



Open International Tender (OIT)

Government of Kenya,
Ministry of Health
Nairobi/Kenya

Tender Document

For

**Supply and Delivery of ARV Medicine
(Atazanavir 300mg/Ritonavir 100mg)**

TENDER No.

KEMSA/GOK – CPF / HIV 17/18 - OIT 001

November, 2017

INVITATION TO TENDER (ITT)

GOVERNMENT OF KENYA COUNTERPART FUNDING

1. The Government of Kenya has set aside funds being Counterpart Funding against the Global Fund Program in Kenya and it intends to use part of the funds for payments for contract (s) for the **Supply and Delivery of ARV Medicine - (Atazanavir 300mg/Ritonavir 100mg)**
2. The **Kenya Medical Supplies Authority (KEMSA)**, on behalf of the Government of Kenya, Ministry of Health herewith invites sealed tender (s) for: **Supply and Delivery of ARV Medicine - (Atazanavir 300mg/Ritonavir 100mg)**
3. This Tender will be conducted through the **Open International Tender (OIT)** procedure specified in the Government of Kenya (GOK), The Public Procurement and Asset Disposals Act, 2015 and the Global Fund's Policies on Procurement and Supply Management, June 2012.
4. Interested eligible bidders may obtain further information from KEMSA office and inspect the bidding documents at the address given below, **Mondays to Fridays between 0900hrs to 1600hrs** except on public Holidays or download at the **IFMIS Supplier portal** <http://supplier.treasury.go.ke> and <http://www.kemsa.co.ke/tenders/>. Documents downloaded are free of charge and bidders are advised to register their bid documents at the procurement office or via email at procurement.programs@kemsa.co.ke (**Refer to registration form in the tender document**).
5. A complete set of bidding documents in English (hardcopy) may be purchased by eligible bidders on the submission of a **written application** on company letterhead to the address below and upon payment of a non-refundable/non-transferable **fee of 13 US Dollars or 1,000 Kenya Shillings**. The method of payment will be by Cash, Bankers cheque or direct deposit to the specified **account no 01141217405100 for KES or 02120217405100 for USD to Co-operative Bank, Enterprise Road Branch, Nairobi, Kenya, and Swift: KCOOKENA**.
6. Completed **paginated and serialized** bidding documents **one original and a copy** in plain sealed envelopes clearly marked on top with the Tender Number and description must be accompanied by a tender security of **44,500.00 or KES 4,680,000.00** or equivalent in a freely convertible currency from commercial Banks or insurance Companies (*as approved by Public Procurement Regulatory Authority*) and must be delivered to the address below on or **before 10:00 AM on 29th November, 2017** and Tenders must be deposited at **KEMSA Tender Box 2 for Global Fund Tenders at KEMSA, Main Reception**. Bulky tenders can be handed over to KEMSA Procurement Director's Office for registration and safe keeping till the tender opening date. Tenders will be opened promptly in public and in the presence of the Tenderers' representatives who choose to attend.
7. Late bids, portion of bids, electronic bids, bids not received, bids not opened and not readout in public at bid opening ceremony shall not be accepted for evaluation irrespective of circumstances.

Address for information on/collection of the Tender Document and Tender Opening venue.

Kenya Medical Supplies Authority (KEMSA) 13 Commercial Street, Industrial Area
P. O. Box 47715-00100 Nairobi, Kenya; Tel: (+254) 20-392 20 00
E-mail: procurement.programs@kemsa.co.ke

Kenya Medical Supplies Authority reserves the right to accept or reject any or all bids without incurring liability to the affected tenderers.

REGISTRATION FORM FOR ONLINE TENDERES/BIDDERS/SUPPLIERS

**IFT No.: KEMSA/GOK – CPF/HIV 17/18 – OIT 001 Supply and Delivery of ARV Medicine -
(Atazanavir 300mg/Ritonavir 100mg)**

Please provide your details below for purposes of communication in case you download this tender document from IFMIS website/KEMSA website:

Name of the firm:.....

Postal Address:.....

Telephone Contacts:.....

Company email address:.....

Contact Person:.....

Once completed please submit this form to the email below:

procurement.programs@kemsaco.ke

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Section I. Instructions to Tenderers

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Instructions to Tenderers (ITT)

A. INTRODUCTION

- 1. Scope of Tender**
- 1.1 The Purchaser, as specified in the Tender Data Sheet (**TDS**) and in the Special Conditions of Contract (**SCC**), invites tenders for the supply of Health Sector Goods as specified in the **TDS** and described in the Schedule of Requirements. The name and identification number of the Contract is provided in the **TDS** and in the **SCC**.
- 1.2 Throughout these tender documents, the terms “in writing” means communicated in written form (e.g. by mail, e-mail fax or telex) with proof of receipt and “day” means calendar day. Singular also means plural.
- 2. Source of Funds**
- 2.1 The Beneficiary named in the **TDS** has received funding as identified in the **TDS** to the amount indicated in the **TDS** toward the cost of the project named in the **TDS**. The Purchaser intends to apply a part of the proceeds of this fund to eligible payments for which these tender documents are issued.
- 3. Fraud and Corruption**
- 3.1 It is the Purchaser’s policy to require that beneficiaries, as well as Tenderers/Suppliers/Contractors under the Purchaser’s financed contracts, observe the highest standard of ethics during the procurement and execution of such. In pursuance of this policy, the Government of Kenya defines, for the purposes of this provision, the terms set forth below as follows:
- (a) (i) “corrupt practice” means the offering, giving, receiving, or soliciting of anything or any advantage of value to influence the action of a public official in the procurement process or in execution; and
- (a) (ii) “fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a tender to the detriment of the Beneficiary it includes collusive practices among Tenderers (prior to or after tender submission) designed to establish tender prices at artificial, noncompetitive levels and to deprive the Beneficiary of the benefits of free and open competition
- and that it
- (b) Will not accept a Purchaser’s proposal for award if it determines that the Tenderer recommended for award has engaged in corrupt or fraudulent practices in competing for the tender in question.
- (c) will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Purchaser’s financed contract if it at any time determines that the

firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Purchaser's financed contract.

3.2 Furthermore, Tenderers shall be aware of the provision stated in sub-clause 23.1 (d) of the GCC.

3.3 In pursuance of the policy defined in ITT sub-clause 3.1, the Purchaser will cancel the portion of the fund allocated to a contract for Goods or Works if he at any time determines that corrupt or fraudulent practices were engaged in by the representatives of the Beneficiary of the funds during the procurement or the execution of that contract, without the Beneficiary having taken timely and appropriate action satisfactory to the Purchaser to remedy the situation.

4. Eligibility

4.1 Except as provided in ITT sub-clauses 4.2 and 4.3, this tender process is open to:

- (a) those prequalified firms where a pre-qualification process has been undertaken for the contract(s) for which these tender documents have been issued or:
- (b) all candidates as defined in the Public Procurement and Disposals Act 2005 and Public Procurement Regulations 2006 (Public Procurement Act)

4.2 Firms may be excluded from tendering if:

- (a) either, as a matter of law or official regulation, the Beneficiary's country prohibits commercial relations with that country, provided that the Purchaser is satisfied that such exclusion does not preclude effective competition for the supply of the goods required;
- (b) a firm has been engaged by
 - i) the Beneficiary or
 - ii) the Purchaser or
 - iii) A Purchasing Agent that has been duly authorized to act on behalf of the Purchaser to provide consulting services for the preparation of the design, specifications and other documents to be used for the procurement of the goods described in these tender documents.
- (c) government-owned enterprises in the Beneficiary's country may participate only if they can establish that they
 - (i) are legally and financially autonomous and
 - (ii) Operate under commercial law. No dependent agency of the Beneficiary under a Purchaser's

financed project shall be permitted to tender or submit a proposal for the procurement of goods under the project.

4.3 A firm declared ineligible in accordance with ITT sub-clause 3.1 (c) shall be ineligible to tender for a contract awarded by the Purchaser during the period of time determined by the Purchaser.

4.4 Pursuant to ITT sub-clause 14.1, the Tenderer shall furnish, as part of its tender, documents establishing, to the Purchaser's satisfaction, the Tenderer's eligibility to tender.

4.5 Tenderers shall provide such evidence of their continued eligibility satisfactory to the Purchaser as the Purchaser shall reasonably request.

5. Eligible Goods and Services

5.1 Funds from the Purchaser are disbursed only on account of expenditures for the goods and services, provided by nationals of, and produced in or supplied from, eligible source countries as defined in the edition of the Public Procurement Act or as specified in the **TDS**.

5.2 For purposes of this clause, the nationality of the Tenderer is distinct from the country from where the goods and services are supplied.

5.3 For purposes of this clause,

(a) the term "Goods" includes any Goods that are the subject of this Invitation for Tenders and

(b) The term "services" includes related services such as transportation, insurance, commissioning and training.

6. Documents Establishing Eligibility of Goods and Services and Conformity to Tender Documents

6.1 Pursuant to ITT Clause 14, the Tenderer shall furnish, as part of its tender, documents establishing, to the Purchaser's satisfaction, the eligibility of the Health Sector Goods and services to be supplied under the contract.

6.2 The documentary evidence of the eligibility of the Goods and services shall consist of a statement in the Price Schedule of the country of origin of the goods and services offered that shall be confirmed by a Certificate of Origin, issued shortly before the time of shipment.

6.3 The documentary evidence of conformity of the Goods and services to the Tender Documents may be in the form of literature, drawings, and data and shall consist of:

(a) a detailed description of the essential technical and performance characteristics of the goods;

(b) an item-by-item commentary on the Purchaser's Technical Specifications demonstrating substantial responsiveness of the goods and services to those specifications, or a statement of (even allegedly minor) deviations and exceptions to the provisions of

the Technical Specifications;

- (c) Any other procurement-specific documentation requirement as stated in the **TDS**.

6.4 Unless the **TDS** stipulates otherwise, the Goods to be supplied under the contract shall be registered with the relevant authority in the Purchaser's country. A Tenderer who has already registered its goods by the time of tendering shall submit a copy of the Registration Certificate with its tender. Otherwise, the successful Tenderer, by the time of contract signing, shall submit to the Purchaser evidence establishing to the Purchaser's satisfaction that the Tenderer has complied with all the documentary requirements for registration as specified in the **TDS**.

6.4.1 The Purchaser shall at all times cooperate with the successful Tenderer to facilitate the registration process within the Purchaser's country. The agency and contact person able to provide additional information about registration are identified in the **TDS**.

6.4.2 If the goods offered by the successful Tenderer have not been registered in the Purchaser's country at the time of contract signing, the contract shall become effective upon such date as the Certificate of Registration is obtained.

6.5 For purposes of the commentary to be furnished pursuant to ITT clause 6.3 (b) above, the Tenderer shall note that standards as well as references to brand names designated by the Purchaser in its Technical Specifications are intended to be descriptive only and not restrictive. The Tenderer may substitute alternative standards, brand names, and/or catalogue numbers in its tender, provided that it demonstrates to the Purchaser's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.

7. Qualifications of the Tenderer

7.1 The Tenderer shall provide documentary evidence to establish to the Purchaser's satisfaction that:

- (a) The Tenderer has the financial and technical capability necessary to perform the contract, meets the qualification criteria specified in the **TDS**, and has a successful performance history in accordance with criteria specified in the **TDS**. If a prequalification process has been undertaken for the contract, the Tenderer shall, as part of its tender, update any information submitted with its application for prequalification.

- (b) in the case of a Tenderer offering to supply Health Sector Goods identified in the **TDS**, that the Tenderer did not manufacture or otherwise produce, the Tenderer has been duly authorized by the manufacturer or producer of such goods to supply the Goods in the Purchaser's

country;

- (c) in the case of a Tenderer who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Tenderer is or will be (if awarded the contract) represented by a local service/maintenance provider in the Purchaser's country, equipped and able to carry out the Tenderer's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications.

- 8. One Tender per Tenderer** 8.1 A firm shall submit only one tender either individually or as a partner of a joint venture (other than in cases of alternatives pursuant to ITT clause 20). A firm that submits either individually or, as a member of a joint venture, more than one tender will cause all the proposals with the firm's participation to be disqualified.
- 9. Cost of Tendering** 9.1 The Tenderer shall bear all costs associated with the preparation and submission of its tender, and the Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the tendering process.

B. THE TENDER DOCUMENTS

- 10. Content of Tender Documents** 10.1 The Tender Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITT clause 12.
 - Section I. Instructions to Tenderers (ITT)
 - Section II. Tender Data Sheet (**TDS**)
 - Section III. General Conditions of Contract (GCC)
 - Section IV. Special Conditions of Contract (**SCC**)
 - Section V. Schedule of Requirements (SoR)
 - Section VI. Technical Specifications (TS)
 - Section VII. Sample Forms (including Contract Agreement)
- 10.2 The "Invitation for Tenders" (ITT) does not form part of the Tender Documents and is included as a reference only. In case of discrepancies between the ITT and the Tender Documents listed in 10.1 above, said Tender Documents will take precedence.
- 11. Clarification of Tender Documents** 11.1 A prospective Tenderer requiring any clarification of the Tender Documents shall contact the Purchaser in writing (for these ITT, the term "in writing" means communicated in written form (e.g. email, fax, telex) with proof of receipt at the entity's address as indicated in the **TDS**. The Purchaser will respond in writing to any request for clarification received no later than **Seven (7)** calendar days prior to the deadline of submission of tenders. The content of the Purchaser's response shall be sent to all prospective Tenderers including a description of the inquiry but without identifying the source of the inquiry.

12. Amendment of Tender Documents

- 12.1 At any time prior to the deadline for submission of tenders, the Purchaser may amend the Tender Documents by issuing addenda/amendments.
- 12.2 Any addendum/amendment thus issued shall be part of the Tender Document pursuant to ITT sub-clause 10.1 and shall be communicated in writing to all purchasers of the Tender Documents and will be binding on them. Tenderers are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the addendum/amendment will have been taken into account by the Tenderer in its tender.
- 12.3 To give prospective Tenderers reasonable time in which to take addenda/amendments into account in preparing their tenders, the Purchaser may extend, at its discretion, the deadline for submission of tenders, in which case, the Purchaser will notify all Tenderers in writing of the extended deadline.

C. PREPARATION OF TENDERS

13. Language of Tender

- 13.1 The tender, as well as all correspondence and documents relating to the tender exchanged by the Tenderer and the Purchaser, shall be written in the language specified in the **TDS**. Supporting documents and printed literature furnished by the Tenderer may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **TDS**, in which case, for purposes of interpretation of the Tender, the translation shall govern.

