REPUBLIC OF GHANA

MINISTRY OF HEALTH

PROCUREMENT OF CONTRACEPTIVES

MOH/2019/ICT/B.2.1/02

TENDER DOCUMENTS

INTERNATIONAL COMPETITIVE TENDERING

ECOWAS No: 2014 68 289

FEBRUARY, 2019

Invitation for Tenders (IFT)

REPUBLIC OF GHANA

Ministry of Health

Procurement of Contraceptives

MOH/2019/ICT/B.2.1/02

1. The Government of Ghana has received Funding from the West African Health Organization (WAHO) towards the cost of supporting countries in reducing mother and child mortality in the sub-region and it intends to apply part of the proceeds of this fund to payments under the Contract for Procurement of Contraceptives.

2. The Ministry of Health of the Republic of Ghana now invites sealed tenders from eligible manufacturers or their authorized representatives for the supply of the under-listed contraceptives:

Lot No	Product Description	Dosage form	Strength	Pack Size	Quantity	Delivery
1	**Medroxyprogesterone Acetate (DMPA)**	Injection	150mg/mL	25 vials	55,500	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing
2	**Etonogestrel (Implant)**	rod	68mg	1 set	54,300	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing
3	**Male Condom (MOH Brand)** *Refer to page 105 for foil Artwork*			144 condoms (48 strips of 3)	96,000	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract

						signing
4	**Male Condom (Private Sector Brand)** *Refer to page 105 for foil Artwork*			144 condoms (48 strips of 3)	14,600	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing

3. Tenderers may quote for any one, a combination of lots, or all lots **PROVIDED THEY HAVE REGISTERED THE PRODUCT WITH THE GHANA FOOD AND DRUGS AUTHORITY.** To be responsive, Tenderers shall quote for all items in the required quantities for each lot quoted. Tenderers will be evaluated and a contract awarded on a lot by lot basis. Tenderers who do not offer all the items under a selected lot shall be rejected as incomplete. Delivery shall be within 90 days after **Advance Payment OR within 90 days after contract signing.**

4. Tendering will be conducted through the International Competitive Tendering procedures specified in the Republic of Ghana's Public Procurement Act, 2003, Act 663 as Amended, and is open to all Tenderers from eligible source countries as defined in the Guidelines of the Public Procurement Authority of the Republic of Ghana. **The Invitation for Tender (IFT) will be published in One (1) widely circulated National Dailies, Ghana Public Procurement Authority (PPA) website, dgMarket website, GTAI website, WAHO website**.

5. Tenderers can quote for any number of lots provided the Product is registered with the Ghana Food and Drugs Authority. Evaluation would be on a Lot-by-Lot basis and Tenderers must quote for the required quantities per item in a given Lot and in accordance with the specified pack size. All Tenderers are required to submit with their tenders **SAMPLES of (2 packs/sets each for LOTS 1& 2) and (1500 pieces each for LOTS 3 & 4)** for technical evaluation. Tenders that do not offer the required quantities of samples would be rejected as non-responsive. Tenders that do not offer the complete quantities per item will be rejected as incomplete.

6. Interested eligible tenderers may obtain further information from the Procurement Unit, Room 5 and inspect the tender documents at the address given below (**Paragraph 12**) from **09.00hours to 12.00hours and 14.00hours to 17.00** hours local time each working day.

7. A complete set of Tender Documents in **ENGLISH** may be purchased by interested Tenderers on submission of a written Application to the address below and upon payment of a non-refundable fee of **Two Hundred US Dollars (USD$200.00)** or

(**GHS900.00).** The method of payment will be cash, Bank Draft or direct bank transfer to the account of the Central Medical Stores. The details may be obtained from the address below.

8. The Tender Documents will be sent by courier to interested Tenderers upon an additional payment of **One Hundred US Dollars (US$100.00**) or the equivalent in Ghana Cedis. The documents will be promptly dispatched by courier upon receipt of evidence of payment but no liability can be accepted for loss or late delivery.

9. Sealed tenders must be delivered to the address below on or before **Tuesday, 2nd April, 2019** at **10.00 am, local time**. All tenders must be accompanied by a tender security in US dollars or an equivalent amount in a freely convertible currency of 2% of the tender price. Tender Security must be in the Form of a **Bank Guarantee**. **Insurance Bonds** will not be accepted. Tenders submitted without Tender Securities would be rejected as non-responsive.

10. Late tenders will be rejected. Electronic bidding will not be permitted. Tenders will be opened in the presence of the tenderers' representatives, who choose to attend at the address below on **Tuesday, 2nd April, 2019** at **10.00 am, local time.**

11. As part of the eligibility requirement, all interested manufacturers and suppliers are mandated to register their companies at the online portal of the Ghana Public Procurement Authority available at www.ppaghana.org (Registration fee is US$ 200 for International Firms and 300 Ghana Cedis for Local Firms)

12. The address for purchase of tender documents and submission of tenders is stated below:

THE PROCUREMENT UNIT: ROOM NO. 5
MINISTRY OF HEALTH
28TH FEBRUARY ROAD
NEAR DEPARTMENT OF NATIONAL LOTTERIES
P. O. BOX MB44
ACCRA
Tel.: ***+233*-050 122 8029/ 050 122 8051**
E-mail : **procurementmohghana@gmail.com (queries only)**

----------SIGNED----------
KWAKU AGYEMAN-MANU
HON. MINISTER OF HEALTH

SECTION I. INSTRUCTIONS TO TENDERERS

TABLE OF CLAUSES

Instructions to Tenderers

A. INTRODUCTION

1. Scope of Tender

1.1 The Purchaser, as specified in the **Tender Data Sheet** and in the Special Conditions of Contract (SCC), invites tenders for the supply of the Health Sector Goods as specified in the **Tender Data Sheet** and described in the Schedule of Requirements. The name and identification number of the Contract is provided in the **Tender Data Sheet** and in the SCC.

1.2 Throughout these Tender Documents, the terms "writing" means any handwritten, typewritten, or printed communication, including telex, cable, and facsimile transmission, and "day" means calendar day. Singular also means plural.

