason, the guarantee securing the advance payment may be invoked in order to recover the balance of the advance payment still owed by the Supplier.

33. Forms

33.1 Unless otherwise agreed in writing by the Public Body and the Supplier:

(a). a delivery note shall accompany each delivery of the Pharmaceuticals;

(b). an invoice shall be rendered on the Supplier's own invoice form;

(c). all delivery notes and invoices shall be clearly marked with the Public Body's purchase order number, the name and address of the Public Body and the description and quantity of the Pharmaceuticals, and shall show separately any additional charge for containers and/or any other item not included in the Contract Price or, where no charge is made, whether the containers are required to be returned.

33.2 Sub-Clause 33.1 shall be compatible in all respects with the Contract.

33.3 With the prior written agreement of the Parties, the arrangements set out in Sub-Clause 33.1 may be suspended in favor of alternative arrangements (including new logistics processes).

E. Obligations of the Supplier

34. Supplier's Responsibilities

34.1 The Supplier shall supply all the Pharmaceuticals and Related Services included in the Scope of Supply in accordance with GCC Clause 49, and the Delivery and Completion Schedule, as per GCC Clause 51.

35. Joint Venture, Consortium or Association

35.1 If the Supplier is a joint venture, consortium, or association, all of the parties shall be jointly and severally liable to the Public Body 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 Public Body.

36. Eligibility

36.1 All Pharmaceuticals and Services supplied under the Contract shall have their origin in an eligible country pursuant to Section 5.

36.2 For purposes of this Clause, "origin" means the place where the Pharmaceuticals were mined, grown, or produced, or from which the Services are supplied. Pharmaceuticals are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

36.3 The origin of Pharmaceuticals and Services is distinct from the nationality of the Supplier.

36.4 If Pharmaceuticals are with multiple component and different country of origin, the country of origin shall be mentioned for each component.

37. Code of Conduct

37.1 The Supplier shall, at all times, act loyally and impartially and as a faithful adviser to the Public Body in accordance with the rules and/or code of conduct of its profession as well as with appropriate discretion. The Supplier shall, in particular, at all times refrain from making any public statements concerning the Pharmaceuticals and Related Services without the prior approval of the Public Body, and from engaging in any activity which conflicts with its obligations towards the Public Body under the contract. It shall not commit the Public Body without its prior written consent, and shall, where appropriate, make this obligation clear to third parties.

37.2 If the Supplier or any of its Subcontractors, personnel, agents or servants offers to give or agrees to offer or to give or gives to any person, any bribe, gift, gratuity or commission as an inducement or reward for doing or forbearing to do any act in relation to the contract or any other contract with the Public Body, or for showing favor or disfavor to any person in relation to the contract or any other contract with the Public Body, then the Public Body may terminate the contract, without prejudice to any accrued rights of the Supplier under the contract.

37.3 The payments to the Supplier under the contract shall constitute the only income or benefit it may derive in connection with the contract and neither it nor its personnel shall accept any commission, discount, allowance, indirect payment or other consideration in connection with, or in relation to, or in discharge of, its obligations under the contract.

37.4 The Supplier shall not have the benefit, whether directly or indirectly, of any royalty, gratuity or commission in respect of any patented or protected article or process used in or for the purposes of the contract or the project, without the prior written approval of the Public Body.

37.5 The Supplier and its staff shall maintain professional secrecy, for the duration of the contract and after completion thereof. In this connection, except with the prior written consent of the Public Body, neither the Supplier nor the personnel employed or engaged by it shall at any time communicate to any person or entity any confidential information disclosed to them or discovered by them, or make public any information as to the recommendations formulated in the course of or as a result of the services. Furthermore, they shall not make any use prejudicial to the Public Body, of information supplied to them and of the results of studies, tests and research carried out in the course and for the purpose of performing the contract.

37.6 The execution of the contract shall not give rise to unusual commercial expenses. If such unusual commercial expenses emerge, the contract will be terminated. Unusual commercial expenses are commissions not mentioned in the contract or not stemming from a properly concluded contract referring to the contract, commissions not paid in return for any actual and legitimate service, commissions remitted to a tax haven, commissions paid to a recipient who is not clearly identified or commission paid to a company which has every appearance of being a front company.

37.7 The Supplier shall supply to the Public Body on request supporting evidence regarding the conditions in which the contract is being executed. The Public Body may carry out whatever documentary or on-the spot checks it deems necessary to find evidence in case of suspected unusual commercial expenses.

38. Conflict of Interests

38.1 The Supplier shall take all necessary measures to prevent or end any situation that could compromise the impartial and objective performance of the Contract. Such conflict of interests could arise in particular as a result of economic interest, family or emotional ties, or any other relevant connection or shared interest. Any conflict of interests, which could arise during performance of the Contract, must be notified in writing to the Public Body without delay.