14. Documents Constituting the Tender

- 14.1 The tender submitted by the Tenderer shall comprise the following:
 - (a) duly filled-in Tender Form and Price Schedule, in accordance with the forms indicated in Section VII;
 - (b) original form of tender security in accordance with the provisions of ITT sub-clause 19 (Tender Security);
 - (c) alternative offers, at the Tenderer's option, when permitted;
 - (d) written power of attorney, authorizing the named signatory of the tender to commit the Tenderer and showing the authorizing as well as the authorized person's function in the firm, name and signature;

- (e) in the absence of prequalification, documentary evidence in accordance with ITT sub-clause 4.4 establishing to the Purchaser's satisfaction the Tenderer's eligibility to tender including but not limited to documentary evidence that the Tenderer is legally incorporated in a territory of an eligible source country as defined under ITT clause 4;
- (f) documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITT clause 6 that the goods and ancillary services to be supplied by the Tenderer are eligible goods and services, pursuant to ITT clause 5, and that they conform to the Tender Documents;
- (g) Documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITT clause 7 that the Tenderer is qualified to perform the contract if its tender is accepted. In the case where prequalification of Tenderers has been undertaken, and pursuant to ITT clause 7.1 (a) the Tenderer must provide evidence on any changes in the information submitted as the basis for prequalification, or if there has been no change at all in said information, a statement to this effect;
- (h) Any other documentation as requested in the **TDS**.

15. Tender Form

- 15.1 The Tenderer shall complete the Tender Form and the Price Schedule furnished in the Tender Documents, indicating the goods to be supplied, a brief description of the goods, their country of origin, quantity, and prices.

16. Tender Prices

- 16.1 The Tenderer shall indicate in the Price Schedule, as applicable, the unit prices of each item, total prices of each item and lot, and the total tender price of the goods it proposes to supply under the contract.

Prices indicated on the Price Schedule shall include all costs including taxes, insurances and delivery to the premises of the entity.

- 16.2 The trade terms EXW and DDP shall be governed by the rules prescribed in the current edition at the time of tender submission of the *Incoterms* published by the International Chamber of Commerce, Paris, added by any deviation if so specified in the **TDS**.

- 16.3 Unless otherwise specified in the **TDS**, prices quoted by the Tenderer shall be fixed during the Tenderer's performance of the contract and not subject to variation on any account. A tender submitted with an adjustable price quotation will be treated as non-responsive and will be rejected, pursuant to ITT clause 29. If, however, in accordance with the **TDS**, prices quoted by the Tenderer shall be subject to adjustment during the performance of the contract, a tender submitted with a fixed price quotation will not be rejected, but the price will not

be adjusted.

16.4 Pursuant to sub-clause 16.1 above, and if so indicated in the **TDS**, tenders are being invited for all items or for individual contracts (lots). Each item offered must comprise the full quantity required under each item. Each lot shall comprise at least ninety percent (90%) of all items required under the lot. Tenderers wishing to offer any price reduction for the award of more than one contract (lot) shall specify in their tender the price reductions applicable to each package or, alternatively, to individual contracts within the package. Price reductions may be submitted as an amount or a percentage to be applied to the tender prices.

17. Currencies of Tender

17.1 The Tenderer may express the tender price of the Health Sector Goods to be supplied entirely in any free convertible currency. If the Tenderer wishes to be paid in a combination of different currencies, it must quote its prices accordingly, but no more than three foreign currencies may be used. Tenderers expressing their foreign currency requirements in any of the national currencies should do so in accordance with the provisions of the **TDS**.

18. Period of Validity of Tenders

18.1 Tenders shall remain valid for the period stipulated in the **TDS** after the date of tender submission specified in ITT clause 23. A tender valid for a shorter period shall be rejected by the Purchaser as non-responsive.

18.2 In exceptional circumstances, prior to expiry of the original tender validity period, the Purchaser may request that the Tenderers extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. Except as provided in ITT clause 18.3, a Tenderer agreeing to the request will not be required or permitted to modify its tender, but will be required to extend the validity of its tender security for the period of the extension.

18.3 In the case of fixed price contracts, if the award is delayed by a period exceeding eighty-six (86) days beyond the tender validity specified in the **TDS**, the contract price may be increased by a factor that reflects changes in the cost of inputs.

19. Tender Security

19.1 Unless otherwise specified in the **TDS**, the Tenderer shall furnish, as part of its tender, a tender security in the amount stipulated in the **TDS** in the currency of the Purchaser's country, or the equivalent amount in a freely convertible currency.

19.2 The tender security shall remain valid for a period of thirty (30) days beyond the validity period for the tender.

19.3 The tender security shall be denominated in the currency of the Purchaser's country or in a freely convertible currency and shall be, at the Tenderer's option, in one of the

following forms:

- (a) a cashier's or certified cheque;
- (b) a letter of credit issued by a reputable Bank located in any eligible country;
- (c) An unconditional Bank Guarantee or a bank draft issued by a reputable Bank selected by the Tenderer, located in Kenya or abroad or a guarantee from an insurance company approved by the Public Procurement Oversight Authority in the form provided in TDS and valid for one hundred and twenty (120) days from the date of tender opening. If the institution issuing the tender security is located outside the country, it shall have a corresponding institution located in Kenya to make it enforceable. The format of the Bank Guarantee shall be in accordance with the form of tender security included in Section VII

19.4 Any tender not accompanied by an acceptable tender security shall be rejected by the Purchaser as nonresponsive. The tender security of a joint venture must be in the name of the joint venture submitting the tender.

19.5 The tender securities of unsuccessful Tenderers will be returned as promptly as possible, but not later than 28 days after the expiration of the period of tender validity.

19.6 The tender security of the successful Tenderer will be returned when the Tenderer has signed the Agreement and furnished the required performance security.

19.7 The tender security may be forfeited

- (a) if the Tenderer withdraws its tender, except as provided in ITT sub-clauses 18.2 and 25.3; or
- (b) if the Tenderer does not accept the correction of its tender price, pursuant to ITT clause 30; or
- (c) in the case of a successful Tenderer, if the Tenderer fails within the specified time limit to:
 - (i) sign the agreement, or
 - (ii) Furnish the required performance security.

20. Alternative Proposals by Tenderers

20.1 Unless specified in the **TDS**, alternative tenders shall not be accepted.

21. Format and Signing of Tender

- 21.1 The Tenderer shall prepare an original and the number of copies/sets of the tender indicated in the **TDS**, clearly marking each one as “ORIGINAL TENDER” and “COPY OF TENDER,” as appropriate. In the event of any discrepancy between them, the original shall govern.
- 21.2 Each tender shall contain a separate technical and financial proposal.
 - 21.2.1 The technical proposal consists of: Technical Specifications, Schedule of Requirements, Manufacturer’s Authorizations, and Certificate of a Pharmaceutical Product (if applicable) as well as other technical documentation.
 - 21.2.2 The financial proposal consists of: Tender Form; Price Summary Sheet and Price Schedule(s) and Tender security as well as other financially relevant information like discounts etc.
- 21.3 The original and all copies of the tender, each consisting of the documents listed in ITT sub-clause 14.1, shall be typed or written in indelible ink and shall be signed by the Tenderer or a person or persons duly authorized to bind the Tenderer to the Contract. The authorization shall be indicated by written power of attorney, which pursuant to ITT sub-clause 14.1 (d) shall accompany the tender.
- 21.4 Any interlineation, erasure, or overwriting to correct errors made by the Tenderer shall be initialed by the person or persons signing the tender.
- 21.5 The Tenderer shall furnish in the Tender Form (a sample of which is provided in the Sample Forms Section of the tender documents) information regarding commissions or gratuities, if any, paid or to be paid to agents relating to this tender and to the execution of the contract if the Tenderer is awarded the contract.

D. SUBMISSION OF TENDERS

22. Sealing and Marking of Tenders

- 22.1 The Tenderer shall enclose the original and each copy of the tender including alternative tenders, if permitted in accordance with ITT clause 20, in separate sealed envelopes, duly marking the envelopes as “ORIGINAL” and “COPY.” The envelopes containing the original and copies shall then be enclosed in one outer envelope.
- 22.2 The inner and outer envelopes shall:
 - (a) bear the name and address of the Tenderer;
 - (b) be addressed to the Purchaser at the address given in the **TDS**;

- (c) bear the specific identification of this Tender process indicated in the **TDS**, the Invitation for Tenders (IFT) title and number indicated in the **TDS**; and
 - (d) Bear a statement “DO NOT OPEN BEFORE [date and time]” to be completed with the time and date specified in the **TDS** relating to ITT sub-clause 23.1.
- 22.3 If the outer envelope is not sealed and marked as required by ITT sub-clause 22.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the tender.
- 23. Deadline for Submission of Tenders**
- 23.1 Tenders must be received by the Purchaser at the address specified in the **TDS** relating to ITT sub-clause 22.2 (b) no later than the time and date specified in the **TDS**.
- 23.2 The Purchaser may, at its discretion, extend the deadline for the submission of tenders by amending the Tender Documents in accordance with ITT sub-clause 12.3, in which case all rights and obligations of the Purchaser and Tenderers previously subject to the deadline will thereafter be subject to the deadline as extended.
- 24. Late Tenders**
- 24.1 Any tender received by the Purchaser after the deadline for submission of tenders prescribed by the Purchaser in the **TDS** pursuant to ITT clause 23 will be rejected and returned unopened to the Tenderer.
- 25. Modification and Withdrawal of Tenders**
- 25.1 The Tenderer may modify or withdraw its tender after submission, provided that written notice of the modification, or withdrawal of the tenders duly signed by an authorized representative, is received by the Purchaser prior to the deadline prescribed for submission of tenders.
- 25.2 The Tenderer’s modification shall be prepared, sealed, marked, and dispatched as follows:
- (a) The Tenderer shall provide an original and the number of copies specified in the **TDS** of any modifications to its tender, clearly identified as such, in two inner envelopes duly marked “TENDER MODIFICATION-ORIGINAL” and “TENDER MODIFICATION-COPIES.” The inner envelopes shall be sealed in an outer envelope, which shall be duly marked “TENDER MODIFICATION.”
 - (b) Other provisions concerning the marking and dispatch of tender modifications shall be in accordance with ITT sub-clauses 22.2 and 22.3.
- 25.3 A Tenderer wishing to withdraw its tender shall notify the Purchaser in writing prior to the deadline prescribed for tender submission. A withdrawal notice shall be received prior to the deadline for submission of tenders. The notice of withdrawal shall:
- (a) be addressed to the Purchaser at the address named

in the **TDS**,

- (b) bear the specific identification of the Tender process (Contract name), the IFT title and IFT number, and the words "TENDER WITHDRAWAL NOTICE," and
- (c) Be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the tender.

25.4 Tenders requested to be withdrawn in accordance with ITT sub-clause 25.3, shall be returned unopened to the Tenderers.

25.5 No tender may be withdrawn in the interval between the tender submission deadline and the expiration of the tender validity period specified in ITT clause 18. Withdrawal of a tender during this interval may result in the forfeiture of the Tenderer's tender security, pursuant to ITT sub-clause 19.7.

E. OPENING AND EVALUATION OF TENDERS

26. Tender Opening

26.1 The Purchaser will open all tenders, including withdrawal notices and modifications, in public, in the presence of Tenderers' representatives who choose to attend, at the time, on the date and at the place specified in the **TDS**. Tenderers' representatives shall sign a register as proof of their attendance.

26.2 Envelopes marked "WITHDRAWAL" shall be read out and the envelope with the corresponding tender shall not be opened but returned to the Tenderer. No tender withdrawal shall be permitted unless the corresponding withdrawal notice is read out at tender opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding tender.

26.3 Tenders shall be opened one at a time, reading out the name of the Tenderer and whether there is a modification; the tender price of each item or lot, as the case may be, including discounts and alternative offers, if allowed in the **TDS**; the presence or absence of a tender security, if required; the presence or absence of requisite powers of attorney; and any other such details as the Purchaser may consider appropriate. No tender shall be rejected at tender opening except for late tenders pursuant to sub-clause 24.1.

26.4 Tenders (and modifications sent pursuant to ITT sub-clause 25.2) that are not opened or read out at tender opening shall not be considered further for evaluation, irrespective of the circumstances.

- 26.5 The Purchaser will prepare minutes of the tender opening at the end of the opening session, including, as a minimum: the name of the Tenderer and whether there was a withdrawal or modification; the tender price; including any discounts or alternatives offered if permitted in the **TDS**; the presence or absence of a tender security; the presence or absence of a duly signed and stamped Tender Form. The Tenderer's representatives who are present shall be requested to sign the minutes. The omission of a Tenderer's signature on the minutes shall not invalidate the content and effect of the minutes. The minutes should be distributed to all Tenderers who request them.
- 27. Clarification of Tenders**
- 27.1 During evaluation of the tenders, the Purchaser may, at its discretion, ask the Tenderer for a clarification of its tender. The request for clarification and the response shall be in writing, and no change in the prices or substance of the tender shall be sought, offered, or permitted, except to correct arithmetic errors identified by the Purchaser in the evaluation of the tenders, in accordance with ITT Sub-Clause 30.1.
- 28. Confidentiality**
- 28.1 Information relating to the examination, clarification, evaluation, and comparison of tenders, and recommendations for the award of a Contract shall not be disclosed to Tenderers or any other persons not officially concerned with such process until the Notification of Contract award is made to all Tenderers.
- 28.2 Any effort by a Tenderer to influence the Purchaser in the Purchaser's tender evaluation, tender comparison, or contract award decisions may result in the rejection of the Tenderer's tender.
- 28.3 From the time of tender opening to the time of Contract award, if any Tenderer wishes to contact the Purchaser on any matter related to its tender, it should do so in writing.
- 29. Examination of Tenders and Determination of Responsiveness**
- 29.1 The Purchaser will examine the tenders to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed, and whether the tenders are generally in order. In the case where a prequalification process has been undertaken for the Contract(s) for which these tender documents have been issued, the Purchaser will ensure that each tender is from a prequalified Tenderer.
- 29.2 The Purchaser may waive any minor informality, nonconformity, or irregularity in a tender that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Tenderer.
- 29.3 Prior to the detailed evaluation, pursuant to ITT Clause 32, the Purchaser will determine whether each tender is of acceptable quality, is complete, and is generally responsive to the tender documents. For purposes of this determination, a

substantially responsive tender is one that conforms to all the terms, conditions, and specifications of the Tender Documents without material deviations, exceptions, objections, conditionality or reservations. A material deviation, exception, objection, conditionality or reservation is one:

- (i) that limits in any substantial way the scope, quality, or performance of the goods and/or related services;
- (ii) that limits, in any substantial way that is inconsistent with the tender documents, the Purchaser's rights or the successful Tenderer's obligations under the Contract;

and

- (iii) The acceptance of which would unfairly affect the competitive position of other Tenderers who have submitted substantially responsive tenders.

29.4 If a tender is not generally responsive, it will be rejected by the Purchaser and cannot subsequently be made responsive by the Tenderer by correction of the nonconformity. The Purchaser's determination of a tender's responsiveness is to be based on the contents of the tender itself, and any written clarification submitted by the Tenderer in accordance with ITT sub-clause 27.1.

30. Correction of Errors

30.1 Arithmetical errors will be rectified as follows. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and the quantity, the unit or subtotal price shall prevail. If there is a discrepancy between subtotals and the total price, the total price shall be corrected. If there is a discrepancy between words and figures, the amount in words will prevail. If a Tenderer does not accept the correction of errors, its tender will be rejected and its tender security may be forfeited.