2. Source of Funds

2.1 The Purchaser named in the **Tender Data Sheet** shall fund this procurement from part of its budgetary allocation.

3. Fraud and Corruption

3.1 It is the policy of the Government of Ghana (GOG) to require that Procurement Entities, as well as Tenderers/Suppliers/Contractors observe the highest standard of ethics during the procurement and execution of Contracts financed from the public funds of the Republic of Ghana. In pursuance of this policy:

(a) the Government of Ghana defines, for the purposes of this provision, the terms set forth below as follows:

(i) "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; and

(ii) "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; 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 Government of the benefits of free

and open competition.

(b) the Government of Ghana, acting by the appropriate Tender Review Board or the Public Procurement Board and in accordance with Ghana's Public Procurement Act, 2003 (Act 663) 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 Contract in question.

(c) the Government of Ghana acting by the Public Procurement Board will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Contract by any Procurement Entity in the Republic of Ghana if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a public-financed contract in Ghana.

3.2 Furthermore, Tenderers shall be aware of the provision stated in Sub-Clauses 5.4 and 23.1 (d) of the General Conditions of Contract.

3.3 In pursuance of the policy defined in ITT Sub-Clause 3.1, the Government will cancel any Contract for Goods or Works if it at any time determines that corrupt or fraudulent practices were engaged in by either the purchaser or the supplier during the procurement or the execution of that Contract.

4. Eligibility

4.1 Except as provided in ITT Sub-Clauses 4.2 and 4.3, this tendering process is open to:

(a) those prequalified firms from eligible source countries as specified by the Public Procurement Board in the Tender Sheet, where a prequalification process has been undertaken for the Contract(s) for which these Bidding Documents have been issued, or

(b) all firms from eligible source countries, as specified by the Public Procurement Board in the Tender Data Sheet, where a prequalification process has not been undertaken for the contract(s) for which these Bidding Documents have been issued.

The Public Procurement Board maintains a list of countries from which Tenderers, Goods and Services are not eligible to participate in procurement financed from public funds of the

Republic of Ghana. The list is regularly updated and can be obtained from the Board. A joint venture, consortium, or association including a member from an ineligible source country or including an ineligible firm shall not be permitted to tender.

4.2 Firms of a particular country may be excluded from tendering if:

(a) either: (i) as a matter of law or official regulation, the Government of Ghana prohibits commercial relations with that country; or (ii) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Government of Ghana prohibits any import of Goods from that country or any payments to persons or entities in that country.

(b) a firm has been engaged by (i) the Government of Ghana or (ii) the Purchaser or (iii) a Purchasing Agent that has been duly authorized to act on behalf of the Government of Ghana or 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 may participate only if they can establish that they (i) are legally and financially autonomous and (ii) operate under commercial law.

4.3 A firm declared ineligible in accordance with ITT Sub-Clause 3.1 (c) shall be ineligible to tender for a public-financed contract during the period of time determined by the Public Procurement Board.

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 All goods and related services to be supplied under the Contract and financed from public funds of the Republic of Ghana, shall have as their country of origin an eligible source country as defined in clause 4.2 (a) (i) or (ii).

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 at 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 deviations and exceptions to the provisions of the Technical Specifications;

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

6.4 Unless the **Tender Data Sheet** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in the Ghana. A Tenderer who has already registered its Goods by the time of tendering should submit a copy of the Registration Certificate with its tender. Otherwise, the successful Tenderer, by the time of Contract signing, shall submit to the Purchaser either:

(a) a copy of the Registration Certificate of the Goods for use in the Ghana.

OR, if such Registration Certificate has not yet been obtained,

(b) evidence establishing to the Purchaser's satisfaction that the Tenderer has complied with all the documentary requirements for registration as specified in the **Tender Data Sheet.**

6.4.1 The Purchaser shall at all times cooperate with the successful Tenderer to facilitate the registration process within the Ghana. The agency and contact person able to provide additional information about registration are identified in the **Tender Data Sheet.**

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 catalog 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, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the **Tender Data Sheet,** and has a successful performance history in accordance with criteria specified in the **Tender Data Sheet.** 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 Tender Data Sheet, 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 Ghana;

(c) in the case of a Tenderer who is not doing business within Ghana (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 Ghana equipped and able to carry out the Tenderer's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

(d) the Tenderer meets the qualification criteria listed in the **Tender Data Sheet** (see additional clauses of Tender Data Sheet for pharmaceuticals and vaccines).

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 comprise those listed 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.	Eligibility for Public Procurement in Ghana
Section IV.	General Conditions of Contract (GCC)
Section V.	Special Conditions of Contract (SCC)
Section VI.	Schedule of Requirements
Section VII.	Technical Specifications
Section VIII.	Sample Forms (including Contract Agreement)

10.2 The "Invitation for Tenders" does not form part of the Tender Documents and is included as a reference only. In case of discrepancies between the Invitation for Tender 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 (or by electronic mail, telex, or facsimile) at the **Purchaser's** address **indicated in the Tender Data Sheet.** The **Purchaser** will respond **in writing to any request for clarification received no later than fourteen (14) calendar days** prior to the deadline of submission of tenders. Copies of the Purchaser's response shall be sent to all prospective Tenderers who have purchased the Tender Documents, including a description of the inquiry but without identifying its source.

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.

12.2 Any addendum thus issued shall be part of the Tender Documents 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 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 the amendment into account in preparing their tenders, the Purchaser shall extend, at its discretion, the deadline for submission of tenders, in which case, the Purchaser will notify all Tenderers by cable confirmed 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 English language. 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 English**,** in which case, for purposes of interpretation of the Tender, the English translation shall govern.

14. Documents Constituting the Tender

14.1 The tender submitted by the Tenderer shall comprise the following:

(a) duly filled-in Form of Tender and Price Schedule, in accordance with the forms indicated in Section VIII;

(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) a power of attorney, duly authorised by a Notary Public indicating that the person(s) signing the tender have the authority to sign the tender and thus the tender is binding upon the Tenderer;

(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 Paragraph 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 **Tender Data Sheet.**

15. Tender Form

15.1 The Tenderer shall complete the Tender Form and the appropriate 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.