38.2 The Public Body reserves the right to verify that such measures are adequate and may require additional measures to be taken if necessary. The Supplier shall ensure that its staff, including its management, is not placed in a situation, which could give rise to conflict of interests. Without prejudice to Clause 24, the Supplier shall replace, immediately and without compensation from the Public Body, any member of its staff exposed to such a situation.

38.3 The Supplier shall refrain from any contact, which would compromise its independence or that of its personnel. If the Supplier fails to maintain such independence, the Public Body may, without prejudice to compensation for any damage, which it may have suffered on this account, terminate the contract forthwith, without giving formal notice thereof.

38.4 The Supplier shall, after the conclusion or termination of the contract, limit its role in connection to the provision of the Pharmaceuticals and Related Services. Except with the written permission of the Public Body, the Supplier and any other supplier with whom the Supplier is associated or affiliated shall be disqualified from the execution of works, Pharmaceuticals or other services for the Public Body in any capacity.

39. Patent Indemnity

39.1 The Supplier shall, subject to the Public Body's compliance with GCC Sub-Clause 39.2, indemnify and hold harmless the Public Body 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 Public Body 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:

(a). The use of the Pharmaceuticals in the Federal Democratic Republic of Ethiopia; and

(b). The sale in any country of the Pharmaceuticals manufactured by the Supplier.

Such indemnity shall not cover any use of the Pharmaceuticals 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 Pharmaceuticals 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.

39.2 If any proceedings are brought or any claim is made against the Public Body arising out of the matters referred to in GCC Sub-Clause 39.1, the Public Body shall promptly give the Supplier a notice thereof, and the Supplier may at its own expense and in the Public Body's name conduct such proceedings or claim and any negotiations for the settlement of any such proceedings or claim.

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

39.4 The Public Body 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.

39.5 The Public Body 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 Public Body.

40. Limitation of Liability

40.1 Except in cases of criminal negligence or wilful misconduct,

(a). The Supplier shall not be liable to the Public Body, 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 Public Body and

(b). The aggregate liability of the Supplier to the Public Body, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price as stated in the SCC, 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 Public Body with respect to patent infringement.

41. Intellectual Property

41.1 Subject to Clause 40, the Supplier agrees to indemnify and keep indemnified the Public Body against any costs, claims, proceedings, expenses and demands arising from the use, application, supply or delivery of any process, article, matter or thing supplied under the Contract that would constitute or is alleged to constitute any infringement of any person's Intellectual Property Rights.

42. Insurance

42.1 Unless otherwise specified in the SCC, the Pharmaceuticals supplied under the Contract shall be fully insured, in a freely convertible currency, against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery, in accordance with the applicable Incoterms.

43. Product Information

43.1 The Supplier shall provide the Public Body the Product Information in such manner and upon such media as agreed between the Supplier and the Public Body from time to time for the sole use by the Public Body.

43.2 The Supplier warrants that the Product Information is complete and accurate as at the date upon which it is delivered to the Public Body and that the Product Information does not contain any data or statement which gives rise to any liability on the part of the Public Body following publication of the same in accordance with this Clause.

43.3 In the event the Product Information ceases to be complete and accurate, the Supplier shall promptly notify the Public Body in writing of any modification or addition to or any inaccuracy or

omission in the Product Information.

43.4 The Supplier grants the Public Body a non-exclusive royalty free license in perpetuity to use and exploit the Product Information and any Intellectual Property therein for the purpose of illustrating the range of Pharmaceuticals and services (including, without limitation, the Pharmaceuticals) available pursuant to the Public Body contracts from time to time. No right to illustrate or advertise the Product Information is granted to the Supplier by the Public Body as a consequence of the license conferred by this Sub-Clause or otherwise under the terms of this Contract.

43.5 The Public Body may reproduce for its sole use the Product Information provided by the Supplier in the Public Body's catalogue from time to time which shall be made available on the Federal Government of Ethiopia internal communications network in electronic format or made available on the Public Body's external website or any other electronic media of the Public Body from time to time.

43.6 Before any publication of the Product Information (electronic or otherwise) is made by the Public Body, the Public Body will submit a copy of the relevant sections of the Public Body's catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Public Body to exhibit the Product Information in any service catalogue as a result of the approval given by it pursuant to this Sub-Clause or otherwise under the terms of this Contract.

43.7 Subject to Clauses 40 and 43.8, the Supplier agrees to indemnify and keep indemnified the Public Body against any liability, loss, costs, expenses, claims or proceedings whatsoever arising out of or in connection with any statement relating to the Pharmaceuticals and services (including, without limitation, the Pharmaceuticals) or information or material on or description of the Pharmaceuticals and services (including, without limitation, the Pharmaceuticals) provided by or on behalf of the Supplier which is included in the Public Body's catalogue or any associated material produced by the Public Body for the purpose of illustrating the range of Pharmaceuticals and services (including, without limitation, the Pharmaceuticals) available pursuant to the Public Body contracts from time to time.