31. Conversion to Single Currency

31.1 To facilitate evaluation and comparison, the Purchaser will convert all tender prices expressed in the various currencies in which they are payable to either:

- (a) the currency of the Purchaser's country at the selling exchange rate established for similar transactions by the Central Bank or a commercial bank in the Purchaser's country

or

- (b) any other freely convertible currency at the selling rate of exchange published in the international press for the amount payable in foreign currency; and at the selling exchange rate established for similar transactions by the Central Bank in the Purchaser's country for the amount payable in the currency of the Purchaser's country

32. Evaluation and Comparison of Tenders

- 31.2 The currency selected for converting tender prices to a common base for the purpose of evaluation, along with the source and date of the exchange rate, are specified in the **TDS**.
- 32.1 The Purchaser will evaluate and compare the tenders that have been determined to be substantially responsive, pursuant to ITT clause 29.
- 32.2 The Purchaser's evaluation of a tenders will exclude and not take into account:
- (a) in the case of goods manufactured in the Purchaser's country or goods of foreign origin already located in the Purchaser's country: sales and other similar taxes, that will be payable on the goods if a contract is awarded to the Tenderer;
 - (b) in the case of goods of foreign origin offered from abroad: customs duties and other similar import taxes that will be payable on the goods if the contract is awarded to the Tenderer; and
 - (c) Any allowance for price adjustment during the period of execution of the Contract, if not provided for in the **TDS**.
- 32.3 The comparison shall be between the EXW (ex-factory/ex-warehouse/off-the-shelf) price of the Goods offered from within the Purchaser's country plus local transportation, such price to include all costs, as well as duties and taxes paid or payable on components and raw material incorporated or to be incorporated in the Goods, and the DDP named place of destination price of the Goods offered from outside the Purchaser's country, plus local transportation.
- 32.4 The Purchaser's evaluation of a tender will take into account one or more of the following factors as specified in the **TDS**, and quantified in ITT sub-clause 32.5:
- (i) delivery schedule offered in the tender;
 - (ii) deviations in payment schedule from that specified in the **SCC**;
 - (iii) Other specific criteria indicated in the **TDS** and/or in the Technical Specifications.
- 32.5 For factors retained in the **TDS** pursuant to ITT sub-clause 32.4, one or more of the following quantification methods will be applied, as detailed in the **TDS**:
- (a) Delivery schedule.
 - (i) The Purchaser requires that the Health Sector Goods under these Tender Documents shall be delivered (shipped) at the time specified in the

Schedule of Requirements. A delivery “adjustment” will be calculated for and added to each tender by applying a percentage, specified in the **TDS**, of the DDP price for each week of delay beyond the requested time of shipment/delivery specified in the Schedule of Requirements for evaluation purposes. No credit shall be given to early delivery.

or

- (ii) The Health Sector Goods covered under these Tender Documents are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirements. No credit will be given to earlier deliveries, and tenders offering delivery beyond this range may be treated as non-responsive. Within this acceptable range, an adjustment per week, as specified in the **TDS**, will be added for evaluation to the tender price of tenders offering deliveries later than the earliest delivery period specified in the Schedule of Requirements.

or

- (iii) The Health Sector Goods covered under this invitation are required to be delivered (shipped) in partial shipments, as specified in the Schedule of Requirements. Tenders offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the tender price a factor equal to a percentage, specified in the **TDS**, of DDP price per week of variation from the specified delivery schedule.

(b) Deviation in payment schedule.

- (i) The **SCC** stipulates the payment schedule offered by the Purchaser.

(c) Past performance:

Tenderers need a satisfactory record of performance:

- (i) Those who have previously been awarded contracts to supply similar commodities and failed to deliver as per the contract terms or delivered and commodities recalled for quality issues and failed to replace the same shall be disqualified if designated for an award.
- (ii) Those who are or have been seriously deficient in current or recent contract performance when the number of contracts and the extent of deficiencies each are considered (in the absence of evidence to the

contrary or circumstances properly beyond their control) shall be presumed to be unable to meet this requirement and shall be disqualified if designated for a contract award.

- (c) Other specific additional criteria to be considered in the evaluation and the evaluation method shall be detailed in the **TDS** and/or in the Technical Specifications.

32.6 Contacting the purchaser

- (a) Subject to paragraph 28, no tenderer shall contact the purchaser on any matter relating to its tender from the time of tender opening to the time of contract award.
- (b) Any effort by a tenderer to influence the purchaser in its decision on tender evaluation, tender comparison, or contract award shall result in the rejection of the tenderer's tender

32.7 Preference where allowed in the evaluation of tenders shall not exceed 15%.

F. AWARD OF CONTRACT

33. Post qualification

- 33.1 In the absence of pre-qualification, the Purchaser will determine to its satisfaction whether the Tenderer that is selected as having submitted the lowest evaluated responsive tender is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITT sub-clause 7.1 and any additional post-qualification criteria stated in the **TDS**. If a prequalification process was undertaken for the Contract(s) for which these tender documents were issued, the Purchaser will determine in the manner described above that no material changes have occurred after the prequalification that negatively affect the ability of the Tenderer that has submitted the lowest evaluated tender to perform the Contract.
- 33.2 The determination will evaluate the Tenderer's financial, technical, and production capabilities. It will be based on an examination of the documentary evidence of the Tenderer's qualifications submitted by the Tenderer, pursuant to ITT sub-clause 7.1, as well as other information the Purchaser deems necessary and appropriate.
- 33.3 An affirmative post qualification determination will be a prerequisite for award of the contract to the lowest evaluated Tenderer. A negative determination will result in rejection of the Tenderer's tender, in which event the Purchaser will proceed to the next-lowest evaluated tender to make a similar determination of that Tenderer's capabilities to

perform satisfactorily.

- 34. Award Criteria** 34.1 Pursuant to ITT clauses 32, 33 and 38, the Purchaser will award the Contract to the Tenderer whose tender has been determined to be substantially responsive and has been determined to be the lowest evaluated tender, provided further that the Tenderer is determined to be qualified to perform the Contract satisfactorily, pursuant to ITT clause 34
- 35. Purchaser's Right to Accept Any Tender and to Reject Any or All Tenders** 35.1 The Purchaser reserves the right to accept or reject any tender, or to annul the Tender process and reject all tenders at any time prior to contract award, without thereby incurring any liability to the affected Tenderer(s).
- 36. Purchaser's Right to Vary Quantities** 36.1 The Purchaser reserves the right during the life of the contract to increase or decrease, by the percentage indicated in the **TDS**, the quantity of goods and services beyond that originally specified in the Schedule of Requirements without any change in unit price or other terms and conditions, except the delivery schedule.
- 37. Notification of Award** 37.1 Prior to the expiration of the period of tender validity, the Purchaser will notify the successful Tenderer in writing that its tender has been accepted, the receipt of which must be confirmed in writing.
- 37.2 A written contract will constitute the formation of the Contract, *subject to "no appeal"* from unsuccessful tenderer's within the period of fourteen (14) days from the date of Notification of Award.
- 37.3 At the same time as the successful tenderer is notified of the award, the unsuccessful tenderer(s) shall be notified that their tender(s) were unsuccessful.
- 37.4 Upon the successful Tenderer's furnishing of the signed Contract Form and performance security pursuant to ITT clause 39, the Purchaser will promptly discharge the tender security of each unsuccessful Tenderer(s), pursuant to ITT clause 19.
- 37.5 If, after notification of award, a Tenderer wishes to ascertain the grounds on which it's tender was not selected, it should address its request to the Purchaser. The Purchaser will promptly respond in writing to the unsuccessful Tenderer.
- 38. Signing of Contract** 38.1 Promptly after the Purchaser notifies the successful Tenderer that its tender has been accepted, the Purchaser will; after fourteen days (14days) but within twenty one days (21days) send the Tenderer the Contract Form provided in the Tender Documents, incorporating all agreements between the parties.
- 38.2 Within five (5) days of receipt of the Contract Form, the successful Tenderer shall sign and date the Contract Form and return it to the Purchaser.

**39. Performance
Security**

- 39.1 Within twenty-one (21) days of the receipt of Notification of Award from the Purchaser, the successful Tenderer shall furnish the Performance Security in accordance with the Conditions of Contract, using the Performance Security Form provided in the Tender Documents or in another form acceptable to the Purchaser.
- 39.2 Failure of the successful Tenderer to comply with the requirement of ITT clause 38 or ITT sub-clause 39.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the tender security, in which event the Purchaser may make the award to the next-lowest evaluated tenderer or call for new tenders.
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Section II. Appendix - Tender Data Sheet (TDS)

Tender Data Sheet (TDS)

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

A. GENERAL

ITT 1.1	<p>Name of Purchaser:</p> <p>Kenya Medical Supplies Authority (KEMSA)</p> <p>Type of goods: Supply and Delivery of ARV Medicine - (Atazanavir 300mg/Ritonavir 100mg)</p> <p>Name and identification number of the Contract:</p> <p>IFT No.: KEMSA/GOK – CPF/HIV 17/18 – OIT 001</p>
ITT 2.1	<p>Name of the Beneficiary: Government of Kenya, Ministry of Health</p> <p>Procurement budget: approx.: KES 900M</p> <p>Name of Project: Counter Part Funding</p>
ITT 4.1 & 5.1	<p>Applicable Guidelines: Government of Kenya (GOK), The Public Procurement and Disposal Act 2005, The Public Procurement and Disposal Regulations 2006 as revised.</p>
ITT 6.3 (c)	<p>Documentation and sample requirements for eligibility of the offered Goods.</p> <p>In addition to the documents stated in Clause 6.2 and 6.3 (a) and (b), the following shall be included with the Tender:</p> <p>For each pharmaceutical product offered, documentary evidence demonstrating that such product has been manufactured in accordance with publicly available monographs and that the finished product meets the standards as described in any of the following pharmacopoeia:</p> <ol style="list-style-type: none"> a) <ol style="list-style-type: none"> I. International Pharmacopeia II. British Pharmacopeia III. United States Pharmacopeia IV. European Pharmacopeia <p>and</p> <p>documentary evidence demonstrating that such product meets one of the following standards must be provided</p> <ol style="list-style-type: none"> a) Have been found to be acceptable by the UN Procurement Quality and Sourcing Project (also known as the WHO Prequalification Project Visit (http://apps.who.int/prequal/)) b) Have been authorized for consumption in their country by a stringent regulatory authority (for further information visit

	<p>(www.picshceme.org,www.ich.org)</p> <p>c) Have been provided with GMP certification in line with WHO requirements www.theglobalfund.org/pdf/guidelines</p> <p>d) The Tenderer is requested to provide, in support of their technical offer, a sample for tests for each of the items offered under separate cover at or before the tender closing date and time. The sample is to be clearly labeled with the tenderer's name, tender reference and identification of the product. The sample requested is to be submitted as per technical specification offered by the Tenderer and shall represent exactly the pharmaceutical product that is intended to be supplied in case of contract award.</p> <p>e) The sample submitted as per the requirements of sect (d) above must contain a Product Insert, which should conform to the technical specifications offered by the tenderer -</p> <p>f) For reasons other than the tender specific labeling requirements, the sample is not consistent with the required technical specifications then the offer for the particular item may be rejected.</p> <p>g) For quality assurance reasons, for each sample provided a protocol (Certificate of Analysis) of a product test conducted by the laboratory of the manufacturer has to be provided from the same batch production.</p>
ITT 6.4	<p>(a) Valid copy of the registration and retention certificate from the Kenya Pharmacy and Poisons Board (PPB) concerning the offered drugs</p> <p>Or</p> <p>(b) Valid copy of application for retention concerning the offered drugs, received by the PPB before closing date of this tender.</p>

B. THE TENDER DOCUMENTS

ITT 11.1	<p>Purchaser's address:</p> <p>Kenya Medical Supplies Authority (KEMSA)</p> <p>Office address:</p> <p style="padding-left: 40px;">The Chief Executive Officer Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya</p> <p>Postal address:</p> <p style="padding-left: 40px;">P.O.Box: 47715 00100 Nairobi Kenya</p> <p style="padding-left: 40px;">Tel: (+254-0)20-3922000/ 0719033000/ 0733606600 Fax: (+254-0)20-3922400 E-Mail: procurement.programs@kemsa.co.ke</p> <p>For clarifications on the Tender document please contact :</p> <p>Procurement Programs Division Attn. Mr. John Kabuchi P. O. Box 47715 00100 Nairobi/Kenya</p> <p style="padding-left: 40px;">Tel: (+254-0)20-3922000 + 0719 033222/240 Fax: (+254-0)20-558100 E-Mail: procurement.programs@kemsa.co.ke</p>
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C. PREPARATION OF TENDERS

ITT 13.1	The language of all correspondence and documents related to the tender is English . Moreover, the key passages of all accompanying printed literature in any other language must be translated into English.
ITT 16.2	The trade term DDP shall include all costs including taxes, insurance and delivery to KEMSA.
ITT 16.3	Prices are fixed
ITT 16.4	Tenders are being invited for individual contracts (one or more items). Tenderers shall quote 100% of the entire quantity for each item quoted, as per Purchaser's Price Schedule.
ITT 18.1	The tender validity period shall be 90 days after the deadline for tender submission, as specified below in reference to ITT clause 23.
ITT 19.1	The amount of tender security required USD 44,500.00 or KES 4,680,000.00 or equivalent in a freely convertible currency.

ITT 19.2	Tender security must be valid thirty (30) days after the end of the tender validity period. I.e. one twenty (120) days from the date of tender opening.
ITT 19.3	Form of Tender Security: a) Cash b) Bank Guarantee c) Letter of Credit d) Guarantee by a deposit taking Micro Finance Institution (SACCO society, Youth Enterprise Development Fund or Women Enterprise Fund Note: (<i>Tender Securities from Insurance Companies shall not be acceptable</i>).
ITT 20.1	Alternative tenders will not be accepted.
ITT 21.1	Required number of copies of the tender: 1 original and 1 copy of the tender shall be submitted.

D. SUBMISSION OF TENDERS

ITT 22.2 (b)	The address for tender submission is: Kenya Medical Supplies Authority (KEMSA) Office Address: Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya Postal Address: P.O. Box: 47715 00100 Nairobi/Kenya
ITT 22.2 (c) & (d)	See the above data for ITT 1.1 for the name of the Contract. The Invitation for Tenders title and number are: Supply and Delivery of ARV Medicine - (Atazanavir 300mg/ Ritonavir 100mg) IFT No.: KEMSA/GOK – CPF/HIV 17/18 – OIT 001 See the below data for ITT sub-clause 23.1 for the deadline for tender submission.
ITT 23.1	See the above data for ITT sub-clause 22.2 (b) for the address and deadline for tender submission. Deadline for tender submission is: 29th November,2017 at 10:00 AM (Nairobi local time)
ITT 24.1	See the above data for ITT sub-clause 23.1 for the deadline for tender submission.
ITT 25.2 (a)	The required number of copies of tender modifications is the same

	as the number of copies of the original tender specified above in the data for ITT sub-clause 21.1.
ITT 25.3 (a)	See the above data for ITT Paragraph 22.2 (b) for the address to use for submission of a tender withdrawal notice.