15.2 For the purpose of granting a margin of domestic preference, tenders will be classified in one of three groups, as follows:

(a) **Group A:** Tenders offering Health Sector Goods manufactured in Ghana, for which (i) labour, raw materials, and components from within Ghana account for more than thirty (30) percent of the EXW price; and (ii) the production facility in which they will be produced or manufactured has been engaged in producing or manufacturing such Goods at least since the date of tender submission.

(b) **Group B:** All other tenders offering Health Sector Goods from within Ghana.

(c) **Group C:** Tenders offering Goods of foreign origin to be imported by the Purchaser directly or through the Supplier's local agent.

15.3 To facilitate this classification by the Purchaser, the Tenderer shall complete whichever version of the Price Schedule furnished in the Tender Documents as appropriately provided. However, the completion of an incorrect version of the Price Schedule by the Tenderer will not result in rejection of its tender, but merely in the Purchaser's reclassification of the tender into its appropriate tender group.

A tenderer claiming to offer domestic Goods belonging to

Group A above, shall submit along with its bid, a completed Form

3.1, Domestic Value Added Calculation Form.

16. Tender Prices

16.1 The Tenderer shall indicate on the appropriate Price Schedule, as applicable, the unit prices of each item, total prices of each lot, and the total Tender price of the Goods it proposes to supply under the Contract.

16.2 Prices indicated on the Price Schedule shall be entered separately in the following manner:

(a) For Goods offered from within Ghana country:

(i) the price of the Goods quoted EXW (ex works, ex factory, ex warehouse, ex showroom, or off-the-shelf, as applicable), including all customs duties and sales tax and other duties and taxes already paid or payable:

- on the components and raw material used in producing or manufacturing the Goods quoted ex works or ex factory;

- on the previously imported Goods of foreign origin quoted ex warehouse, ex showroom, or off-the-shelf.

(ii) any sales and other taxes that will be payable on the Goods in Ghana if the Contract is awarded.

(iii) the price for inland transportation, insurance, and other local costs incidental to delivery of the Goods to their final destination, if specified in the **Tender Data Sheet.**

(iv) the price of other incidental Services, if any, listed in the **Tender Data Sheet.**

(b) For Goods offered from abroad:

(i) the price of the Goods shall be quoted CIF named port of destination, CIP border point, or CIP named place of destination in Ghana, as specified in the **Tender Data Sheet.** In quoting the price, the Tenderer shall be free to use transportation through carriers registered in any eligible countries. Similarly, the Tenderer may obtain insurance services from any eligible source country.

(ii) the price of the Goods quoted FOB port of

shipment (or FCA, as the case may be), if specified in the **Tender Data Sheet.**

(iii) the price of Goods quoted CFR port of destination (or CPT as the case may be), if specified in the **Tender Data Sheet.**

(iv) the price for inland transportation, insurance, and other local costs incidental to delivery of the Goods from the port of entry to their final destination, if specified in the **Tender Data Sheet.**

(v) the price of incidental Services, if any, listed in the **Tender Data Sheet.**

16.3 The terms EXW, CIF, CIP, etc., shall be governed by the rules prescribed in the current edition of *Incoterms* published by the International Chamber of Commerce, Paris.

16.4 The Tenderer's separation of price components in accordance with ITT Clause 16.2 above will be solely for the purpose of facilitating the comparison of tenders by the Purchaser and will not in any way limit the Purchaser's right to contract on any of the terms offered.

16.5 Unless otherwise specified in the **Tender Data Sheet,** 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 nonresponsive and will be rejected, pursuant to ITT Clause 29. If, however, in accordance with the **Tender Data Sheet,** 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.

16.6 Pursuant to Sub-Clause 16.1 above, and if so indicated in the **Tender Data Sheet,** tenders are being invited for one or more items, or for individual Contracts (lots) each comprising at least eighty percent (80%) of the total number of items required under the lot. In both cases, each item offered must comprise the full quantity required under that item. Tenderers wishing to offer any price reduction for the award of more than one Contract shall specify in their tender the price reductions applicable to each package or, alternatively, to individual Contracts within the package.

Price reductions may be submitted as an amount or a percentage to be applied to the tender prices.

17. Currencies of Tender

17.1 Prices shall be quoted in the following currencies:

(a) The Tenderer may express the tender price of the Health Sector Goods to be supplied from outside Ghana entirely in Ghanaian Cedis or in another currency widely used in international trade. If the Tenderer wishes to be paid in a combination of different currencies, it must quote its price accordingly, but no more than three foreign currencies may be used.

(b) Unless otherwise specified in the **Tender Data Sheet,** the Tenderer shall express its prices for such goods to be supplied from within Ghana in Cedis (¢).

18. Period of Validity of Tenders

18.1 Tenders shall remain valid for the period stipulated in the **Tender Data Sheet** 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 nonresponsive.

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. A Tenderer may refuse the request without forfeiting its tender security. 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 fifty-six (56) days beyond the expiry of the first tender validity extension, the contract price will be increased by a factor that reflects changes in the cost of inputs specified in the request for second and subsequent extensions.

19. Tender Security

19.1 Unless otherwise specified in the **Tender Data Sheet,** the Tenderer shall furnish, as part of its tender, a tender security in the amount stipulated in the **Tender Data Sheet** in Cedis, or the equivalent amount in a freely convertible currency.

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

19.3 The tender security shall be denominated in Cedis, 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 check;

(b) a letter of credit issued by a reputable bank located in any eligible country;

(c) a (bank) guarantee issued by a reputable bank selected by the Tenderer located in any eligible country. The format of the (bank) guarantee shall be in accordance with the form of tender security included in Section VIII or any other form acceptable to the Purchaser.

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 30 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 Contract 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 contract, or

(ii) furnish the required performance security.

20. Alternative Tenders by Tenderers

20.1 Unless **specified in the Tender Data Sheet,** 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 **Tender Data Sheet,** 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 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 later authorization shall be indicated by written power of attorney, which pursuant to ITT Sub-Clause 14.1 (d) shall accompany the tender.

21.3 Any interlineation, erasures, or overwriting to correct errors made by the Tenderer should be initialed by the person or persons signing the tender.