43.8 The Supplier shall not be required to indemnify or keep indemnified the Public Body against any liability, loss, costs, expenses, claims or proceedings whatsoever arising under Sub-Clause 43.7 as a result of the Public Body's willful or negligent misrepresentation of any statement relating to the Pharmaceuticals and services (including, without limitation, the Pharmaceuticals) or information or material on or description of the Pharmaceuticals and services (including, without limitation, the Services) provided by or on behalf of the Supplier which is included in the Public Body's catalogue from time to time or any associated material produced by the Public Body for the purpose of illustrating the range of Pharmaceuticals and services (including, without limitation, the Pharmaceuticals) available pursuant to the Public Body contracts from time to time.

44. Accounting, Inspection and Auditing

44.1 The Supplier shall keep accurate and systematic accounts and records in respect of the Pharmaceuticals and Related Services hereunder, in accordance with internationally accepted accounting principles and in such form and detail as will clearly identify all relevant time charges and costs.

44.2 For the purpose of the examination and certification of the Public Body's accounts; or any examination of the economy, efficiency and effectiveness with which the Public Body has used its resources, the Federal Auditor General and the Public Procurement and Property Administration Agency or its auditors may examine such documents as he may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to

produce such oral or written explanation as he considers necessary. The Supplier acknowledges that it will fully cooperate with any counter fraud policy or investigation carried out by authorized body at any time.

45. Data Protection

45.1 The Supplier shall comply with all applicable data protection legislation. In particular the Supplier agrees:

(a). To maintain appropriate technical and organizational security measures;

(b). To only process Personal Data for and on behalf of the Public Body, in accordance with the instructions of the Public Body and for the purpose of performing its obligations under the Contract;

(c). To allow the Public Body to audit the Supplier's compliance with the requirements of this Clause on reasonable notice and/or to provide the Public Body with evidence of its compliance with the obligations set out in this Clause.

45.2 The Supplier agrees to indemnify and keep indemnified the Public Body against all claims and proceedings and all liability, loss, costs and expenses incurred in connection therewith by the Public Body as a result of any claim made or brought by any individual or other legal person in respect of any loss, damage or distress caused to that individual or other legal person as a result of the Supplier's unauthorized processing, unlawful processing, destruction of and/or damage to any Personal Data processed by the Supplier, its employees or agents in the Supplier's performance of the Contract or as otherwise agreed between the Parties.

46. Review

46.1 The Supplier shall attend formal review meetings (each such meeting being a "Review"), as required by the Authorized Officer, to discuss the Public Body's levels of satisfaction in respect of the Pharmaceuticals and Related Services supplied under the Contract and to agree any necessary action to address areas of dissatisfaction. The Supplier will not obstruct or withhold its agreement to any such necessary action. Such Reviews shall be attended by duly authorized and sufficiently senior employees of both the Public Body and the Supplier together with any other relevant attendees. The Parties shall agree a standing agenda for such Reviews.

47. Performance Security

47.1 The Supplier shall, within fifteen (15) days from signing the contract, provide a Performance Security for the due performance of the Contract in the amount specified in the SCC.

47.2 The proceeds of the Performance Security shall be payable to the Public Body as compensation for any loss resulting from the Supplier’s failure to complete its obligations under the Contract.

47.3 The Performance Security shall be denominated in currency specified in the SCC, and shall be in the form of cash, cheque certified by a reputable bank, letter of credit, or Bank Guarantee in the format specified in the SCC.

47.4 The Performance Security shall be discharged by the Public Body 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.

47.5 Notwithstanding the provision of Sub-Clause 47.2 above, the Performance Security may be

returned to the Supplier where the Procurement Endorsing Committee ascertains that the noncompliance of the Supplier does not affect the interest of, or entail additional cost on the Public Body and is not due to the fault of the Supplier.

47.6 The Public Body shall be required to submit any document in its possession in relation to a procurement in which it authorizes the return of the Performance Security to the Supplier and account for its action under the preceding Sub-Clause 47.5 of this GCC to the Public Procurement and Property Administration Agency or other competent body if and when required to do so.

F. Performance of the Contract

48. Scope of Supply

48.1 Subject to the SCC, the Pharmaceuticals and Related Services to be supplied shall be as specified in the Section 6, Statement of Requirements.

48.2 Unless otherwise stipulated in the Contract, the Supply shall include all such items not specifically mentioned in the Contract but that can be reasonably inferred from the Contract as being required for attaining Delivery and Completion of the Pharmaceuticals and Related Services as if such items were expressly mentioned in the Contract.