E. TENDER OPENING AND EVALUATION

ITT 26.1	<p>Time, date, and place for tender opening are:</p> <p style="text-align: center;">29th November, 2017 at 10:00 AM (Nairobi local time)</p> <p style="text-align: center;">at</p> <p style="text-align: center;">Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya</p>
ITT 31.2	<p>The currency chosen for the purpose of converting to a common currency is Kenya Shillings.</p> <p>The source of exchange rate is the Central Bank of Kenya, Nairobi</p> <p>The date of exchange rate determination is the rate on the day of tender opening</p>
ITT 32.3	<p>Evaluation criteria for items/lots</p> <p>Tenderers shall bid for one or more items in the Price Schedule. Bids will be evaluated item by item:</p> <p style="padding-left: 40px;">(a) Tenderers shall quote for one, more or all items and the entire quantity for each item quoted, as per Purchaser's Price Schedule;</p> <p style="padding-left: 40px;">and</p> <p style="padding-left: 40px;">(b) The items offered as per Purchaser's Price Schedule must be responsive to the Tender Document.</p> <p>Tendered items not complying with (a) and (b) above shall be treated as non-responsive.</p> <p>Tender evaluation will be made on individual item basis and contract award(s) on individual item basis or combined as one contract for all items awarded to individual successful bidder's</p>
ITT 32.5 (a) (ii)	<p>Delivery schedule</p> <p>The adjustment per week for delivery later than the earliest delivery period within the acceptable range of weeks specified in the Schedule of Requirements is one-half (0.5) percent per week</p>
ITT 32.5 (b) (ii)	<p>The Purchaser will not accept deviations from the payment schedule as stipulated in the SCC.</p>
ITT 33	<p>A margin of preference will apply pursuant to the provisions of ITB clause 33 as detailed under Appendix 1.</p>

F. AWARD OF CONTRACT

ITT 36.1	Percentage for increase or decrease of quantity of goods and services originally specified: 10% during the life of the contract as stipulated under ITT 38.3.
ITT 38.1	Prior to the expiration of the period of tender validity, the Purchaser shall notify the successful Tenderer in writing to be subsequently confirmed within three (3) working days also in writing that its tender has been accepted.
ITT 38.2	Within five (5) days of receipt of the Contract Form, the successful Tenderer shall sign and date the Contract Form and return it to the Purchaser.
ITT 38.3	The supply period shall be twelve (12) months after effective date of contract within which period the purchaser would have made all the calls.

Section III. General Conditions of Contract
(for Health Sector Goods)

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General Conditions of Contract (GCC)

1. Definitions

1.1 In this Contract, the following terms shall be interpreted as indicated:

- (a) "The Contract" means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
- (b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.
- (c) "Day" means calendar day.
- (d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.
- (e) "End User" means the organization (s) where the goods will be used, as named in the **SCC**.
- (f) "GCC" means the General Conditions of Contract contained in this section.
- (g) "The Goods" 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 Purchaser under the Contract.
- (h) "The Purchaser" means the organization purchasing the Goods, as named in the **SCC**.
- (i) "The Purchaser's country" is the country named in the **SCC**.
- (j) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser's country in accordance with the applicable law.
- (k) "**SCC**" means the Special Conditions of Contract.
- (l) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.
- (m) "The Site," where applicable, means the place or places named in the **SCC**.

(n) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract, as named in the **SCC**.

- 2. Application** 2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.
- 3. Country of Origin** 3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules of the Government of Kenya, or as further elaborated in the **SCC**.
- 3.2 For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods 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.
- 3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.
- 4. Standards** 4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.
- 5. Use of Contract Documents and Information;** 5.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.
- 5.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Sub-Clause 5.1 except for purposes of performing the Contract.
- 5.3 Any document, other than the Contract itself, enumerated in GCC Sub-Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.

- 6. Certification of Goods in Accordance with Laws of the Purchaser's Country**
- 6.1 If required under the applicable law, Goods supplied under the Contract shall be registered for use in the Purchaser's country. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Purchaser's country.
- 6.2 Unless otherwise specified in the **SCC**, the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's country that the Goods have been registered for use in the Purchaser's country.
- 6.3 If thirty (30) days, or such longer period specified in the **SCC**, elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 6.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's performance security shall be promptly returned.
- 7. Patent Rights**
- 7.1 The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in the Purchaser's country.
- 8. Performance Security**
- 8.1 Within twenty one (21) days of receipt of the notification of Contract award, the successful Tenderer shall furnish to the Purchaser the performance security in the amount specified in the **SCC**.
- 8.2 The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.
- 8.3 The performance security shall be denominated in the currency of the Contract, or in a freely convertible currency acceptable to the Purchaser, and shall be in one of the following forms:
- (a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Purchaser's country or abroad, acceptable to the Purchaser, in the format provided in the Tender Documents or another format acceptable to the Purchaser; or
- (b) a cashier's or certified cheque.
- 8.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than thirty (30) 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**.
- 9. Inspections and Tests**
- 9.1 a) The Supplier shall demonstrate conformity to Kenya Standards or approved equivalents by evidence of Test report or Certificate from ISO/IEC 17025 or EN 45002 accredited laboratory, recognized by the International

Laboratory Accreditation Co-operation (ILAC) or preferable from any conformity body recognized by the International Federation of Inspection Agencies (IFIA) prior to shipment. Cost shall be borne by the supplier.

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

- 9.2 Where the Supplier contests the validity of the rejection by the Purchaser or his representative, of any inspection as required by 9.1 above conducted before shipment or at ultimate destination, whether based on product or packing grounds, a sample drawn jointly by the Supplier and Purchaser or his or her representative and authenticated by both, will be forwarded for umpire analysis within four weeks of the time the Supplier contests to an independent agency mutually agreed by the Purchaser and Supplier. The umpire's finding, which will be promptly obtained, will be final and binding on both parties. The cost of umpire analysis will be borne by the losing party.

10. Packing

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

11. Delivery and Documents

- 11.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in the **SCC**.
- 11.2 For purposes of the Contract, "EXW", "DDP" and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of *Incoterms* published by the International Chamber of

Commerce, Paris.

11.3 Documents to be submitted by the Supplier are specified in the **SCC**. *Incoterms* provides a set of international rules for the interpretation of the more commonly used trade terms.

12. Insurance

12.1 The Goods 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 the manner specified in the **SCC**.

13. Transportation

13.1 Where the Supplier is required under Contract to deliver the Goods FOB, transport of the Goods, up to and including the point of putting the Goods on board the vessel at the specified port of loading, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price. Where the Supplier is required under the Contract to deliver the Goods FCA, transport of the Goods and delivery into the custody of the carrier at the place named by the Purchaser or other agreed point shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

13.2 Where the Supplier is required under Contract to deliver the Goods CIF or DDP, customs clearance and transport of the Goods to the port of destination or such other named place of destination in the Purchaser's country, as shall be specified in the Contract, shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

13.3 Where the Supplier is required under the Contract to transport the Goods to a specified place of destination within the Purchaser's country, defined as the Site, transport to such place of destination in the Purchaser's country, including customs clearance, insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

13.4 Where the Supplier is required under Contract to deliver the Goods CIF or DDP, no restriction shall be placed on the choice of carrier. Where the Supplier is required under Contract (a) to deliver the Goods FOB or FCA, and (b) to arrange on behalf and at the expense of the Purchaser for international transportation on specified carriers or on national flag carriers of the Purchaser's country, the Supplier may arrange for such transportation on alternative carriers if the specified or national flag carriers are not available to transport the Goods within the period(s) specified in the Contract.

14. Incidental Services

14.1 The Supplier shall provide such incidental services, if any, as are specified in the **SCC**.

14.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the

prevailing rates charged to other parties by the Supplier for similar services.

15. Warranty

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

The Supplier further warrants that all Goods supplied under the Contract will have remaining a minimum of five-sixths (5/6) of the specified shelf life upon delivery at port/airport of entry for goods with a shelf life of more than two years and three-fourths (3/4) for goods with a shelf life of two years or less, unless otherwise specified in the **SCC**; have "overages" within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

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

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

- 15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period specified in the **SCC**, the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.

- 15.5 Recalls. In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with

Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

16. Payment

- 16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be specified in the **SCC**.
- 16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 11, and upon fulfillment of other obligations stipulated in the Contract.
- 16.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.
- 16.4 The currency or currencies in which payment is made to the Supplier under this Contract shall be specified in the **SCC** subject to the following general principle: Payment will be made in the currency or currencies in which the payment has been requested in the Supplier's tender.
- 16.5 All payments shall be made in the currency or currencies specified in the **SCC** pursuant to GCC 16.4.

17. Prices

- 17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its tender, with the exception of any price adjustments authorized in the **SCC** or in the Purchaser's request for tender validity extension, as the case may be.

18. Change Orders

- 18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:
 - (a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;
 - (b) the method of shipment or packing;
 - (c) the place of delivery; and/or
 - (d) the Services to be provided by the Supplier.
- 18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the

		date of the Supplier's receipt of the Purchaser's change order.
19. Contract Amendments	19.1	Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.
20. Assignment	20.1	The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Purchaser's prior written consent.
21. Delays in the Supplier's Performance	21.1	Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.
	21.2	If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.
	21.3	Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of liquidated damages.
22. Liquidated Damages	22.1	Subject to GCC Clause 24, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified in the SCC of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in the SCC . Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 23.
23. Termination for Default	23.1	The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part: <ul style="list-style-type: none"> (a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser

pursuant to GCC Clause 21; or

- (b) if the Goods do not meet the Technical Specifications stated in the Contract; or
- (c) if the Supplier fails to provide any registration or other certificates in respect of the Goods within the time specified in the **SCC**.
- (d) if the Supplier, in the judgment of the Purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

“corrupt practice” means the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official in the procurement process or in Contract execution.

“fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a Contract to the detriment of the Purchaser, and includes collusive practice among Tenderers (prior to or after tender submission) designed to establish tender prices at artificial noncompetitive levels and to deprive the Purchaser of the benefits of free and open competition.

- (e) if the Supplier fails to perform any other obligation(s) under the Contract.

23.2 In the event the Purchaser terminates the Contract in whole or in part, pursuant to GCC Clause 23.1, the Purchaser may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Purchaser for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

24. Force Majeure

24.1 Notwithstanding the provisions of GCC Clauses 21, 22, and 23, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

24.2 For purposes of this clause, “Force Majeure” means an event beyond the control of the Supplier and not involving the Supplier’s fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

24.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition

and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

- 25. Termination for Insolvency** 25.1 The Purchaser may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser.
- 26. Termination for Convenience** 26.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.
- 26.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect:
- (a) to have any portion completed and delivered at the Contract terms and prices; and/or
 - (b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.
- 27. Settlement of Disputes** 27.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.
- 27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.
- 27.2.1 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.
- 27.2.2 Arbitration proceedings shall be conducted in accordance

with the rules of procedure specified in the **SCC**.

- 27.3 Notwithstanding any reference to arbitration herein,
- (a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and
 - (b) the Purchaser shall pay the Supplier any monies due the Supplier.

28. Limitation of Liability

- 28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,
- (a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and
 - (b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

29. Governing Language

- 29.1 The Contract shall be written in the language specified in the **SCC**. Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in the same language.

30. Applicable Law

- 30.1 The Contract shall be interpreted in accordance with the laws of the Purchaser's country, unless otherwise specified in the **SCC**.

31. Notices

- 31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex, or facsimile and confirmed in writing to the other party's address specified in the **SCC**.
- 31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

32. Taxes and Duties

- 32.1 A Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside the Purchaser's country. Commodities being procured under this GFATM grant are free of local taxes and duties. The Purchaser will facilitate the tax exemptions upon receipt of the required documentation from the supplier.
- 32.2 A Supplier supplying Goods offered locally shall be entirely responsible for all taxes, duties, license fees, etc., incurred

until delivery of the contracted Goods to the Purchaser

33. Inspections and Tests

- 33.1 The Procuring entity or its representative shall have the right to inspect and/or to test the Medical commodities to confirm their conformity to the Contract specifications. The Procuring entity shall notify the tenderer in writing, in a timely manner, of the identity of any representatives retained for these purposes.
- 33.2 The inspections and tests may be conducted on the premises of the tenderer or its subcontractor(s), at point of delivery, and/or at the Medical commodities' final destination. If conducted on the premises of the tenderer or its subcontractor(s), all reasonable facilities and assistance, including access to drawings and production data, shall be provided to the inspectors at no charge to the Procuring entity.
- 33.3 Should any inspected or tested Medical commodities fail to conform to the Specifications, the Procuring entity may reject the Medical commodities, and the tenderer shall either replace the rejected Medical commodities or make alterations necessary to meet specification requirements free of cost to the Procuring entity.
- 33.4 The Procuring entity's right to inspect, test and, where necessary, reject the Medical commodities after the Medical commodities' arrival shall in no way be limited or waived by reason of the Medical commodities having previously been inspected, tested, and passed by the Procuring entity or its representative prior to the Medical commodities' delivery.
- 33.5 Nothing in paragraph 8 shall in any way release the tenderer from any warranty or other obligations under this Contract.