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 another 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 **Tender Data Sheet;**

(c) bear the specific identification of this tendering process indicated in the **Tender Data Sheet,** the Invitation for Tenders (IFT) title and number indicated in the **Tender Data Sheet;** and

(d) bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the Tender Data Sheet 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 **Tender Data Sheet** relating to ITT Sub-Clause 22.2 (b) no later than the time and date specified in the **Tender Data Sheet.**

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 **Tender Data Sheet** 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 **Tender Data Sheet** 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 **Tender Data Sheet,**

(b) bear the specific identification of the tendering 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 **Tender Data Sheet.** 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 notice 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 Tender Data Sheet; 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 and 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 Tender Data Sheet; the presence or absence of a tender security; the presence or absence of requisite powers of attorney.

A copy of the minutes shall be sent to all tenderers who submitted a tender.

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 the 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 substantially 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, conditionalities, 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 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) that 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 substantially responsive, it will be rejected by the Purchaser and may not 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 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 Ghana Cedis at the selling exchange rate established for similar transactions by Ghana Association of Bankers or a commercial bank in Ghana.

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 **Tender Data Sheet.**

32. Evaluation and Comparison of Tenders

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 tender will exclude and not take into account:

(a) in the case of Goods manufactured in Ghana or Goods of foreign origin already located in Ghana, 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 provided in the tender.

32.3 The comparison shall be between the EXW price of the Goods offered from within Ghana, 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 CIF named port of destination (or CIP border point, or CIP named place of destination) price of the Goods offered from outside Ghana.

32.4 The Purchaser's evaluation of a tender will take into account, in addition to the tender price quoted in accordance with ITT Sub-Clause 16.2, one or more of the following factors as specified in the TDS, and quantified in ITT Sub-Clause 32.5*:*

(a) subject to ITT Sub-Clause 16.2 (a) (iii) ore 16.2 (b) (iv) the cost of inland transportation, insurance, and other costs within Ghana incidental to delivery of the Goods to their final destination;

(b) delivery schedule offered in the tender;

(c) deviations in payment schedule from that specified in the Special Conditions of Contract;

(d) other specific criteria indicated in the **Tender Data Sheet** and/or in the Technical Specifications.

32.5 For factors retained in the **Tender Data Sheet** pursuant to ITT Sub-Clause 32.4, one or more of the following quantification methods will be applied, as detailed in the **Tender Data Sheet:**

(a) Inland transportation from EXW/port of entry/border point, insurance, and incidentals.

Inland transportation, insurance, and other incidental costs for delivery of the Health Sector Goods from EXW/port of entry/border point to the site named in the **Tender Data Sheet** will be computed for each tender by the Purchaser on the basis of published tariffs by the rail or road transport agencies, insurance companies, and/or other appropriate sources. To facilitate such computation, Tenderer shall furnish in its tender the estimated dimensions and shipping weight and the approximate EXW/CIF (or CIP border point) value of each package. The above cost will be added by the Purchaser to EXW/CIF/CIP border point price.

(b) 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. The estimated time of arrival of the Health Sector Goods at the site will be calculated for each tender after allowing for reasonable international and inland

transportation time. A delivery "adjustment" will be calculated for and added to each tender by applying a percentage, specified in the **Tender Data Sheet,** of the EXW/CIF/CIP price for each week of delay beyond the expected time of arrival specified in the Tender Documents 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 will be treated as nonresponsive. Within this acceptable range, an adjustment per week, as specified in the **Tender Data Sheet,** 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 **Tender Data Sheet,** of EXW/CIF/CIP price per week of variation from the specified delivery schedule.

(c) Deviation in payment schedule.

(i) Tenderers shall state their tender price for the payment schedule outlined in the SCC. Tenders will be evaluated on the basis of this base price. Tenderers are, however, permitted to state an alternative payment schedule and indicate the reduction in tender price they wish to offer for such alternative payment schedule. The Purchaser may consider the alternative payment

schedule offered by the selected Tenderer.

or

(ii) The SCC stipulate the payment schedule offered by the Purchaser. If a tender deviates from the schedule and if such deviation is permitted in the **Tender Data Sheet,** the tender will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the tender as compared with those stipulated in this invitation, at the rate per annum specified in the **Tender Data Sheet.**

(d) Other specific additional criteria to be considered in the evaluation and the evaluation method shall be detailed in the **Tender Data Sheet** and/or in the Technical Specifications.

33. Domestic Preference

33.1 If indicated in the **Tender Data Sheet** and for the purpose of tender comparison, the Purchaser will grant a margin of preference to Goods manufactured in Ghana. This margin of preference will be granted in accordance with the procedures outlined in subsequent paragraphs, provided the Tenderer shall have established to the satisfaction of the Purchaser that its tender complies with the criteria specified in ITT Paragraph 15.2 (a).

33.2 The Purchaser will first review the tenders to confirm the appropriateness of, and to modify if necessary, the tender group classification to which Tenderers assigned their tenders in preparing their Tender Forms and Price Schedules.

33.3 All evaluated tenders in each group will then be compared among themselves to determine the lowest evaluated tender of each group. The lowest evaluated tender of each group will next be compared with the lowest evaluated tenders of the other groups. If this comparison results in a tender from Group A or Group B being the lowest, it will be selected for Contract award.

33.4 If, as a result of the preceding comparison, the lowest evaluated tender is from Group C, all Group C tenders will then be further compared with the lowest evaluated tender from Group A, after adding to the evaluated tender price of the imported Goods offered in each Group C tender, for the purpose of this further comparison only:

(a) the amount of customs duties and other import taxes that a nonexempt importer would have to pay for the importation of Goods offered in each Group C tender*;*

or

(b) fifteen (15) percent of the CIF (or CIP border point or CIP named place of destination, as the case may be) tender price of such Goods, if the customs duties that a nonexempt importer would have to pay and taxes exceed fifteen (15) percent of the CIF (or CIP border point or CIP place of destination) price of such Goods.

(c) Domestic preference will be applied only to those items indicated in the Schedule of Requirements that meet the criteria under Paragraph 15.2 (a).

If the Group A tender in the further comparison is the lowest, it will be selected for award. If not, the lowest evaluated tender from Group C, as determined from the comparison under ITT Sub-Clause 33.3 above, will be selected for award.