49. Specifications and Standards

49.1 Technical Specifications and Drawings

(a). The Supplier shall ensure that the Pharmaceuticals and Related Services comply with technical specifications and other provisions of the Contract.

(b). The Supplier shall be entitled to disclaim responsibility for any design, data, drawing, specification or other document, or any modification thereof provided or designed by or on behalf of the Public Body, by giving a notice of such disclaimer to the Public Body.

(c). The Pharmaceuticals and Related Services supplied under this Contract shall conform to the standards mentioned in the Statement of Requirements and, when no applicable standard is mentioned, the standard shall be equivalent or superior to the official standards whose application is appropriate to the Pharmaceuticals' country of origin.

49.2 Wherever references are made in the Contract to codes and standards in accordance with which it shall be executed, the edition or the revised version of such codes and standards shall be those specified in the Statement of Requirements. During Contract execution, any changes in any such codes and standards shall be applied only after approval by the Public Body and shall be treated in accordance with GCC Clause 14.

50. Delivery

50.1 The Supplier shall deliver the Pharmaceuticals to the Location and in accordance with any delivery instructions in the SCC, Purchase Order or as agreed by the Parties in writing.

50.2 Delivery shall be completed when the Pharmaceuticals have been unloaded at the Location and such delivery has been accepted by a duly authorized agent, employee or Location representative of the Public Body. The Public Body shall procure that such duly authorized agent, employee or Location representative of the Public Body is at the delivery location in order to accept such delivery.

50.3 In the event that the Public Body require next day or short notice deliveries which are not provided for in the SCC Clause 50.1, the Supplier may pass on any additional costs relating to the

delivery of the Pharmaceuticals to the Public Body placing the Purchase Order.

50.4 Early or partial deliveries require the explicit written consent of the Public Body, which consent shall not be unreasonably withheld.

50.5 Unless otherwise stated in the SCC, the Supplier is responsible for obtaining all export and import licenses for the Pharmaceuticals and shall be responsible for any delays due to such licenses not being available when required.

50.6 In the case of any Pharmaceuticals supplied from outside the Federal Democratic Republic of Ethiopia, the Supplier shall ensure that accurate information is provided to the Public Body as to the country of origin of the Pharmaceuticals and shall be liable to the Public Body for any additional duties or taxes for which the Public Body may be accountable should the country of origin prove to be different from that advised by the Supplier.

50.7 Where the Public Body agrees in writing to accept delivery by installments the Contract will be construed as a single contract in respect of each installment. Failure by the Supplier to deliver any one installment may allow the Public Body at its option to treat the whole Contract as repudiated depending upon the circumstances of the non-delivery, such option not to be unreasonably invoked.

50.8 Any arrangement to deliver the Pharmaceuticals where carriage is to be charged separately or any arrangement by which the Pharmaceuticals are collected by the Public Body in return for a discount on the Contract Price shall be recorded in writing and signed by a duly authorized signatory on behalf of the Public Body. Where due to an emergency such arrangements cannot be committed to writing and signed off as aforesaid the Parties shall confirm such arrangements in writing as soon as possible thereafter.

50.9 The details of shipping and other documents to be furnished by the Supplier are specified in the SCC.

51. Packing, Marking, and Documents

51.1 The Supplier shall provide such packing of the Pharmaceuticals as is required to prevent their damage or deterioration during shipment to their final destination, as indicated in the Contract. During shipment, 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 Pharmaceuticals' final destination and the absence of heavy handling facilities at all points in transit.

51.2 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 or Technical Specifications, and in any subsequent instructions ordered by the Public Body.

52. Identification of Pharmaceuticals

52.1 All Pharmaceuticals that customarily bear any mark, tab, brand, label or other device indicating place of origin, inspection by any government or other body or standard of quality must be delivered with all the said marks, tabs, brands, labels, serial numbers or other devices intact.

53. Containers and Pallets

53.1 The Supplier shall collect without charge any returnable containers (including pallets) within 21 days of the date of the relevant delivery note unless otherwise instructed by the Public Body. Empty containers not so removed may be returned by the Public Body at the Supplier's expense or otherwise disposed of at the Public Body's discretion. The Supplier shall credit in full any charged containers upon collection or return.

54. Property and Risk

54.1 Notwithstanding delivery, ownership of the Pharmaceuticals shall not have passed from the Supplier until the full Contract Price of such Pharmaceuticals has been paid.

54.2 All tools, equipment and materials of the Supplier required in the performance of the Supplier's obligations under the Contract shall be and remain at the sole risk of the Supplier whether or not they are situated at the Location.

55. Tools etc.

55.1 Any tools, patterns, materials, drawings, specifications and/or other data provided by the Public Body to the Supplier in connection with the Purchase Order will at all times be at the Supplier's risk and remain the property of the Public Body and shall be delivered up to the Public Body immediately on request and are to be used by the Supplier solely for the purpose of completing the Purchase Order.