Section IV. Special Conditions of Contract (SCC)
(for Health Sector Goods)

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Special Conditions of Contract (SCC) For Pharmaceuticals

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. The corresponding clause number of the GCC is indicated in parentheses

1. Definitions (GCC Clause 1)	
GCC 1.1 (f)	The end user is: Ministry of Health
GCC 1.1 (i)	The Purchaser is: Kenya Medical Supplies Authority
GCC 1.1 (j)	The Purchaser's country is: Kenya
GCC 1.1 (n)	The Site is: KEMSA, Industrial Area, Nairobi
GCC 1.1 (o)	The Supplier is:
6. Certification of Goods in Accordance with Laws of the Purchaser's Country (GCC Clause 6)	

GCC 6.1	Drugs shall be registered with the Kenya Pharmacy and Poisons Board, Ministry of Health, before importing, selling or distributing in Kenya. Any award of contract for the supply and delivery of pharmaceuticals offered under this IFT will be subject to the proof of registration with the Kenyan National Drug Registration Authority (Pharmacy and Poisons Board).
8. Performance Security (GCC Clause 8)	
GCC 8.1	Performance security shall be for an amount not less than ten (10) % of the contract price. The performance security shall be in the form of a banker's Cheque, bank guarantee, irrevocable letter of credit issued by a reputable bank.
9. Inspections and Tests (GCC Clause 9)	
GCC 9.1	<p>a) Imports of Goods to Kenya are subject to the (PVoC) Pre-shipment verification of conformity. Any waiver on this requirement will be communicated to the Supplier by the Purchaser.</p> <p>b) The supplier is requested to provide for batch by batch Certificates of Compliance by ISO/IEC 17025/ EN 45002 accredited test laboratories to prove the conformity to the technical specifications and applicable quality standards. The cost of such inspection shall be to the supplier's account.</p> <p>c) The Goods shall not be shipped unless a copy of satisfactory documentary proof for has been submitted to the Purchaser.</p> <p>d) The Purchaser shall analyze all new brands of products, and products that have previously failed quality analysis tests, before confirming an order. The cost of analysis shall be borne by the Tenderer and shall be paid in full prior to analysis.</p>
10. Packing (GCC Clause 10)	
GCC 10.2	<p>Additional requirements for packing and transport are indicated in</p> <p>(a) Section VI, Technical Specifications</p> <p>and</p> <p>(b) General Packing Instructions</p>
11. Delivery and Documents (GCC Clause 11)	
GCC 11.1 & 11.3	<p>For goods supplied from abroad under Incoterms DDP,KEMSA</p> <p>Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours</p>

ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. Under all transport modes, the Supplier shall fax and then send by courier the following documents to the Purchaser, with a copy to the insurance company:

- (i) Three originals and two copies of the Supplier's invoice, showing Purchaser as Consignee; the Contract number, grant no., goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;
- (ii) one original and two copies of the negotiable, clean, on-board through MT Document marked "freight prepaid" and showing Purchaser as Consignee and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multi-modal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;
- (iii) four copies of the packing list identifying contents of each package;
- (iv) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary;
- (v) one original of the manufacturer's or supplier's Warranty Certificate covering all items supplied;
- (vi) one original of the Supplier's Certificate of Origin covering all items supplied;
- (vii) original and six copies of the Certificate of Compliance/Test Report furnished to the supplier by ISO/IEC 17025 accredited test laboratories;
- (viii) any other procurement-specific documents required for delivery/payment purposes;
- (ix) one original of the Certificate of Pharmaceutical Product as per the WHO's recommended template for each of the items supplied;
- (x) One original and one copy of a protocol (certificate of analysis) of a product test per batch conducted by the laboratory of the manufacturer.
- (xi) one original and one copy of the certificate of quality control test results per batch, in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the goods. These tests shall be conducted by respective laboratories that

	<p>(a) are accredited in accordance with ISO/IEC 17025 or EN 45002</p> <p>Or</p> <p>(c) have been accepted by a stringent authority in a PIC/S country;</p> <p>(xii) One original of the certificate of weight issued by the port authority/licensed authority and six copies.</p> <p>At arrival of the goods at port of clearance, the Supplier or its Shipping agent shall provide the Purchaser with:</p> <p style="padding-left: 40px;">1) Arrival notice</p> <p style="padding-left: 40px;">and</p> <p style="padding-left: 40px;">2) Delivery note.</p> <p>The above documents 1) and 2) shall be received by the Purchaser immediately after arrival of the Goods at port of clearance and, if not received, the Supplier will be responsible for any consequent expenses.</p> <p>Note: In the event that the documents presented by the Supplier are not in accordance with the Contract, payment will be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 9 (GCC 9) above.</p>
	<p>For goods supplied from within the Purchaser's country under Incoterms EXW, delivered to named place of destination:</p> <p>The Supplier shall notify the Purchaser at least forty-eight (48) hours ahead of delivery of the goods in writing and deliver the following documents to the Purchaser:</p> <p>(i) Two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, grant number, goods description, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;</p> <p>(ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as consignee and delivery through to final destination as stated in the Contract;</p> <p>(iii) copy of the Insurance Certificate, showing the Purchaser as the Beneficiary;</p> <p>(iv) four copies of the packing list identifying contents of each package;</p> <p>(v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;</p> <p>(vi) one original of the Supplier's Certificate of Origin covering</p>

	<p>all items supplied;</p> <p>(vii) One original and six copies of a protocol (certificate of analysis) of a product test per batch conducted by the laboratory of the manufacturer.</p> <p>(viii) other procurement-specific documents required for delivery/payment purposes</p> <p>(ix) One original and one copy of the certificate of quality control test results <u>per batch</u>, in conformity with the World Health Organization “Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade” stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods. These tests shall be conducted by respective laboratories that</p> <p>(a) Are accredited in accordance with ISO/IEC 17025 or EN 45002.</p>
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12. Insurance (GCC Clause 12)

GCC 12.1	The Insurance shall be in an amount equal to 110 percent of the DDP value of the goods from “warehouse” to “warehouse” on “All Risks” basis, including War Risks and Strikes, and must be valid for 120 days following the date of delivery to the place of destination mentioned in the TDS
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14. Incidental Services (GCC Clause 14)

GCC 14.1	<p>Incidental services to be provided:</p> <p>The Supplier shall provide all necessary licenses and permissions for use of the Goods in the Purchaser’s country that may be required for the Goods. The cost shall be deemed included in the Contract Price.</p>
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15. Warranty (GCC Clause 15)

GCC 15.4	The period for the replacement of defective goods is twelve (12) weeks
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16. Payment (GCC Clause 16)

GCC 16.1 & 16.4	<p>The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:</p> <p>Payment for Goods supplied from abroad:</p> <p>Payment of foreign currency portion shall be made in the currency of the Contract in the following manner:</p> <p>100% On Delivery & Acceptance: shall be paid within 60 days</p>
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	<p>of delivery to Named place of delivery, and submission of documents specified in GCC Clause 11 including an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser, by direct bank transfer to the Supplier's nominated bank account.</p> <p>Payment shall be made in Kenya Shilling or Currency of Bid</p> <p>Payment for Goods and Services supplied from within the Purchaser's country:</p> <p>Payment for Goods and Services supplied from within the Purchaser's country shall be made in the currency of the contract as follows:</p> <p>100% On Delivery & Acceptance: shall be paid within 60 days of delivery to Named place of delivery, and submission of documents specified in GCC Clause 11 including an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser, by direct bank transfer to the Supplier's nominated bank account.</p> <p>Payment shall be made in Kenya Shilling or Currency of Bid</p>
	<p>17.1 Prices (GCC Clause 17.1)</p>
GCC 17.1	<p>(i) Prices quoted should include all costs of shipment and handling until the medical commodities are received at KEMSA.</p> <p>(ii) To facilitate evaluation and comparison, the Procuring entity will convert all bid prices expressed in the amounts in the various currencies in which bid price is payable, to the Kenya shillings using the Central Bank of Kenya (CBK) Rate on the day the bids are opened.</p> <p>(iii) The Procuring entity reserves the right to award the contract in whole or in part without any change in the Unit price or other terms and conditions.</p>
	<p>22. Liquidated Damages (GCC Clause 22)</p>
GCC 22.1	<p>The applicable rate is one-half (0.5) percent per week, the maximum rate is ten (10) percent of the Contract Price.</p>
	<p>27. Settlement of Disputes (GCC Clause 27)</p>
GCC 27.2.2	<p>Clause 27.2.2 (a) shall be retained in the case of a Contract with a foreign Supplier and Clause 27.2.2 (b) shall be retained in the case of a Contract with a national of the Purchaser's country. The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 27.2.2 shall be as follows:</p>

	<p>(i) Contracts with foreign Supplier:</p> <p>GCC 27.2.2 (a)–All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said rules.</p> <p>(ii) Contracts with Supplier national of the Purchaser's country:</p> <p>In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's country.</p>
29. Governing Language (GCC Clause 29)	
GCC 29.1	English language
30. Applicable Law (GCC Clause 30)	
GCC 30.1	The Contract shall be interpreted in accordance with the laws of the Republic of Kenya
31. Notices (GCC Clause 31)	
GCC 31.1	<p>Procurement agent's address</p> <p>Kenya Medical Supplies Authority (KEMSA)</p> <p>Office Address: Kenya Medical Supplies Authority (KEMSA) Commercial Street, Industrial Area Nairobi/Kenya</p> <p>Postal Address: P. O. Box: 47715 00100 Nairobi/Kenya</p> <p>Tel: (+254-0)20-3922000/ 0719033000/ 0733606600 Fax: (+254-0)20-558 100 E-Mail: procurement.programs@kemsaco.ke</p> <p>Supplier's address: Supplier's address:</p>

	33. Inspections and Tests (GCC Clause 33.1)
GCC 33.1	<p>(i) Overseas Bidders shall ensure that all Medical commodities are inspected prior to shipment. Any charges incurred as a result of failure to comply with this requirement shall be borne by the tenderer.</p> <p>(ii) The Purchaser shall analyze all new brands of products, and products that have previously failed quality analysis tests, before confirming an order. The cost of analysis shall be borne by the Tenderer and shall be paid in full prior to analysis.</p>
	33. Inspections and Tests (GCC Clause 33.1)
GCC 33.1	<p>(i) Overseas Bidders shall ensure that all Medical commodities are inspected prior to shipment. Any charges incurred as a result of failure to comply with this requirement shall be borne by the tenderer.</p> <p>(ii) The Purchaser shall analyze all new brands of products, and products that have previously failed quality analysis tests, before confirming an order. The cost of analysis shall be borne by the Tenderer and shall be paid in full prior to analysis.</p>
	33. Replacement of faulty Medical commodities (GCC Clause 33.3)
GCC 33.3	<p>If any item fails to comply with the technical specifications, the Procuring entity shall notify the supplier in writing. The supplier shall within fourteen (14) days, take steps to replace the product in question at its own cost with a fresh batch of acceptable product, or withdraw and give a full refund if the product has been taken off the market due to safety problems</p>
	33. Product Recall (GCC Clause 33.3)
GCC 33.3	<p>In the event any of the Medical commodities are recalled, because of problems with product quality or adverse reactions to the product, the supplier will be obligated to notify the Procuring entity within fourteen (14) days, providing full details about the reason leading to the recall, and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable product, or withdraw and give a full refund if the product has been taken off the market due to safety problems</p>
	33 Handling of rejected Medical commodities (GCC Clause 33.4)

GCC 33.4	<p>(i) Rejected medical commodities shall be collected promptly upon notification and not later than 7 days from date of notification, failure to which demurrage charges shall accrue at a rate of 2% of the total value. The commodities shall be disposed after 21 days at Tenderer's cost.</p> <p>(ii) The Tenderer shall advise The Procuring entity on whether to return rejected medical commodities at Tenderer's cost, to arrange for collection from The Procuring entity, or to destroy in the presence of the Tenderer's agent as witness, at Tenderer's cost</p>
	<p>33. Right to inspect medical commodities after Receipt (GCC Clause 33.5)</p>
GCC 33.5	<p>The Procuring entity may undertake further quality control testing and may reject the whole consignment if the samples tested fail to meet the required standards</p>
	<p>35. Variations in Order Quantities (ITT Clause 37.1)</p>
ITT 35.1	<p>The purchaser reserves the right at the time of initial contract award to increase or decrease the quantity of medical commodities beyond that originally specified in the schedule of Requirements without any change in unit price or other terms and conditions</p>

Appendix 1: Domestic Preferences

DOMESTIC PREFERENCE AND RESERVATIONS

The purchaser will grant a margin of preference and reservation in the evaluation of bids to bidders offering goods manufactured in the country of the purchaser when compared to bids offering such goods manufactured elsewhere. The methods and stages set forth hereunder shall be followed on the evaluation and comparison of bids.

1. Purchaser shall grant exclusive preference to local contractors offering goods manufactured in Kenya (National Reservation). A firm shall be qualified as a local contractor, if it is registered in Kenya. Where goods are not manufactured in Kenya then the Citizen and Local contractors will enjoy exclusive preference.
2. The threshold up to which exclusive preference shall be given to citizen contractors on all procurements using open tender methods shall be the sum of One Hundred million shillings for procurements in respect of goods. A firm shall be qualified as a citizen contractor, if its owners and shareholders are Kenyan citizens.
3. A fifteen percent margin of preference in the evaluated price of the tender shall be given to candidates offering goods manufactured in Kenya (National preference) for goods with values beyond exclusive preference threshold.
4. A margin of preference for goods may be applied depending on the percentage of shareholding of the locals on a graduating scale as follows.
 - (a) Six percent of the evaluated price of the tender, where the percentage of shareholding of the Kenyan citizens is less than twenty percent.
 - (b) Eight percent of the evaluated price of the tender, where the percentage of shareholding of Kenyan citizen is less than fifty one percent but above twenty percent and
 - (c) Ten percent of the evaluated price of the tender where the percentage of shareholding of Kenyan citizens is more than fifty percent.
5. Where citizen contractors have entered into contractual arrangements with foreign contractors, a ten percent margin of preference in the evaluated price of the tender shall be applied.

A bidder shall only be entitled to **ONE** preference or reservation scheme. Where a bidder is entitled to more than one scheme, the scheme with the highest advantage to the bidder will apply.

NOTE: Bidders should provide CR 12 certificate showing shareholding and nationality of shareholders issued by the Registrar of Companies as evidence of eligibility to any of the schemes above.

Section V. Price Schedule

- 1. Price Schedule**
- 2. Schedule of Requirements(Refer to attached Price Schedule)**

Price Schedule for Goods Offered From Abroad

Supply and Delivery of ARV Medicine (Atazanavir 300mg/Ritonavir 100mg)

IFB Number: KEMSA/GOK-CPF/HIV 17/18 - OIT 001

1	2	3	4				5	6	7	8	9	10	
No.	Product Description	UOM	Quantity Offered	Unit Price				TOTAL UNIT PRICE (4a+b+c+d)	TOTAL PRICE (3x5)	Manufacturer	Country of Origin	Delivery Period	Delivery Period offered by Bidder
				(a) Unit Price FOB Port of Loading	(b) Unit Price named place of destination	(c) Inland transport, insurance and other local	(d) Other incidental cost as defined in the SCC						
1	ATAZANAVIR/RITONAVIR 300/100 MG TABLET	PACK OF 30S	540,730									8 to 12 Weeks	

* Note. In case of discrepancy between the unit price and total, the unit price shall prevail.

DDP, Named Final Destination	Grand TOTAL BID PRICE (Sum of Lots)	In Figures	
	Currency	In Words	

Procurement financed under GOK -Counter Part Funding shall be subjected to any custom duties, tariffs, import taxes or similar levies (including VAT) imposed under laws in effect in Kenya

Bidder's Name and Address	Date	Signature and Stamp

Price Schedule for Goods Offered Within The Country

IFB Number: KEMSA/GOK-CPF/HIV 17/18 - OIT 001

Supply and Delivery of ARV Medicine (Atazanavir 300mg/Ritonavir 100mg)											
	1	2	3	4			5	6	7	9	10
No.	Product Description	UOM	Quantity Offered	Unit Price			TOTAL UNIT PRICE (4a+b+c+d)	TOTAL PRICE (3x5)	Manufacturer	Delivery Period	Delivery Period offered by Bidder
				(a) Unit Price Port of Entry	(b) Inland transport, insurance and other local costs incidental to delivery	(c) Other incidental cost as defined in the SCC					
1	ATAZANAVIR/RITONAVIR 300/100 MG TABLET	PACK OF 30S	540,730							8 to 12 Weeks	
Currency		TOTAL PRICE (Sum of Column 6)			In Figures						
					In Words						
DDP, Named Final Destination											
Procurement financed under GOK -Counter Part Funding shall be subjected to any custom duties,tarrifs,import taxes or similar levies (including VAT) imposed under laws in effect in Kenya											
Note. In case of discrepancy between the unit price and total, the unit price shall prevail.											
Currency		Grand TOTAL BID PRICE (Sum of Lots)			In Figures						
					In Words						
Bidder's Name and Address				Date				Signature and Stamp			

Remarks

General Technical Specifications

Pharmaceuticals

1. General Technical Specifications

2. Technical Specifications

3. General Packing Instructions

Technical Specifications

No.	International Non-Proprietary name (INN)	Formulation and Strength	Packaging	Additional requirements
1.	Atazanavir/Ritonavir 300/100mg	Fixed Dose Combination Tablets 300/100mg	Pack of 30's	Film coated

Note:

1. Product and Manufacturing Site must be WHO prequalified/SRA approved.
2. Should be accompanied by the following in the technical tender: the WHO Prequalification reference number and/or proof of registration by a stringent regulatory authority and/or USFDA approval/ tentative approval reference number.
3. Should adhere to Good manufacturing Practices (GMP) standards set out by the WHO in all respects for manufacturing, packaging and labeling of products
4. Must provide Current Manufacturing License
5. Current Certificate of Analysis
6. Must provide Valid Registration and retention certificates or application for retention with QR code from the Kenya Pharmacy and Poisons Board (PPB).
7. Must provide product insert in English
8. Primary and Secondary packages should have;
 - a) Generic name or INN (International Non-propriety Name)
 - b) Brand Name
 - c) Presentation, strength, quantity in each container
 - d) Manufacturer's Name and Address (Manufacturer's site as approved by WHO must be clearly indicated on the primary package)
 - e) Batch Number;
 - f) Date of Manufacture and date of Expiry;
 - g) Content per pack
 - h) Instructions for use
 - i) The phrase "Keep out of the reach of children"
 - j) Special storage requirements
 - k) Any cautionary statement
9. Submit product sample for evaluation

These specifications describe the basic requirements for Medical commodities. Bidders are requested to submit with their offers the detailed specifications and **Samples** for the products they intend to supply.