F. AWARD OF CONTRACT

34. Postqualification

34.1 In the absence of prequalification, 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 **Tender Data Sheet.** 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.

34.2 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.

34.3 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 Tenderer to make a similar determination of that Tenderer's capabilities to perform satisfactorily.

35. Award Criteria

35.1 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 best evaluated tender, provided further that the Tenderer is determined to be qualified to perform the Contract satisfactorily, pursuant to ITT Clause 34.

36. Purchaser's Right to Accept Any Tender and to Reject Any or All Tenders

36.1 The Purchaser reserves the right to accept or reject any tender, or to annul the tendering process and reject all tenders at any time prior to contract award, without thereby incurring any liability to the affected Tenderer or Tenderers.

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

37.1 The Purchaser reserves the right at the time of Contract award to increase or decrease, by the percentage indicated in the **Tender Data Sheet,** 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.

38. Notification of Award

38.1 Prior to the expiration of the period of tender validity, the Purchaser will notify the successful Tenderer in writing by registered letter or by fax, email or telex, to be subsequently confirmed in writing by registered letter, that its tender has been accepted.

38.2 The notification of award will constitute the formation of the Contract.

38.3 Upon the successful Tenderer's furnishing of the signed Contract Form and performance security pursuant to ITT Clause 40, the Purchaser will promptly notify each unsuccessful Tenderer and will discharge its tender security, pursuant to ITT Clause 19.

38.4 If, after notification of award, a Tenderer wishes to ascertain the grounds on which its tender was not selected, it should address its request to the Purchaser. The Purchaser will promptly respond in writing to the unsuccessful Tenderer.

39. Signing of Contract

39.1 Promptly after the Purchaser notifies the successful Tenderer that its tender has been accepted, the Purchaser will send the Tenderer the Contract Form provided in the Tender Documents, incorporating all agreements between the parties.

39.2 Within thirty (30) days of receipt of the Contract Form, the successful Tenderer shall sign and date the Contract Form and return it to the Purchaser.

40. Performance Security

40.1 Within thirty (30) 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.

40.2 Failure of the successful Tenderer to comply with the requirement of ITT Clause 39 or ITT Sub-Clause 40.1 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 tender submitted by a qualified Tenderer or call for new tenders.

Section II. Tender Data Sheet

The following specific data for the Health Sector 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

Name of Purchaser: Ministry of Health, Ghana

Type of goods: **Contraceptives**

Name and identification number of the Contract: Procurement of Contraceptives

IFT No: **MOH/2019/ICT/B.2.1/02**

Lot	Pack Size	Description	Quantity	Delivery Period
1	25 vials	Medroxyprogesterone Acetate (DMPA)	55,500	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing
2	1 set	Etonogestrel (Implant)	54,300	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing
3	144 condoms (48 strips of 3)	Male Condom (MOH Brand)	96,000	Delivery shall be within 90 days after receipt of an Advance payment OR

					within 90 days after contract signing
	4	144 condoms (48 strips of 3)	Male Condom (Private Sector Brand)	14,600	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing

ITT 2.1	Source of Funds: West Africa Health Organization (WAHO-ECOWAS) 2014 68 289
ITT 4.1 & 5.1	Applicable edition of the Published List of Eligible Countries as issued by the Public Procurement Authority of the Republic of Ghana

ITT 6.3 (c)	Documentation requirements for eligibility of Goods. In addition to the documents stated in Clause 6.2 and 6.3 (a) and (b), the following documents should be included with the Tender: **a. Certified Copy of Registration Certificates of all products tendered from the National Drug Regulatory Authority (NDRA) in the country of manufacture.** **b. Certified Copy of Registration Certificates of all products tendered from the Ghana Food and Drugs Authority.** **c. For Lots 1 and 2, tenderers must submit the results of Manufacturer's own quality control laboratory tests for each batch, and except for <u>WHO prequalified</u> products or SRA registered products, all products undergo independent quality control testing before shipment through batch sampling and subsequent testing by independent quality control laboratory.** **d. For Lots 3 and 4, tenderers must submit the results of Manufacturer's own quality control laboratory tests for each batch, and <u>unless purchased directly with UNFPA funds</u>, all Condom products undergo independent quality control testing before shipment through batch sampling and subsequent testing by an independent quality control laboratory.**

ITT 6.4	Health sector Goods to be supplied under the contract does require registration with the Food & Drugs Authority of The Republic of Ghana. Tender must contain copies of documentary evidence to prove that the Pharmaceuticals tendered are manufactured according to GMP (Good manufacturing practice). In addition, tender must contain documentary evidence to prove that the product has been registered in the country of manufacture and according to the authoritative standard appropriate to the goods' country of origin, and such standards should be the latest, issued by the concerned institution
ITT 6.4 (b)	By the time of tendering, each Tenderer should have complied with the necessary documentary requirements (Current WHO GMP Certification, Certificate of Pharmaceutical Product from country of origin, Product dossier of every drug being offered and current Manufacturer's Authorization for Tenderers who are not themselves manufacturers) as required by the Ghana Food & Drugs Authority of the Republic of Ghana, in order to register the Goods to be supplied under the Contract. **Note:** Because of the potential for delay when various government agencies must intervene in the registration process, Tenderers are alerted to inquire about registration requirements and procedures as early as possible.
ITT 6.4.1	For the purpose of obtaining additional information about the requirements for registration, Tenderers may contact: **FOOD AND DRUGS AUTHORITY** P.O.BOX CT2783 ACCRA, GHANA TEL: 233-302 233 200/235 100 FAX : 233-302 229 794 E-MAIL : fdb@ghana.com CONTACT PERSON: **MRS. DELASE DARKO**

ITT 7.1 (a)	Qualification requirements for Tenderers are: The qualification criteria and the supporting document/information to be submitted along with the bid are detailed below: **A. Manufacturer Tenderers** (i) that, in the case of a Tenderer offering to supply Goods under the Contract that the Tenderer manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Tenderer: (a) is incorporated in the country of manufacture of the Goods; (b) has been licensed by the regulatory authority in the country of manufacture to supply the Goods; (c) has manufactured and marketed the specific goods covered by this Tender Document, for at least two (2) years, and for similar Goods for at least five (5) years evidenced by an award or contract letter; (d) has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the goods or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the quality standards during the past two years prior to tender submission; (e) A Certificate of Pharmaceutical Product as recommended by the WHO for each item offered (f) Provides the evidence that it has the financial capability to perform the contract and that it has successfully completed or substantially completed at least one similar contract within the period of the last five years (preceding two months before the date of opening of tenders) for the supply of similar products against each Lot offered by a tenderer with a value of above US$100,000.00 The Tenderer shall also submit the following additional information: (a) a statement of installed manufacturing capacity; (b) copies of its audited financial statements for the past two fiscal years;

(c) details of on-site quality control laboratory facilities and services and range of tests conducted;

(d) list of two (2) major supply contracts conducted within the last five years.