55.2 Any tools which the Supplier may construct or acquire specifically in connection with the Pharmaceuticals will remain the property of the Supplier unless it is agreed in writing that the property of the tools will be transferred to the Public Body upon payment by the Public Body of a charge.

56. Quality

56.1 The Pharmaceuticals shall be new, and shall be supplied strictly in accordance with the Specification and/or any sample previously provided to the Public Body and, unless otherwise agreed in writing, shall conform to all relevant standards, specifications and conditions and all work performed by the Supplier shall be in accordance with best practice. For the avoidance of doubt, the Supplier warrants that the Pharmaceuticals a re not scrap Pharmaceuticals.

56.2 The Supplier warrants its expertise and confirms the accuracy of all statements and representations made in respect of the Pharmaceuticals prior to and subsequent to, the Purchase Order.

56.3 The Supplier agrees to assign to the Public Body upon request the benefit of any warranty, guarantee or similar right which it has against any third party manufacturer or supplier of the Pharmaceuticals or any part thereof.

57. Inspections and Tests

57.1 The Supplier shall carry out at its own expense and at no cost to the Public Body all such tests and/or inspections of the Pharmaceuticals and Related Services as are specified in the SCC or in the Statement of Requirements.

57.2 The inspections and tests may be conducted on the premises of the Supplier or its Subcontractor, at point of delivery, and/or at the Pharmaceuticals' final destination, or in another place in the Federal Democratic Republic of Ethiopia as specified in the SCC. Subject to GCC Sub-Clause 57.3, if conducted on the premises of the Supplier or its Subcontractor, all reasonable facilities and assistance, including access to drawings and production data, shall be furnished to the inspectors at no charge to the Public Body.

57.3 The Public Body or its designated representative shall be entitled to attend the tests and/or inspections referred to in GCC Sub-Clause 57.2, provided that the Public Body bear all of its own costs and expenses incurred in connection with such attendance including, but not limited to, all travelling and board and lodging expenses.

57.4 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 Public Body. The Supplier shall obtain from any relevant third party or manufacturer any necessary permission or consent to enable the Public Body or its designated representative to attend the test and/or inspection.

57.5 The Public Body 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 Pharmaceuticals comply with the technical specifications codes and standards under the Contract, provided that the Supplier's reasonable costs and expenses incurred in the carrying out of such test and/or inspection shall be added to the Contract Price. Further, if such test and/or inspection impede 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.

57.6 The Supplier shall provide the Public Body with a report of the results of any such test and/or inspection.

57.7 The Public Body may reject any Pharmaceuticals 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 Pharmaceuticals or parts thereof or make alterations necessary to meet the specifications at no cost to the Public Body, and shall repeat the test and/or inspection, at no cost to the Public Body, upon giving a notice pursuant to GCC Sub-Clause 57.4.

57.8 The Supplier agrees that neither the execution of a test and/or inspection of the Pharmaceuticals or any part thereof, nor the attendance by the Public Body or its representative, nor the issue of any report pursuant to GCC Sub-Clause 57.6, shall release the Supplier from any warranties or other obligations under the Contract.

58. Rejection of Pharmaceuticals

58.1 Without prejudice to the operation of Sub-Clause 58.4, the Pharmaceuticals shall be inspected by the Public Body or on behalf of it within a reasonable time after delivery under Clause 51 of the Contract and may be rejected if found to be defective or inferior in quality to or differing in form or material from the Statement of Requirements of the Contract, or if they do not comply with any term, whether expressed or implied, of the Contract.

58.2 Without prejudice to the operation of Sub-Clause 58.4, the Public Body shall notify the Supplier of:

(a). The discovery of any defect within a reasonable time of its discovery and shall give the

Supplier all reasonable opportunities to investigate such defect; and

(b). Any shortage or damage caused in transit and found on delivery within 14 days of delivery or such time as agreed by the Parties.

58.3 The whole of any delivery may be rejected if a reasonable sample of the Pharmaceuticals taken indiscriminately from that delivery is found not to conform in every material respect to the Statement of Requirements of the Contract.

58.4 The Public Body's right of rejection shall continue irrespective of whether the Public Body has in law accepted the Pharmaceuticals. In particular, taking delivery, inspection, use or payment by the Public Body of the Pharmaceuticals or part of them shall not constitute acceptance, waiver or approval and shall be without prejudice to any right or remedy that the Public Body may have against the Supplier provided that the right of rejection shall cease within a reasonable time from the date on which the Public Body discovers or might reasonably be expected to discover the latent defect or other relevant breach of contract.