The Bidders are requested to present information along with their offers indicating the shortest possible delivery period of each product.

Particulars

1. Qualifications of Manufacturers.

The Tenderer shall provide copies of all certificates and documents issued by the proper National Authorities, that the Manufacturer of the pharmaceuticals and medical supplies proposed is authorised to manufacture and sell these products.

2. Appraisal

A manufacturer, who has not dealt with the Procuring entity in the past must provide evidence of certification by an internationally recognized authority (e.g. Food Drug Authority, WHO or similar organizations) or be subject, at the Manufacturer's expense, to inspection by a competent authority designated by the Procuring entity in conjunction with the national regulatory authority.

3. Documentary Evidence

3.1 Bidders must provide the following documentary evidence of the Tenderer's qualifications to perform the Contract in support of their bid;

- (i) That in the case of a bidder offering to supply Medical commodities under the Contract that the Tenderer manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder:
 - (a) Is incorporated in the country of manufacture of the Medical commodities
 - (b) Has been licensed by the regulatory authority in the country of manufacture to supply the medical commodities
 - (c) Has received satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce. Where the Kenyan Regulatory Authority has inspected the site their findings shall super cedes any other findings by other regulatory authorities.
 - (d) For Disinfectants, Topical Preparations and Antiseptics, bidders must submit valid certificates of quality issued by recognized authorities.

- (e) Has manufactured and marketed specific goods for at least two (2) years and similar goods for at least five (5) years.
- (ii) That, in the case of a Tenderer offering to supply Medical commodities under the Contract that the Tenderer does not manufacture or otherwise produce,
 - (a) That the Tenderer has been duly authorized by a manufacturer of the Medical commodities that meets the Criteria under (i) above to supply the Medical commodities in Kenya, and
 - (b) That the Tenderer has been duly authorized by a manufacturer of the Medical commodities that meets the Criteria under C above
 - (c) That the Tenderer has a Good Distribution Practice (GDP) certificate where appropriate
 - (d) In the case of Pharmaceutical and allied Medical commodities, that
 - (i) The Tenderer has a Superintendent Pharmacist. Please submit personal identification of the same.
 - (ii) That the Tenderer's premises have been registered by the National Regulatory Authority.

4. Certificates

- 4.1 All certificates granted to distributors and or manufacturers from the country of origin or/and recognized regulatory authorities should be valid and clear.
- 4.2 Good manufacturing practice should be issued by the national competent authority of the country of origin or a recognized regulatory authority as communicated in the WHO certification scheme on the quality of pharmaceutical products moving in the international commerce. Where the Kenyan Regulatory Authority has inspected the site their findings shall supercede any other findings by other regulatory authorities.
 - 4.2.1 The certificate of Good manufacturing practice should indicate
 - a) That the manufacturer has been approved and registered by the National Health Authority as a manufacturer of pharmaceutical drugs
 - b) The types of pharmaceutical dosage forms approved for manufacture
 - c) That the manufacturing plant in which the products are produced is subject to inspection at regular intervals.

- d) That the manufacture conforms to requirements of good manufacturing and quality control as recommended by WHO in respect of products to be sold or distributed in the country of origin or to be exported.
- e) The date the certificate is issued and the period of its validity.

4.3 All certificates indicated above and all other technical documents required to qualify for the tender participation should be submitted together with the bid on or before the closing date. Any bid not accompanied by the certificates shall be rejected as non-responsive

5. Standards of Quality Assurance for Supply.

5.1 All products must:

- a) Be manufactured in conformity with the latest edition of British, International, United States, French or European Pharmacopoeia. If the product is not included in the specified Compendia, the Bidder upon being awarded the order must provide the reference standards and testing protocols to allow for Quality Control.
- b) Be manufactured in accordance with Good manufacturing Practices (GMP).
- c) Be registered by the Kenya Pharmacy & Poison's Board, and the registration status must be current.
- d) Meet the requirements of manufacturing legislation and regulation of pharmaceutical and medical products in the country of Origin;
- e) Be certified by a competent authority in the manufacturer's country according to resolution WHO 28-65B, of the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce"¹.
- f) Conform to all the specifications contained herein; and

5.2 In case of new bidders to the procuring entity who succeed to win an item or more in price and other preliminary evaluation parameters, the procuring entity reserves the right to send samples to the National Quality Control laboratory or other competent laboratory for quality control test. In such cases, the bidder shall cover the expense up on request by the procuring entity.

5.3 The successful Bidder will be required to provide to the Procuring entity:

- a) Batch certificates for each batch of drugs supplied

- b) With each consignment, a certificate of quality assurance test results in conformity with the WHO Certification Scheme concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit and other tests, as applicable to the product being supplied and Section C of these Specifications.
- c) Assay methodology of any or all tests if requested.
- d) Evidence of bio-availability and/or bio-equivalence for certain critical pharmaceuticals or vaccines upon request
- e) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.
- f) Ensure that Medical commodities arrive at the port of entry (for imported pharmaceuticals or vaccines) or ex-factory (for local purchases) with a remaining shelf life of at least five sixths (5/6ths) of the total stipulated shelf life for medical commodities with a shelf life of more than two years and three-fourths (3/4) of the total stipulated shelf life for medical commodities with a shelf life of two years or less.
- g) On request, make available samples and studies showing bioavailability and stability, especially stability under conditions of high temperature and humidity.

5.4 Certificates of analysis should:

- (a) Be written/translated in English Language
- (b) Bear the letter head of the manufacturer or accredited laboratory as stated on the Tenderer's quotation.
- (c) Indicate the Pharmacopoeia Standard used for analysis
- (d) Have the products generic (non-proprietary) name, strength and unit pack conspicuously displayed on the certificate.
- (e) Have actual values of test results indicated against each test. A general indication of the word "complies" or "conforms" is not sufficient.

5.5 The Procuring entity shall reject drugs delivered without a VALID analysis certificates as described in 4.1 (e) and 4.3 above.

5.6 The analysis of tablets and capsules must include dissolution test if the test is specified in any of either EUR P /BP/USP/International Pharmacopoeia, irrespective of the particular pharmacopoeia standard used for analysis.

5.7 The successful Bidder will also be required to provide the Procuring entity with access to its manufacturing facilities to inspect its facilities, quality control

procedures for raw materials, test methods, in-process tests, and finished dosage forms.

6. Product information

6.1 The Pharmaceuticals and Vaccines to be purchased by the Procuring entity under this invitation for bids are included in the Procuring entity's National Essential Drugs list or National Formulary. 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.")

6.2 Only tropical formulations and packages should be supplied. All products supplied should remain stable within the product's shelf life. The Procuring entity reserves the right to reject medical commodities that are not suitable for the tropical climate. The product should be stable at control room temperature up to 30°C through out the shelf life. This needs to be substantiated with real time stability data.

6.3 Product Specifications indicate dosage form (e.g., tablet, liquid, injectable, emulsion, suspension, etc), and the drug content (exact number of mg or % v/v with acceptable range). The product should conform to standards specified in one of the following compendia: the British Pharmacopoeia, the United States Pharmacopoeia, the French VIPAL Pharmacopoeia or the International Pharmacopoeia. In case the Pharmaceutical or Vaccine product is not included in the specified compendium, the Supplier, upon award of the contract, must provide the reference standards and testing protocols to allow for quality control testing.

6.4 The following information will be required, when applicable, for each product offered by the tenderer:

- (i) Generic name or INN (International Non-propriety Name)
- (ii) Presentation, strength, quantity in each container
- (iii) Country of origin, name and address of the Manufacturer
- (iv) Pharmacopoeia or other applicable compendia standards
- (v) Shelf life

Failure to include any of this information may, at the discretion of the Procuring entity, disqualify the bid.

7. Packaging Specifications:

7.1 General

7.1.1 Not only the Pharmaceutical or Vaccine item, but also the packaging components (e.g., bottles and closures) should meet specifications suitable

for use in a climate similar to that prevailing in the country of Procuring entity. All packaging must be properly sealed and tamper-proof.

- 7.1.2 The successful bidder shall provide such packing of the Medical commodities as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Medical commodities' final destination and the absence of heavy handling facilities at all points in transit.
- 7.1.3 Whenever plastics are used as packing for I.V. Fluids
- 7.1.4 Type of plastics used should be clearly indicated in the offer and standards certificates relating to their properties.
- 7.1.5 Certificate of quality control for sterility, Pyrogenicity, Acute toxicity and physicochemical test.
- 7.1.6 Method of analysis of the same accompanied with the samples, if different method of analysis is used than indicates in USP or BP, should be submitted along with the offer
- 7.1.7 Light-sensitive pharmaceuticals must be packed in containers that allow maximum protection from light. Labels on the containers should bear "Protect from Light"
- 7.1.8 Packing should be suitable to resist heat & humidity at the port of embarkation for:-
 - Humidity up to 12-100%
 - Temperature up to 50o C
- 7.1.9 All plastic and glass containers should be of Pharmaceutical Grade and should meet the parameters in BP or USP for containers.

8. Specific

The following are some of the packing conditions for the tender:-

8.1 Infusions

For all plastic containers a study at least covering sterility, pyrogenicity, acute toxicity, and physicochemical test should accompany the offer during the supply of the products. The concentration of electrolytes shall be stated on the label in mill equivalents (meq).

The label of the product shall also indicate the quantity of ingredients in terms of weight or percentage concentration.

8.2 Ampoules and Vials

Ampoules must be packed in rigid paperboard boxes, strong enough to resist crushing during transportation in units of 5, 10 or similar multiples.

8.3 Topical Preparations

Content with less than 50gm in leak-proof collapsible metallic or plastic tube, for volumes above 50gm in aluminum foil or plastic jars with close fitting caps or slip on lids

8.4 Elixir Oral Suspension & Syrup

Pilfer proof cap amber colored glass or non-transparent plastic bottles, with measuring spoon wherever applicable, packed in well-padded strong carton. Bottles of powder for oral suspension should have a clear marking to show the required volume. The cap and wad on every bottle should be watertight and leak proof.

8.5 Tablets, Capsules

Tablets should be packed in suitable polythene bags or blister pack laminated aluminum strips, packed in well closed and light resistant containers of appropriate size. The containers should be tamper-proof and sealed.

9. Packaging of Products

Items should be packaged as follows:

- (i) 100 ml bottles, not more than 100 per carton
- (ii) 200 ml bottles, not more than 50 per carton
- (iii) 500 ml bottles, not more than 24 per carton
- (iv) 1.0 l bottles, not more than 12 per carton
- (v) 2.5 l bottles, not more than 6 per carton
- (vi) 5.0 l bottles, not more than 4 per carton
- (vii) For ear- and eye drops a maximum of 24 should be packed in each carton and the box must be partitioned if the contents are more than 6.

Specifications for plastic containers used shall be as follows:

- 5 Litre Jerry can- High Density

- 2 Litre Jerry can- High Density
- 1 Litre jerry can- High Density

1. Tertiary Packing

- 10.1 Tertiary packing shall be undertaken in Heavy Duty five-ply cartons, **(175K/B/175K/C/175K)** duly labeled and marked. The shapes of the cartons must be consistent and complementary to allow stacking.
- 10.2 The cartons must have consistent dimensions of length, width and height. The cartons must contain polyethylene sheets inside to ensure that water does not seep through.
- 10.3 The size of the carton should be proportional to its content, with the addition of appropriate padding to prevent damage to the product during transport.
- 10.4 All carton flaps must be properly secured and sealed with special repackers gum paper tapes. Two strong plastic strappings should be tied around the carton properly bound by a machine and stapled tightly.
- 10.5 To facilitate manual loading and off-loading, the dimensions of each carton should not exceed 610mm x 460mm x 355 mm. The Gross weight of each packed carton should not exceed 35kg

11 Labeling Instructions.

11.1 The Label for each pharmaceutical and vaccine products shall meet the W210 GMP standard and include:

- l) The INN or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name.
- m) The active ingredient "per unit, dose, tablet or capsule, etc."
- n) The applicable pharmacopoeia standard
- o) The Procuring entity's logo and code number if required in the special conditions of these Specifications.
- p) Content per pack
- q) Instructions for use
- r) The phrase " Keep out of the reach of children"
- s) Special storage requirements
- t) Batch number
- u) Date of manufacture and date of expiry (in clear language, not code)
- v) Name and address of manufacturer (Manufacturer's site approved by WHO must be clearly indicated)
- w) Any cautionary statement.

11.2 All labeling and packaging inserts shall be in English.

11.3 All outer cartons should be labeled as follows:

**GOVERNMENT OF KENYA
TENDER NO. – KEMSA/GOK – CPF/HIV 17/18 – OIT 001
KENYA MEDICAL SUPPLIES AUTHORITY
COMMERCIAL STREET
P. O. BOX 47715-00100
NAIROBI**

11.4 Pharmaceuticals and vaccines requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.

11.5 The outer case or carton should also display the above information.

12 Case Identification.

12.1 All cases should prominently indicate the following:

- a) Procuring entity's Name and Address
- b) The generic name of product
- c) The dosage form (tablet, ampoule, syrup);
- d) Date of manufacture and expiry
- e) Batch number
- f) Quantity per case
- g) Package Number
- h) Special instructions for storage;
- x) Name and address of manufacture;(manufacturer (Manufacturer's site approved by WHO must be clearly indicated)
- i) Gross weight and net weight in kilograms
- j) The legends: " Top, do not turn over " Handle with Care" ...etc
- k) Any additional cautionary statements.

12.2 No case should contain pharmaceutical or vaccine products from more than one batch.

13 Unique Identifiers

13.1 "GOK- MOH Not for Sale" shall be extensively and conspicuously imprinted on the primary, secondary and tertiary packaging of products to be supplied to the procuring entity.