(B) Non Manufacturer Tenderer

(ii) that, in the case of a Tenderer offering to supply Goods under the Contract that the Tenderer does not manufacture or otherwise produce **provide all supporting documents indicating that the Tenderer is duly authorized by the manufacturer of the Goods who meets the criteria under (A) above**), as per authorization Form 8 in Section VIII and that the Tenderer has been duly authorized by a manufacturer of the Goods that meets the criteria under (A) above to supply the Goods in the Purchaser's country;

(a) that the Tenderer has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Ghana;

(b) The Tenderer has successfully completed at least two similar contracts within the period of last five years (preceding two months before the date of opening of Tenders) for supply of goods against each Lot Offered by a tenderer of a value above US$100,000.00

(c) The Tenderer will also submit the list of five (5) major supply contracts completed within the last five years evidenced by an award or contract letter.

For Both (A) and (B)
Additional Qualification requirements:
(i) The Tenderer shall disclose instances of previous past performance that may have resulted in adverse actions taken against the Tenderer and the manufacturers whose products are being offered by the Tenderer, in the last five years. Such adverse actions (including suspension or cancellation of its manufacturing license by regulatory authorities, product recalls etc.) may be treated as unsatisfactory performance history while deciding the award of contract. If no instance of previous past performance has resulted in adverse actions this should be clearly indicated in the Tenderer's bid.

B. THE TENDER DOCUMENTS

ITT 11.1	Purchaser's/duly authorized Purchasing Agent's address is: **THE PROCUREMENT UNIT (ROOM NO.5)** **MINISTRY OF HEALTH** **28TH FEBRUARY ROAD, NEAR DEPARTMENT** **OF NATIONAL LOTTERIES** **P.O. BOX MB-44, ACCRA, GHANA** **Tel: -+ 233-050 122 8029/ 050 122 8051** E-mail: **procurementmohghana@**gmail.com **(for queries only).** **Attn: MRS JOYCELYN AZEEZ** Period prior to deadline for submission of tenders for Tenderers to request clarification: **[14] Fourteen calendar days prior to the deadline for submission of tenders.**

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 14.1 (i)	In addition to the documents stated in Paragraphs 14.1 (a) through (h), the following documents must be included with the Tender: **i Certified Copy of KFW Declaration of Understanding (for sample form see page 146)** **j. Certified Copy of Registration Certificate of each product tendered from the National Drug Regulatory Authority (NDRA) in the country of manufacture to supply the goods.** Tenderers who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce pharmaceuticals or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling, and quality testing. The Tenderer shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Goods offered.
ITT 16.2 (a) (iii), (iv)	The price of Goods offered from outside Ghana shall be quoted: **DELIVERY AT PLACE, DAP (INCOTERMS 2010) MOH TEMPORARY CENTRAL MEDICAL STORE, SPINTEX ROAD, ACCRA, GHANA** **Conditions of DAP: Supplier shall:** 1. Bear the responsibility and risks to deliver the goods to the named place (**MOH Temporary Central Medical Store, Spintex Road, Accra**,) 2. Obtain contract of carriage that matches the contract of sale 3. Be required to clear the goods **The Purchaser:** Shall Expedite Exemption From Customs Duties and Other Local Taxes such as VAT/NHIL
ITT 16.2 (b) (i) (ii), (iii), (iv), (v)	Prices for Goods offered from abroad shall be quoted as **Delivery At Place (DAP) MOH Temporary Central Medical Stores,**

	Spintex Road, Accra, Ghana. This is without VAT&NHIL. **Tenderers are required to quote FOB prices in their Price Schedules in addition to the DAP Prices.**
ITT 16.5	Prices quoted by the Tenderer shall be fixed
ITT 16.6	Tenders are being invited for one or more procurement lots.
ITT 17.1 (a)	Tender prices may be expressed in the currency of the tenderers' country or preferably in EUROS since contract prices shall be in EUROS
ITT 17.1 (b)	The currency to be used for quoting prices of the Goods and Services components of the Goods offered from within Ghana, as well as local currency expenditures for local technical support, training, maintenance, transportation, insurance, and other local costs incidental to delivery, is Ghana Cedi or preferably in EUROS since contract prices shall be in EUROS.
ITT 18.1	**The tender validity period shall be 120 DAYS** after the deadline for tender submission, as specified below in reference to ITT Clause 23. Accordingly, a tender shall be valid up to **31st July, 2019.** (DAYS means: Calendar Days) **Tender Security must be valid Twenty-Eight (28) days** after the end of the tender validity period. Accordingly, a tender with a tender security that expires before **28th August, 2019** shall be rejected as non-responsive.
ITT 19.1	Tender shall include a Tender Security (issued by a Commercial Bank included in Section VIII: Sample Forms The amount of tender security required is not less than **2%** of the total tender value. The **Tender Security shall be in the form of a Bank Guarantee** from a reputable Banking Institution in favour of the Purchaser (i.e. Ministry of Health, Ghana) i.e. a Banking Institution certified by the Central Bank of the country of origin. The format of the Bank Guarantee shall be in accordance with the forms included in Section VIII of this tender document.
ITT 20.1	**Alternative Tenders will not be accepted.** In the event of a supplier submitting more than one Tender: 1. All Tenders marked alternative Tenders will be rejected and only the basic Tender will be evaluated 2. All Tenders will be rejected if no indication is provided as to which Tenders are alternative Tenders.
ITT 21.1	Required Number of Copies of tender submission is **One Original and Three Copies.**