58.5 Pharmaceuticals so rejected after delivery shall be removed by the Supplier at its own expense within fourteen days from the date of notification of rejection. If the Supplier fails to remove them within such period the Public Body may return the rejected Pharmaceuticals at the Supplier's risk and expense and charge the Supplier for the cost of storage from the date of rejection.

59. Extensions of Time

59.1 If at any time during performance of the Contract, the Supplier or its subcontractors should encounter conditions impeding timely delivery of the Pharmaceuticals or completion of Related Services pursuant to GCC Clause 51, the Supplier shall promptly notify the Public Body in writing of the delay, its likely duration, and its cause. As soon as practicable after receipt of the Supplier's notice, the Public Body 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.

59.2 Except in case of Force Majeure, as provided under GCC Clause 17, 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 25, unless an extension of time is agreed upon, pursuant to GCC Sub-Clause 59.1 without application of liquidated damages.

60. Performance Measurement

60.1 The Public Body shall ascertain whether the Supplier's provision of the Pharmaceuticals in question meets any performance criteria as specified in the Statement of Requirements or, if the criteria are not so specified, meets the standards of a professional supplier of the Pharmaceuticals. On or before the fifteenth working day of each calendar month during the Contract Period and within 14 days after termination of the Contract, the Public Body may:

(a). Each Performance Notice issued by the Public Body shall include a proposed rebate of the Contract Price commensurate to the under-performance of the Supplier as recorded in the Performance Notice;

(b). If the Supplier disputes any matter referred to in any Performance Notice and/or the proposed rebate of the Contract Price, the Supplier may raise this objection with the Public Body and if this matter is not resolved within 7 days the matter shall be referred to the Dispute Resolution Procedure; and

(c). If the Supplier has not risen any objection to the Performance Notice within 7 days of receipt

(or such other period as agreed between the Parties) then that Performance Notice shall be deemed to have been accepted by the Supplier and the rebate on the Contract Price referred to therein shall become immediately effective.

60.2 The Public Body's rights under this Clause are without prejudice to any other rights or remedies the Public Body may be entitled to.

60.3 If required by the Public Body, the Parties shall co-operate in sharing information and developing performance measurement criteria with the object of improving the Parties' efficiency. Any such agreements shall be fully recorded in writing by the Public Body.

Section 8. Special Conditions of Contract

Table of Clauses

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

GCC Clause Reference	Section 8. Special Conditions of Contract
	A. General Provisions
	Procurement Reference Number is:
GCC 1.2 (u)	The Public Body is:
GCC 1.2 (z)	The Supplier is:
GCC 6.3 (a)	The meaning of the trade terms shall be as prescribed by .
GCC 6.3 (b)	The version of Incoterms shall be:
	B. The Contract
GCC 7.1 (j)	In addition to documents listed in GCC Clause 7.1 the following documents shall form the Contract: Purchase order, Letter of Credit (LC) or Bank approved PO (in case of CAD) accepted amendments, special import permit……..
GCC 7.2	The Public Body's authorized representative shall be: Authorized Representative: P.O. Box: Street Address: Town/City: Post Code: Country: Ethiopia Telephone: Facsimile: E-mail address The Supplier's authorized representative shall be: Authorized Representative: P.O. Box: Street Address: Town/City: Post Code: Country: Telephone: Facsimile: E-mail address

<table>
<tr><th>GCC Clause Reference</th><th>Section 8. Special Conditions of Contract</th></tr>
<tr><td>GCC 8.1</td><td>The governing law shall be .</td></tr>
<tr><td>GCC 10.2 and 10.3</td><td>For <u>notices</u>, the Public Body’s address shall be:
<table>
<tr><td>Public Body:</td><td></td></tr>
<tr><td>Attention:</td><td></td></tr>
<tr><td>Floor/Room number:</td><td></td></tr>
<tr><td>P.O. Box:</td><td></td></tr>
<tr><td>Street Address:</td><td></td></tr>
<tr><td>Town/City:</td><td></td></tr>
<tr><td>Post Code:</td><td></td></tr>
<tr><td>Country:</td><td>Ethiopia</td></tr>
<tr><td>Telephone:</td><td></td></tr>
<tr><td>Facsimile:</td><td></td></tr>
<tr><td>E-mail address</td><td></td></tr>
</table>
For <u>notices</u>, the Supplier’s address shall be:
<table>
<tr><td>Supplier:</td><td></td></tr>
<tr><td>Attention:</td><td></td></tr>
<tr><td>Floor/Room number:</td><td></td></tr>
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<tr><td>Facsimile:</td><td></td></tr>
<tr><td>E-mail address</td><td></td></tr>
</table></td></tr>
<tr><td>GCC 15.1</td><td>In case of change of laws and regulation after the deadline for submission of the Bid Contract Price be correspondingly increased or decreased and/or the Delivery Date be reasonably adjusted to the extent that Supplier has thereby been affected in the performance of any of its obligations under the Contract.</td></tr>
<tr><td>GCC 16.1</td><td>For Pharmaceuticals supplied from outside the Federal Democratic Republic of Ethiopia The Supplier shall be responsible for all taxes, custom duties, formalities, license fees except for the following:</td></tr>
<tr><td>GCC 16.2</td><td>For Pharmaceuticals supplied from within the Federal Democratic Republic of Ethiopia the Supplier shall be responsible for all taxes, formalities, license fees except for the following:</td></tr>
<tr><td>GCC 23.2</td><td>Shelf life of the pharmaceuticals should be……</td></tr>
<tr><td>GCC 23.2</td><td>For the procurement of vaccines the Public Body reserves the right to request evidence of bio-availability and/or bio-equivalence data and/or evidence of the</td></tr>
</table>