14 Bar coding Requirements For All Kemsal Medical Supplies (Application of International Barcoding Standards)

Section A

Primary packaging (Item level and Mono carton level)

- a) GS1 Linear-'barcode Symbology,(EAN-13/UPC-A/EAN-8)'to encode GTIN (Global Trade Identification Number) within the barcode,
or
- b) GS1 Data Matrix symbology to encode 14 digits product code (GTIN-14) within the Barcode and using (01) Application Identifier (To be used where printing space is extremely limited)

Examples of the same are reproduced at Annexure "A"

All other human readable Information on product packaging shall be as required under Existing Regulatory labeling & marking requirements

Section B.

Secondary Level Packaging

1. Product Identification Code (GTIN-14 of secondary pack) using Application Identifier (01)
2. Expiry date in YYMMDD format using Application Identifier (17)
3. Batch/Lot Number using Application Identifier (10)

GS1-128 barcode symbology to be used to generate the barcode, Examples of the same are reproduced at Annexure "B"

All other human readable Information on product packaging shall be as required under existing Regulatory labeling & marking requirements.

Section C

Tertiary level packaging (Pallet level packaging)

At Shipper/Pallet level packaging, a single label containing two barcodes needs to be generated and stickered. The barcode will encode the following information;

The first barcode will contain the 'following information.

1. Product Identification Code (GTIN-14 or shipper level pack) using Application Identifier (01)
2. Expiry Date in YYMMDD format using Application Identifier (17)
3. Batch/Lot Number using Application Identifier (10)

The second barcode will contain the following information;

1. SSCC (Serial Shipping Container Code) using Application Identifier (00)

Examples of the same are reproduced at annexure "C".

All other human readable Information on product packaging shall be as required under existing Regulatory labelling & marking requirements,

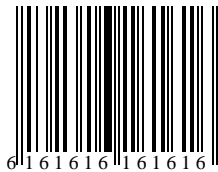
ANNEXURE "A"

Example of Primary Level Packaging

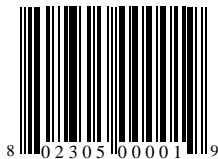
For generation of GS1 barcode at primary level packaging either of the mentioned symbologies can be used, following GS1 General Specifications

The following GS1 barcode symbologies are available as options:

1. The bar code sample of EAN-13 bar code symbology encoding GTIN -13



2. The bar code sample UPC - A bar code symbology encoding GTIN - 12

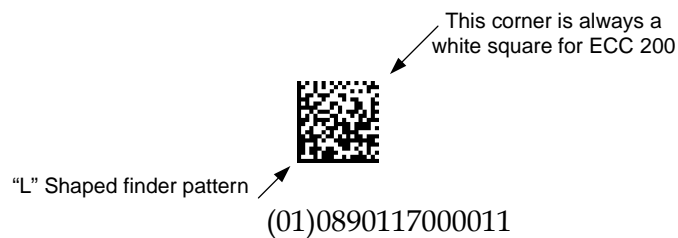


Note: Both GTIN-13 and GTIN - 12 are in extensive use worldwide.

3. The bar code sample for EAN - 8 bar code symbology encoding GTIN - 8 (Used where printing space is a constraint)



4. The bar code sample for GS1 Data Matrix barcode symbology encoding GTIN - 14 (used where printing space is extremely limited)

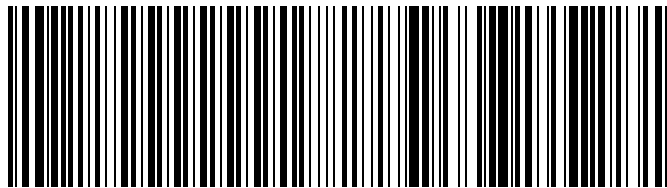


Annexure "B"

Example of Secondary Level Packaging

The bar code will encode:

- 1) Product identification (GTIN-14 of secondary pack) using application identifier (01)
- 2) Expiry Date in YYMMDD format using application identifier (17)
- 3) Batch/Lot Number using application identifier (10)



(00)06161616161616(17)100410(10)ab12345

Annexure "C"

Example of Tertiary Level Packaging (Shipper Level Packaging)

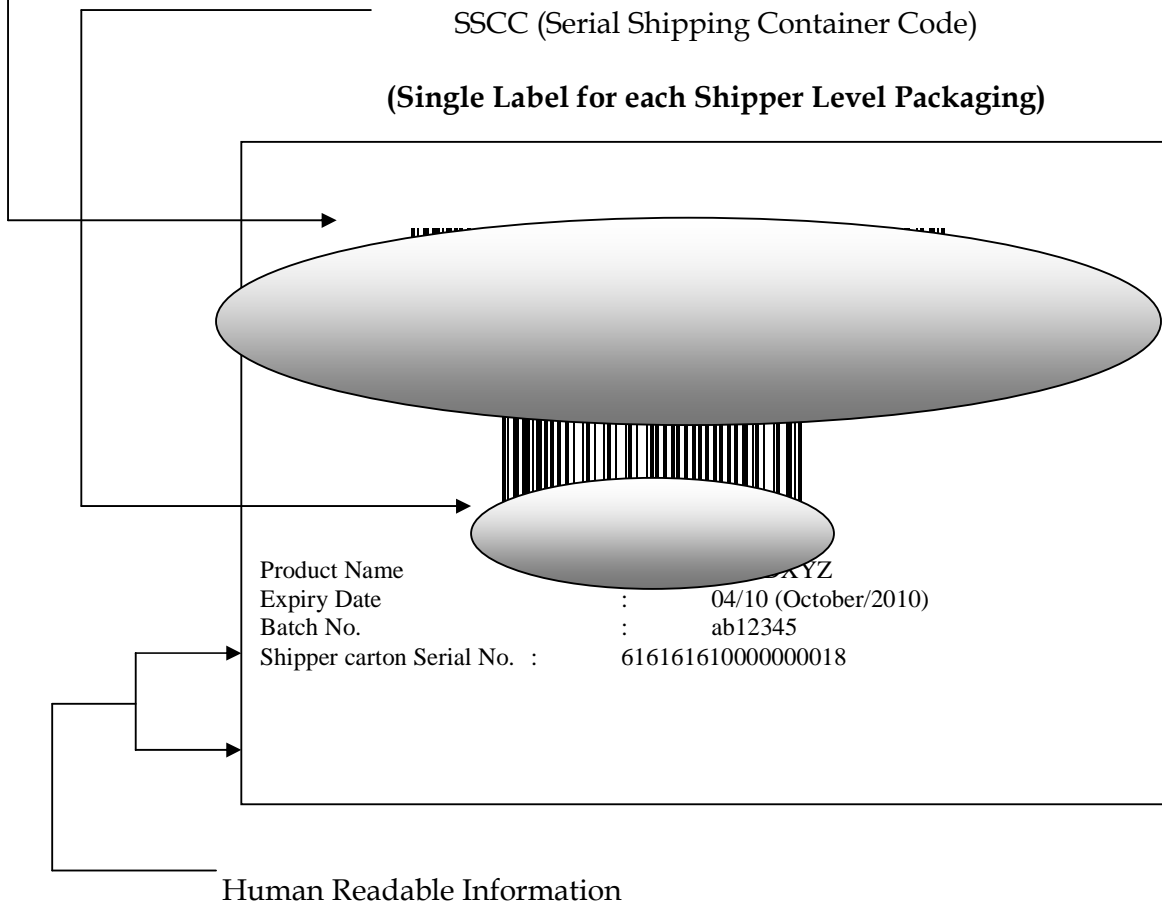
The first bar code will encode the following:

- 1) Product identification (GTIN - 14 of Shipper Pack) using application identifier (01)
- 2) Expiry Date in YYMMDD format using application identifier (17)
- 3) Batch/Lot Number using application identifier (10)

The second bar code will encode the following:

SSCC (Serial Shipping Container Code)

(Single Label for each Shipper Level Packaging)



Complete details on GS1 standards along with technical guidelines are available at www.gs1kenya.org or www.gs1.org

15 Sample

15.1 A Properly labeled non-returnable sample of each item quoted must be delivered to Kenya Medical Supplies Authority on or before closing of the tender at 10.00 a.m. on **29th November, 2017** The sample must be of the required pack size as indicated in the schedule of requirements.

15.2 The sample including literature should be submitted in their normal or usual commercial packing as registered by the Kenya Pharmacy and Poison's Board, and should be labeled in English. The sample must be a true representative of the product tendered for.

15.3 Bidders who submit two different samples for any given item will have their samples disqualified.

16 Product Specifications

All specifications stated in the tender and confirmed in the contract must be adhered to, i.e. stated strength, pack size, manufacturer, labeling and markings, etc. The Procuring entity may in exceptional circumstances approve change of manufacturer of the items to be supplied.

Section VII. Sample Forms

Sample Forms

1. **Tender Form**
2. **Tender Security Form**
3. **Insurance Tender Security Form**
4. **Form of Contract Agreement**
5. **Performance Security Bank Guarantee**
6. **Manufacturer's Authorization Form**
7. **Declaration of Undertaking (Integrity Statement)**
8. **Supplier Data Record**

1. Form of Tender

IFT N°.: KEMSA/GOK – CPF/HIV 17/18 – OIT 001

Supply and Delivery of ARV Medicines – (Atazanavir 300mg/Ritonavir 100mg)

To: Kenya Medical Supplies Authority (KEMSA)
13 Commercial Street, Industrial Area
P.O. Box 47715-00100
Nairobi, Kenya;

Dear Sir or Madam,

- 1. Having examined the tender documents including Addenda Nos.....[Insert numbers] the receipt of which is hereby duly acknowledged, we, the undersigned, offer to Supply and Delivery of ARV Medicines – (Atazanavir 300mg/Ritonavir 100mg)
2. in conformity with the said tender documents for the sum of [Insert: Total tender amount in words and figures]
or such other sums as may be ascertained in accordance with the Schedule of Prices attached herewith and made part of this Tender.
3. We undertake, if our Tender is accepted, to deliver the goods in accordance with the delivery schedule specified in the Schedule of Requirements.
4. If our Tender is accepted, we will obtain the guarantee of a bank in a sum equivalent to 10% Percent of the Contract Price for the due performance of the Contract, in the form prescribed by Kenya Medical Supplies Authority (KEMSA).
5. We agree to abide by this Tender for a period of 90 days from the date fixed for tender opening of the Instructions to Bidders, and it shall remain binding upon us and may be accepted at any time before the expiration of that period.
6. Until a formal Contract is prepared and executed, this Tender, together with your written acceptance thereof and your notification of award, shall constitute a binding Contract between us.
7. We understand that you are not bound to accept the lowest or any tender you may receive.

Dated this day of 20.....

Signed.....

In the capacity of [insert: title or position].....

Duly authorized to sign tender for and on behalf of [insert: name of tenderer]

2. Tender Security Form

IFT N°.: KEMSA/GOK – CPF/HIV 17/18 – OIT 001

Supply and Delivery of ARV Medicines – (Atazanavir 300mg/Ritonavir 100mg)

**To: Kenya Medical Supplies Authority (KEMSA)
13 Commercial Street, Industrial Area
P.O. Box 47715-00100
Nairobi, Kenya;**

WHEREAS *[insert: **name of Tenderer**]* (hereinafter called “the Tenderer”) has submitted its tender dated *[insert: **date of tender**]* for the performance of the above-named Contract (hereinafter called “the Tender”)

KNOW ALL PERSONS by these present that WE *[insert: **name of bank**]* of *[insert: **address of bank**]* (hereinafter called “the Bank”) are bound unto *[insert: **name of Purchaser**]* (hereinafter called “the Purchaser”) in the sum of: *[insert: **amount**]*, for which payment well and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents.

Sealed with the Common Seal of the said Guarantor this *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*.

THE CONDITIONS of this obligation are:

1. If after tender opening the tenderer withdraws his tender during the period of tender validity specified in the instructions to tenderers or
2. If the tenderer rejects the correction of an error upon prompt notice by the procuring entity and
3. If the tenderer, having been notified of the acceptance of his tender by the employer during the period of tender validity:
 - a) Fails or refuses to execute the form of agreement in accordance with the instructions to tenderers if required or
 - b) Fails or refuses to furnish the Performance Security, in accordance with instructions to tenderers

We undertake to pay to the Procuring Entity up to the above amount upon receipt of its first written demand, without the Procuring Entity having to substantiate its demand, provided that in its demand the Procuring Entity will note that the amount claimed by it is due to it, owing to the occurrence of one or both of the two conditions specifying the occurred condition or conditions.

This guarantee will remain in full force up to and including **thirty (30) days** after the period of tender validity and any demand in respect thereof should reach the Guarantor not later than the above date.

Signature of the Guarantor..... **Date**:.....

(Witness) **Date**:.....

Common Seal of the Bank

3. Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

the [insert: **number**] day of [insert: **month**], [insert: **year**].

BETWEEN

- 1 THIS AGREEMENT made the _____ day of _____ 20____ between.....[*name of Procurement entity*] of.....[*country of Procurement entity*] (hereinafter called “the Procuring entity”) of the one part and [insert: **name of Tenderer**], a corporation incorporated under the laws of [insert: **country of Tenderer**] and having its principal place of business at [insert: **address of Tenderer**] (hereinafter called “the Supplier”).
- 2 WHEREAS the Procuring entity invited tenders for certain goods and ancillary services, viz., [insert: **brief description of goods and services**] and has accepted a tender by the tenderer for the supply of those goods and services in the sum of [insert: **contract price in words and figures**] (hereinafter called “the Contract Price”).

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

- 2.4.1 In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
- 2.4.2 The following documents shall constitute the Contract between the Purchaser and the Tenderer, and each shall be read and construed as an integral part of the Contract:
 - (a) This Contract Agreement
 - (b) Special Conditions of Contract
 - (c) General Conditions of Contract
 - (d) Technical Requirements (including Functional Requirements and Implementation Schedule)
 - (e) The Supplier’s tender and original Price Schedules
 - (f) The Purchaser’s Notification of Award
 - (g) The Supplier’s Acceptance letter
 - (h) [Add here: **any other documents**]
3. In consideration of the payments to be made by the Procuring Entity to the Tenderer as hereinafter mentioned, the Tenderer hereby covenants with the Procuring Entity to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

The Procuring Entity hereby covenants to pay the Tenderer in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

For and on behalf of the Procuring Entity

Signed: _____
in the capacity of [insert: **title or other appropriate designation**]

in the presence of _____

For and on behalf of the Tenderer

Signed: _____
in the capacity of [insert: **title or other appropriate designation**]

in the presence of _____

CONTRACT AGREEMENT

dated the [insert: **number**] day of [insert: **month**], [insert: **year**]

BETWEEN

[insert: **name of Procuring Entity**], “the Purchaser”

and

[insert: **name of Tenderer**], “the Supplier”

4. Performance Security Bank Guarantee (unconditional)

IFT N°.: KEMSA/GOK – CPF/HIV 17/18 – OIT 001

Supply and Delivery of ARV Medicines – (Atazanavir 300mg/Ritonavir 100mg)

**To: Kenya Medical Supplies Authority (KEMSA)
13 Commercial Street, Industrial Area
P.O. Box 47715-00100
Nairobi, Kenya;**

We refer to the Contract Agreement (“the Contract”) signed on [*insert: **date***] between you and [*insert: **name of Tenderer***] (“the Supplier”) concerning the supply and delivery of [*insert: **a brief description of the Goods***]. By this letter we, the undersigned, [*insert: **name of bank***], a bank (or company) organized under the laws of [*insert: **country of bank***] and having its registered/principal office at [*insert: **address of bank***], (hereinafter, “the Bank”) do hereby jointly and severally with the Tenderer irrevocably guarantee payment owed to you by the Tenderer, pursuant to the Contract, up to the sum of [*insert: **amount in numbers and words***]. This guarantee shall be reduced or expire as provided for by GCC Sub-Clause 8.4.