D. SUBMISSION OF TENDERS

ITT 22.1	Tenderers shall not have the option of submitting their Tenders Electronically. Accordingly Electronic Tenders **will be Rejected** as Non-responsive
ITT 22.2 (b)	The address for Tender submission is: **MINISTRY OF HEALTH** **PROCUREMENT UNIT** **ROOM NO. 5** **28TH FEBRUARY, ROAD NEAR DEPARTMENT OF NATIONAL LOTTERIES).** **P.O. BOX MB-44** **ACCRA** **GHANA.** **ATTENTION: MRS. JOYCELYN AZEEZ** THE DEADLINE FOR THE SUBMISSION OF TENDERS IS: **DATE: TUESDAY, 2ND APRIL, 2019** **TIME: 10.00 AM (LOCAL TIME)** **All Tenderers are required to submit SAMPLES of each lot quoted as follows as part of bid submission requirement:** **Lot No** — **Quantity of Samples Required** **1. Medroxyprogesterone Acetate 150mg/mL** — ***2 packs*** ***2.*** **Etonogestrel (Implant)** ***68mg*** — ***2 sets*** ***3*****& 4. Male Condoms** — **1500 condoms (Per Lot)** **These will be used for technical evaluation. Tenderers must note that this is different from the requirement of submission of samples to the Food and Drugs Authority (i.e. The National Regulatory Authority)**

	for registration purposes. Samples of products would be required by the successful Tenderer for registration purposes and also at the time of shipment of any batch of the product for destination inspection and laboratory testing by the Ghana Food and Drugs Authority.
ITT 22.2 (c) & (d)	INVITATION FOR TENDER TITLE: **PROCUREMENT OF CONTRACEPTIVES** IFT No.: **MOH/2019/ICT/B.2.1/02** THE DEADLINE FOR THE SUBMISSION OF TENDERS IS: **DATE: TUESDAY, 2ND APRIL, 2019** **TIME: 10.00 AM (LOCAL TIME)**
ITT 23.1	The address for Tender submission is: **MINISTRY OF HEALTH** **PROCUREMENT UNIT** **ROOM NO. 5** **28TH FEBRUARY, ROAD NEAR DEPARTMENT OF NATIONAL LOTTERIES).** **P.O. BOX MB-44** **ACCRA-GHANA** **ATTENTION: MRS. JOYCELYN AZEEZ**
ITT 24.1	THE DEADLINE FOR THE SUBMISSION OF TENDERS IS: **DATE: TUESDAY, 2ND APRIL, 2019** **TIME: 10.00 AM (LOCAL TIME)** "In the event of the specified date for the submission of Tenders being declared a holiday for the Purchaser, the Tenders will be received up to the appointed time on the next working day
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	Time, date, and place for tender opening are: **DATE: TUESDAY, 2ND APRIL, 2019** **TIME: 10.00 AM (LOCAL TIME)** PLACE OF TENDER OPENING **MINISTRY OF HEALTH** **PROCUREMENT UNIT** **ROOM NO. 5** **28TH FEBRUARY, ROAD** **NEAR DEPARTMENT OF NATIONAL LOTTERIES).** **P.O. BOX MB-44** **ACCRA-GHANA** "In the event of the specified date for the submission of Tenders being declared a holiday for the Purchaser, the Tenders will be received up to the appointed time on the next working day"
ITT 29.4	The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence
ITT 31.2	**The currency chosen for the purpose of converting to a common currency is*: EUROS*** The source of exchange rate is: **Bank of Ghana** The date of exchange rate determination is the date of opening of tenders i.e. **TUESDAY, 2ND APRIL, 2019**

ITT 32.4 (d)	The evaluation will take into account ability of each firm to comply with all the requirements stated in ITT 7.1 of the Tender Data Sheet and the Specific Instructions to Tenderers. **The evaluation criteria are:** **1.The ability of firm to comply with all the requirements stated in ITT 7.1, the Tender Data Sheet and the Specific Instructions to Tenderers.** **2. Qualification status of Tenderer** **3. Submission of a duly signed Tender Form and Price Schedule** **4. Evidence of Manufacturer's Authorization for firms who are not themselves manufacturers** **5. Submission of Tender Security covering a minimum of 2% of Total Tender Price and valid until the specified Validity date.** **7. Submission of Samples for Lots 1, 2, 3 and 4** **8. Compliance to Technical Requirements of products** **9. Price Competitiveness** **10. Documentary Evidence that products (Lots 1&2) are either WHO Prequalified or registered by a Stringent Regulatory Authority** **11. Documentary Evidence that products (Lot 3&4) are UNFPA Prequalified** **12.Registration of Product by the Ghana Food & Drugs Authority (FDA)** **13. Evidence of Registration of Company with Ghana PPA** **14. Submission of a duly signed declaration of undertaking**
ITT 32.5	The factors retained pursuant to ITT Sub-Clause 32.4 and the quantification methods are**: Delivery Schedule offered in the Tender**
ITT 32.5 (a)	Tenderer shall furnish: *estimated dimensions and shipping weight of each package and approximate EXW/CIF/CIP/DAP value of each package*
ITT 32.5 (b) (i), (ii) & (iii)	The Purchaser will not accept deviations in the Delivery Schedule.
ITT 32.5 (c) (ii)	The Purchaser will not accept deviations in the payment schedule in the SCC.
ITT 32.5 (d)	Tenderers can tender for one or more lots. Tenders will be evaluated on a lot by lot basis. Tenderers must quote for the entire quantity of each item in the lot to be treated as substantially responsive. Purchaser will not accept any deviation to quantities and technical specifications.
ITT 33.1	A 15% margin of domestic preference: **NOT APPLICABLE**

F. AWARD OF CONTRACT

ITT 34.1	After determining the lowest-evaluated bid in accordance with ITT 20.1, the Purchaser shall carry out the post qualification of the Tenderer in accordance with ITT Clause 34, using only the requirements specified. Requirements not included in the text below shall not be used in the evaluation of the Tenderer's qualifications. <u>Financial Capability</u> The Tenderer shall furnish documentary evidence that it meets the following financial requirement(s): • Copies of audited accounts for the 2016 and 2017 years
ITT 37.1	**Percentage for increase or decrease** of quantity of Goods and Services originally specified shall not be more than **20%.**

Tender Data Sheet

PHARMACEUTICALS

ITT 6.3 (c)	The Goods offered should meet the specified pharmacopoeial standards as stated in the Technical Specification. If the Goods offered are not included in one of the specified pharmacopoeias (e.g., the case of a new drug), the Tenderer will provide testing protocols and alternative reference standards.
ITT 7.1 (a) & (d)	Documentary evidence of the Tenderer's qualifications to perform the Contract if its tender is accepted: (ii) (d) has a Good Distribution Practice (GDP) Certificate where appropriate. The Tenderer will submit the following additional information: (e) list of pharmaceuticals being manufactured by the Tenderer with product registration/license number and date. (f) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered.