GCC Clause Reference	Section 8. Special Conditions of Contract
	basis for expiration dating and other stability data concerning the Pharmaceuticals to verify shelf life claimed for the Pharmaceuticals. If an adverse event following immunization (AEFI) occurs in the Federal Democratic Republic of Ethiopia and the cause of such event cannot be immediately established, the Public Body will, with all urgency and in accordance with the procedures laid down by the Ethiopian Medicine and Health Care Administration and Control Authority, take steps to advise the Supplier in order that an investigation may be launched immediately. If the vaccine has been supplied through an agency of the United Nations, the most current procedures laid down by the WHO for such situations will be used. (NA).
GCC 23.3	The period of validity of the Warranty shall be:
GCC 23.5	The replace period of defective Pharmaceuticals will be:
GCC 27.1	The copyright of all drawings, documents, and other materials containing data resides with: (NA)
	C. Obligations of the Public Body
GCC 29.1	The Public Body shall, if so required by the Supplier, assist the Supplier in complying with the following requirements: (NA)
	D. Payment
GCC 32.4	The Public Body shall pay the Contract Price to the Supplier, within the period of the .
GCC 32.5	For Pharmaceuticals and Services supplied locally all payment to the Supplier under this Contract shall be made in ETB. For Pharmaceuticals supplied from outside the Federal Democratic Republic of Ethiopia all payment to the Supplier under this Contract shall be made in .
	E. Obligations of the Supplier
GCC 40.1 (b)	The amount of aggregate liability shall be:
GCC 42.1	The insurance coverage shall be in accordance with the following Incoterms:
GCC 47.1	The amount of the Performance Security shall be:
GCC 47.3	The types of acceptable Performance Securities are: . The currency shall be: .
GCC 47.4	Discharge of the Performance Security shall take place:

GCC Clause Reference	Section 8. Special Conditions of Contract
	F. Performance of the Contract
GCC 48.1	The Scope of Supply shall be defined in:
GCC 50.1	The Supplier shall deliver the Pharmaceuticals to the following Locations: .
GCC 50.5	The Supplier responsible for obtaining all export and import licenses for the Pharmaceuticals
GCC 50.9	(a). The shipping and other documents to be furnished by the Supplier are: (i) Three Original and two copies of the Air Waybill or Bill of Lading (ii) Three original and two copies of chamberized commercial invoice (iii) Packing lists identifying contents of each package; (iv) Insurance certificates, showing the Public Body as the beneficiary; (v) Manufacturer's or Supplier's Warranty Certificate covering all items supplied; (vi) Supplier's original chamberized Certificate of Origin covering all items supplied; (vii) Certificate of Inspection furnished to Supplier by the nominated inspection agency (where inspection is required); (viii) Certificate of analysis (ix) Delivery note, signed by a representative of the Public Body; (x) Any other procurement-specific documents required for delivery / payment purposes. (b). For the procurement of pharmaceuticals: (i) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied; (ii) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Pharmaceuticals. (iii) Original copy of the certificate of weight issued by the licensed authority. (c). For the procurement of vaccines: (i) One copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped. (ii) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the

GCC Clause Reference	Section 8. Special Conditions of Contract
	Pharmaceuticals. (iii) Original copy of the certificate of weight issued by the licensed authority. (d). For the procurement of contraceptives: (i) Original copy of quality control tests for each consignment as stated in SCC Clause 57.1 below; (ii) Original copy of the certificate of inspection furnished to Supplier by nominated inspection agency (where separate inspection is required).
GCC 51.2	Requirements with respect to packing, marking, and documentation are the following : (i) ☐ Necessary requirements with respect to packing, marking, and documentation are the following: (ii) ☒ Requirements with respect to packing, marking, and documentation are indicated in the Technical Specification.
GCC 57.1	For the procurement of contraceptives the Supplier shall test batches of Pharmaceuticals ready for shipment in accordance with the WHO specification. The size of the sample for testing will be calculated by reference to ISO2859-1. With each consignment, the Supplier must provide a certificate of quality control test results in conformity with the standards laid down in ISO 2859-1 and in accordance with the general sampling levels appropriate to each feature as necessary. The Supplier will bear the cost of such tests .
GCC 57.2	Inspections and tests will be conducted at:

Section 9. Contract Forms

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A. Contract Agreement

for the Procurement of

Procurement Reference No:

This Contract Agreement is made on the day of the month of , **BETWEEN**

of the Federal Democratic Republic of Ethiopia, and having its principal place of business (hereinafter called the "Public Body"),

and

a corporation incorporated under the laws of and having its principal place of business at (hereinafter called the "Supplier"), of the other part

WHEREAS

(a). The Public Body invited bids for certain Pharmaceuticals and Related Services (hereinafter called the "Pharmaceuticals"), and has accepted a Bid by the Supplier for the supply of those Pharmaceuticals and Related Services in the sum of (hereinafter called "the Contract Price") in the manner and on the terms described herein

(b). The Supplier having represented to the Public Body that it has the required skills, personnel and technical resources, has agreed to provide the Pharmaceuticals on the terms and conditions set forth in this Contract;

NOW THEREFORE the parties hereto hereby agree as follows:

1. The Agreement

1.1 In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

1.2 The following documents shall constitute the Contract between the Public Body and the Supplier, and each shall be read and construed as an integral part of the Contract:

1. This Contract Agreement;
2. The Special Conditions of Contract;
3. The General Conditions of Contract;
4. The Bid Submission Sheet with Annexes;
5. Price Schedule;
6. List of accepted items including their unit price;
7. Bidder Certification of Compliance with Annexes;
8. Technical Specification + Technical Offer + Compliance Sheet with Annexes;
9.

1.3 This Contract shall prevail over all other Contract documents. In the event of any discrepancy or inconsistency within the Contract documents, then the documents shall prevail in the order listed above.

1.4 In consideration of the payments to be made by the Public Body to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Public Body to provide the Pharmaceuticals and Related Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

1.5 The Public Body hereby covenants to pay the Supplier in consideration of the provision of the Pharmaceuticals and Related 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.

2. Effective Date of Contract Agreement

2.1 The Contract Agreement shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the Ethiopian Medicine and Health Care Administration and Control Authority that the Pharmaceuticals have been registered for use in the Federal Democratic Republic of Ethiopia.

2.2 If thirty (30) days elapse from the date of Contract Agreement signing and the Contract has not become effective pursuant to Sub-Clause 1.6 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.

2.3 Under no circumstances may implementation commence before the date on which the Contract Agreement become effective.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be signed in their respective names as of the day and year first above written.

SIGNED for and on behalf of **Signature:** **Name:** **Position:** **Date:**	**WITNESS** to signature on behalf of **Signature:** **Name:** **Position:** **Date:**
SIGNED for and on behalf of **Signature:** **Name:** **Position:** **Date:**	**WITNESS** to signature on behalf of **Signature:** **Name:** **Position:** **Date:**

B. Performance Security
(Bank Guarantee)

Date:
Procurement Reference No:

To:

WHEREAS (hereinafter "the Supplier") has undertaken, pursuant to Contract No. dated , to supply (hereinafter "the Contract").

AND WHEREAS it has been stipulated by you in the aforementioned Contract that the Supplier shall furnish you with a security issued by a reputable guarantor for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.

AND WHEREAS the undersigned , legally domiciled in [insert complete address of Guarantor], (hereinafter the" Guarantor"), have agreed to give the Supplier a security:

THEREFORE WE hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract, without cavil or argument, any sum or sums within the limits of as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This security is valid until the day of , .

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No 458.

Name:
In the capacity of

Signed:

Duly authorized to sign the Security for and on behalf of:

Dated on [insert day] day of], 20

C. Advance Payment Security
(Bank Guarantee)

Date:
Procurement Reference No:

To:

In accordance with the payment provision included in the Contract, in relation to advance payments, (hereinafter called "the Supplier") shall deposit with the Public Body a security consisting of , to guarantee its proper and faithful performance of the obligations imposed by said Clause of the Contract, in the amount of .

We, the undersigned , legally domiciled in (hereinafter "the Guarantor"), as instructed by the Supplier, agree unconditionally and irrevocably to guarantee as primary obligor and not as surety merely, the payment to the Public Body on its first demand without whatsoever right of objection on our part and without its first claim to the Supplier, in the amount not exceeding .

This security shall remain valid and in full effect from the date of the advance payment received by the Supplier under the Contract until , [insert year].

Name:
In the capacity of

Signed:

Duly authorized to sign the Security for and on behalf of:

Dated on [insert day] day of], 20