We undertake to make payment under this Letter of Guarantee upon receipt by us of your first written demand signed by your duly authorized officer declaring the Tenderer to be in default under the Contract and without cavil or argument any sum or sums within the above-named limits, without your need to prove or show grounds or reasons for your demand and without the right of the Tenderer to dispute or question such demand. Our liability under this Letter of Guarantee shall be to pay to you whichever is the lesser of the sum so requested or the amount then guaranteed under this Letter in respect of any demand duly made under this Letter prior to expiry of this Letter of Guarantee, without being entitled to inquire whether or not this payment is lawfully demanded.

This Letter of Guarantee shall be valid from the date of issue until the date of expiration of the guarantee, as governed by the Contract. Except for the documents herein specified, no other documents or other action shall be required, notwithstanding any applicable law or regulation. Our liability under this Letter of Guarantee shall become null and void immediately upon its expiry, whether it is returned or not, and no claim may be made under this Letter after such expiry or after the aggregate of the sums paid by us to you shall equal the sums guaranteed under this Letter, whichever is the earlier. All notices to be given under this Letter shall be given by registered (airmail) post to the addressee at the address herein set out or as otherwise advised by and between the parties hereto.

We hereby agree that any part of the Contract may be amended, renewed, extended, modified, compromised, released, or discharged by mutual agreement between you and the Tenderer, and this security may be exchanged or surrendered without in any way impairing or affecting our liabilities hereunder without notice to us and without the necessity for any additional endorsement, consent, or guarantee by us, provided, however, that the sum guaranteed shall not be increased or decreased.

No action, event, or condition that by any applicable law should operate to discharge us from liability hereunder shall have any effect, and we hereby waive any right we may have to apply such law, so that in all respects our liability hereunder shall be irrevocable and, except as stated herein, unconditional in all respects.

For and on behalf of the Bank

Signature of the Guarantor..... Date:.....

(Witness)Date:..... Common Seal of the Bank

5. Manufacturer's Authorization Form

(Must be on Manufacturer's or Producer's letterhead)

**To. Kenya Medical Supplies Authority
13 Commercial Street, Industrial Area
P.O Box 47715-00100
Nairobi, Kenya**

Dear Sirs,

WHEREAS [*insert: name of the manufacturer or producer*] (hereinafter, "we" or "us") who are established and reputable manufacturers or producers of [*insert: name and/or description of the Goods requiring this authorization*] (hereinafter, "Goods") having production facilities at [*insert: address of factory*] do hereby authorize [*insert: name and address of Tenderer*] (hereinafter, the "Tenderer") to submit a tender, and subsequently negotiate and sign the Contract with you against IFT N^o.: **KEMSA/GOK – CPF/HIV 17/18 – OIT 001 for Supply and Delivery of ARV Medicines – (Atazanavir 300mg/Ritonavir 100mg)** including the above Goods produced by us.

We hereby extend our full guarantee and warranty for the above specified Goods against these tender documents.

For and on behalf of the Manufacturer or Producer

Signed: _____

Date: _____

In the capacity of [*insert: title, position, or other appropriate designation*] and duly authorize to sign this Authorization on behalf of [*insert: name of manufacturer or producer*]

NOTE: Manufacturer's Authorization must be ON LETTER HEAD and addressed to KEMSA and must be tender and item specific and signed by an authorized signatory. - MANDATORY

6. Declaration of Undertaking (Integrity Statement)***Ethics and Anti – Corruption Policy in the Procurement Process*****Undertaking by Bidder on Anti – Corruption Policy / Code of Conduct and Compliance Programme**

The governments of Kenya is committed to fighting corruption in all its forms and in all its institutions to ensure that all the government earned revenues are utilized prudently and for the purpose intended with a view to promoting economic development as the country work towards actualizing Vision 2030.

Kenya Medical Supplies Authority (KEMSA) is a state corporation under the Ministry of Health established under the KEMSA Act 2013 to procure, warehouse and distribute drugs and medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals in Kenya, on behalf of the government, we are highly committed to fighting any form of corruption in our organization to ensure that all the monies that the government entrust with us, is optimally and prudently utilized for the benefits of all the people we serve.

The following is a requirement that every Bidder wishing to do business with KEMSA must comply with:

- (1) Each bidder must submit a statement, as part of the tender documents, in the format given and which must be signed personally by the Chief Executive Officer or other appropriate senior corporate officer of the bidding company and, where relevant, of its subsidiary in Kenya. If a tender is submitted by a subsidiary, a statement to this effect will also be required of the parent company, signed by its Chief Executive Officer or other appropriate senior corporate officer.
- (2) Bidders will also be required to submit similar No-bribery commitments from their subcontractors and consortium partners; the bidder may cover the subcontractors and consortium partners in its own statement, provided the bidder assumes full responsibility.
- (3)
 - a) Payment to agents and other third parties shall be limited to appropriate compensation for legitimate services.
 - b) Each bidder will make full disclosure in the tender documentation of the beneficiaries and amounts of all payments made, or intended to be made, to agents or other third parties (including political parties or electoral candidates) relating to the tender and, if successful, the implementation of the contract.
 - c) The successful bidder will also make full disclosure [quarterly or semi- annually] of all payments to agents and other third parties during the execution of the contract.
 - d) Within six months of the completion of the performance of the contract, the successful bidder will formally certify that no bribes or other illicit commissions have been paid. The final accounting shall include brief details of the goods and services provided that are sufficient to establish the legitimacy of the payments made.
 - e) Statements required according to subparagraphs (b) and (d) of this paragraph will have to be certified by the company's Chief Executive Officer, or other appropriate senior corporate officer.

- (4) Tenders which do not conform to these requirements shall not be considered.
- (5) If the successful bidder fails to comply with its No-bribery commitment, significant sanctions will apply. The sanctions may include all or any of the following:
- a) Cancellation of the contract;
 - b) Liability for damages to the public authority and/or the unsuccessful competitors in the bidding possibly in the form of a lump sum representing a pre-set percentage of the contract value (liquidated).
- (6) Bidders shall make available, as part of their tender, copies of their anti-Bribery Policy/Code of Conduct, if any, and of their-general or project - specific - Compliance Program.
- (7) The Government of Kenya through Ethics and Anti-Corruption Commission has made special arrangements for adequate oversight of the procurement process and the execution of the contract. Those charged with the oversight responsibility will have full access if need be to all documentation submitted by Bidders for this contract, and to which in turn all Bidders and other parties involved or affected by the project shall have full access (provided, however, that no proprietary information concerning a bidder may be disclosed to another bidder or to the public).

MEMORANDUM (FORMAT)

(Clause 41, 62 and 66 of Kenya Public Procurement and Asset Disposal Act 2015)

This company _____ (*name of company*) has issued, for the purposes of this tender, a Compliance Program copy attached -which includes all reasonable steps necessary to assure that the No-bribery commitment given in this statement will be complied with by its managers and employees, as well as by all third parties working with this company on the public sector projects or contract including agents, consultants, consortium partners, subcontractors and suppliers'")"

Authorized Signature: _____

Name and Title of Signatory: _____

Name of Bidder: _____

Address: _____

7. Supplier Data Record

SUPPLIER BUSINESS DETAILS (fill in Block letters)		
Company Name:		
Company Post Office Address:		
Telephone Nos: Office No. ----- Mobile No. ----- _____	Fax No. (with entering your fax no. here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken): _____	e-Mail Address (with entering your e-Mail address here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken): _____
Company Registration Number: 1. Location of business premises ----- 2. Building name and number ----- 3. Floor Number ----- 4. Room number ----- 5. Plot Number ----- 6. VAT Certificate Number ----- 7. Local Authority License Number ----- Expiry Date ----- 8. PIN certificate Number ----- 9. Website if any -----		
When submitting your bid, please ensure that you submit copies of the following documents; 1. Copy of Certificate of incorporation 2. Copy of current Tax Compliance Certificate		
Contact Name:		Job Title:
Telephone No. _____	Fax No. (with entering your fax no. here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken): _____	e-Mail Address (with entering your e-Mail address here you consent that this means of communication will be used for any communication during the tender process and that you will ensure that notice will be taken): _____

Main business activity	
<u>Please NOTE giving false information in this section will lead to outright Disqualification from tendering process.</u>	
Type of organization (please tick as necessary)	
<ol style="list-style-type: none"> 1. Partnership 2. Co-operative 3. Private Ltd. 4. Public Company 5. Other. 	
Type of premises (tick as necessary)	Freehold
<ol style="list-style-type: none"> 1. Factory 2. Warehouse 3. Other. 	Leasehold
Names of executives	
Chairman -----Nationality ----- Shares held -----	
Managing Director -----Nationality ----- Shares held -----	
Company Secretary -----Nationality ----- Shares held -----	
Name of Directors	
1. ----- Nationality ----- Shares held -----	
2. -----Nationality ----- Shares held -----	
3. -----Nationality ----- Shares held -----	
4. -----Nationality ----- Shares held -----	
5. -----Nationality ----- Shares held -----	
Name and address of ultimate holding company and any subsidiary companies	
Total no. of employees in group	No. of locations/premises in group
Member of a Trade Association?	
Details of any Certification e.g. ISO 9000 (attach copies of valid certificates)	
Name product(s) for which you act as an Authorized Dealer / Distributor and attach copies of valid certificates of authority.	
1.	5.
2.	6.
3.	7.
4.	8.

Bidders should only provide documentation for products they are offering to supply in the tender

Bank References and other details

A) Primary Bank (The Main Bank)

- 1) Name: -----
- 2) Postal Address:-----
- 3) Telephone Land line number:-----
- 4) Fax Number: -----
- 5) Email Address:-----

Name of the account: -----

Account number: -----	Number of years operated:-----
-----------------------	--------------------------------

SECONDARY BANKERS (if applicable)

Bank name and address: -----

Name of the account: -----

Account number: -----	Years of operation -----
-----------------------	--------------------------

Commercial References

Provide names and contact details of four customers that have done business with you in the last three years.

A) Trade References - customer 1

Activity: -----	Period of relationship: (Year) -----
-----------------	--------------------------------------

Contact name: ----- -----	Fax no. ----- Email address: -----
Value of contract orders in USD-----	
Telephone No. ----- Physical address; -----	
B) Trade References - Customer 2	
Activity: ----- -----	Period of relationship: (Year) -----
Contact name: ----- -----	Fax no. ----- Email address: -----
Value of contract orders in USD-----	
Telephone No. ----- Physical address; -----	
Trade References - customer 3	
Business Activity: ----- -----	Period of relationship (year) -----
Contact name: -----	Fax no.-----

-----	Email address: -----
Value of contract orders in Kenya Shillings KSHS -----	
Telephone No. Mobile -----	
Telephone Number Land line -----	
Physical address: -----	
Trade References - customer 4	
Business Activity: -----	Period of relationship (year) -----
Contact name: ----- -----	Fax no.----- Email address: -----
Value of contract orders in Kenya Shillings KSHS -----	
Telephone No. Mobile -----	
Telephone Number Land line -----	
Physical address: -----	
SUPPORT SERVICES AVAILABLE	
What after sales / warranty / spare parts / support services / local agent / repair are available? (Please feel free to attach any further supporting information with this form)	
DECLARATION BY THE APPLICANT	
Full names: -----	Job title of signatory:-----
Telephone Number mobile -----	
Telephone No. Land Line -----	
Signature of the applicant.....	Date of application: -----

Please affix company rubber stamp or seal

Section VIII: Evaluation Criteria

A –Preliminary Examination	87
B –Technical Evaluation	87
1) Documents Examination	
2) Product Evaluation	
C – Financial Evaluation	88

A) Preliminary Examination

Tenderers are required to comply with the followings;

1. Must serialize all the pages of the bid documents, failure to which shall lead to disqualification **(MANDATORY)**.
2. Copy of Certificate of incorporation/registration **(MANDATORY)**.
3. Copy of current Tax Compliance Certificate (For local bidders only) **(MANDATORY)**.
4. Tender form duly completed and signed by the tenderer or his authorized agent **(MANDATORY)**.
5. Original Bid Bond provided and valid for 120 days from date of tender opening. Value of bid bond should be **USD 44,500.00 or KES 4,680,000.00** or equivalent in a freely convertible currency **(MANDATORY)**.
6. Declaration of Undertaking (Integrity Statement) must be dully filled and signed **(MANDATORY)**.
7. Dully filled and signed Supplier Data Record **(MANDATORY)**.

NOTE: Failure to comply with Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

B) Technical Evaluation**1) Documents Examination**

- i) Must provide duly signed Manufacturer's Authorization letter (if Tenderer is not a Manufacturer) **(MANDATORY)**.
- ii) Product and Manufacturing Site must be WHO prequalified/SRA approved.**(MANDATORY)**
- iii) Should be accompanied by the following in the technical tender: the WHO Prequalification reference number and/or proof of registration by a stringent regulatory authority and/or USFDA approval/ tentative approval reference number. **(MANDATORY)**.
- iv) Current Good Manufacturing Practice (GMP) Certificate **(MANDATORY)**.
- v) Current Manufacturing License **(MANDATORY)**.
- vi) Current Certificate of Analysis **(MANDATORY)**.
- vii) Must provide Valid Registration and retention certificates or application for retention with QR code from the Kenya Pharmacy and Poisons Board (PPB) **(MANDATORY)**.

NOTE: Failure to comply with Mandatory requirements will lead to disqualification. Only bidders who are successful at this stage will proceed to the next stage of evaluation.

2) Product Evaluation

The technical evaluation will involve the product evaluation, packaging evaluation and labeling evaluation. The evaluation will be based on product type, product form i.e. the physical configuration and shape, product ingredients i.e. content, components and composition, measurements i.e. dimension and weight, elasticity where applicable, absorbency where applicable, texture where applicable and the packaging criteria will be based on securely wrapped, quality of packaging material, unit package, individual package, presence of peel off sign and peel ability (ease of opening the package), presence of tamper-proof seal, Product and Manufacturing Site must be WHO prequalified/SRA approved, while the labeling criteria will be drawn from the technical specifications spelt out in the tender document.

The evaluation will be on a “**Yes/No**” basis.

NOTE: Only bidders who are successful at this stage will proceed to the next stage of evaluation.

C) Financial Evaluation

Tenderers who are successful at preceding stages will have their prices and delivery period compared and award recommended to the lowest evaluated responsive bid.