Tender Data Sheet

VACCINES

A. GENERAL

ITT 6.3 (c)	1. The Goods to be supplied under the Contract must be licensed both in the country of manufacture and in Ghana by the time of Contract signing by a recognized NCA. An NCA is an organization that performs all six critical functions for control of biological products as defined by the World Health Organization, namely: licensing based on published set of requirements; surveillance of vaccine field performance; system of lot release for vaccines; use of laboratory when needed; regular inspections for good manufacturing practice and evaluation of clinical performance. The license from country of manufacture must state that the Tenderer is licensed to manufacture the Goods by the NCA in the manufacturing country. Documentary evidence in the form of a certified copy of the license and a copy of the vaccine license/registration that the offered vaccine has been licensed by the NCAs of the manufacturer's country shall accompany the tender and a copy of the license issued by an NCA in Ghana must be submitted by Contract signing. If there is no NCA with specific biologics expertise in Ghana, the Tenderer shall furnish evidence that the Goods meet the qualification criteria in the Technical Specifications. 2. If the Goods offered do not meet the specified pharmacopoeial standards as stated in the Technical Specification, the Tenderer will provide testing protocols and alternative reference standards.
ITT 7.1 (a) & (d)	Documentary evidence of the Tenderer's qualifications to perform the Contract if its tender is accepted: (e) is certified by a competent authority in the country of manufacture according to resolution WHA 28 65 (2) of the World Health Organization's Certificate Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. The Tenderer will submit the following additional information: (f) list of vaccines being manufactured by the Tenderer with product registration/license number and date.

SECTION III.

ELIGIBILITY FOR THE PROVISION OF GOODS, WORKS AND SERVICES FINANCED WITH PUBLIC FUNDS OF THE REPUBLIC OF GHANA

Section III. Eligible Countries

Public Procurement Authority of the Republic of Ghana

Eligibility for the Provision of Goods, Works and Services financed from the Public Funds of the Republic of Ghana

Bidders should check for list of countries from which Tenderers, goods and services are not eligible to participate in procurement financed from the public funds of the Republic of Ghana at the Public Procurement Authority website: www.ppbghana.org

SECTION IV. GENERAL CONDITIONS OF CONTRACT

TABLE OF CLAUSES

General Conditions of Contract

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) "Eligible Country" means the countries and territories eligible for participation in procurements financed from the public funds of the Republic of Ghana.

(f) "End User" means the organization(s) where the goods will be used, as **named in the SCC.**

(g) "GCC" means the General Conditions of Contract contained in this section.

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

(i) "The Purchaser" means the organization purchasing the Goods, as **named in the SCC.**

(j) "The Republic of Ghana" is the country **named in the SCC.**

(k) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in Ghana in

accordance with the Applicable Law.

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

(m) "The Services" means those services ancillaries 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.

(n) "The Site," where applicable, means the place or places **named in the SCC.**

(o) "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 Republic of Ghana, 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; Inspection and Audit by the Government of Ghana

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.

5.4 The Supplier shall permit the Government of Ghana to inspect the Supplier's accounts and records relating to the performance of the Contract and to have them audited by auditors appointed by the Government of Ghana, if so required.

6. Certification of Goods in Accordance with the Laws of Ghana

6.1 If required under the Applicable Law, Goods supplied under the Contract shall be registered for use in the Ghana. The Purchaser undertakes to cooperate with the Supplier to facilitate registration of the Goods for use in the Ghana.

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 Ghana that the Goods have been registered for use in Ghana.

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 Ghana.

8. Performance Security

8.1 Within twenty-eight (28) days of receipt of the notification of Contract award, the successful Tenderer shall furnish to the Purchaser a performance security for the due performance of the Contract 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 Ghanaian Cedis 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 Ghana 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 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications. The **SCC** and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

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

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

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

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 heavy 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

11.1 Delivery of the Goods shall be made by the Supplier in

Documents

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," "FOB," "FCA," "CIF," "CIP," DAP 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.**

12.2 Where delivery of the Goods is required by the Purchaser on a CIF or CIP basis, the Supplier shall arrange and pay for cargo insurance, naming the Purchaser as beneficiary. Where delivery is on an FOB or C&F basis, insurance shall be the responsibility of the Purchaser.

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 C&F, 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 CIP, transport of the Goods to the port of destination or such other named place of destination in Ghana, 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 Contact to transport the Goods to a specified place of destination

within Ghana, defined as the Site, transport to such place of destination in Ghana, including 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 CIP, no restriction shall be placed on the choice of carrier. Where the Supplier is required under Contract (a) to deliver the Goods FOB or C&F, 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 Ghana, 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 thirty (30) 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:

(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 Special Conditions.

(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 English**.** All correspondence and other documents pertaining to the Contract that are exchanged by the parties shall be written in English.

30. Applicable Law

30.1 The Contract shall be interpreted in accordance with the laws of the Republic of Ghana, 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, facsimile or electronic mail 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 Ghana.

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.

SECTION V. SPECIAL CONDITIONS OF CONTRACT

TABLE OF CLAUSES

Special Conditions of Contract

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. 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, Ghana
GCC 1.1 (i)	The Purchaser is: Ministry of Health, Ghana
GCC 1.1 (o)	The Supplier is: To be provided at the time of contract signing
GCC 1.1 (n)	The Site(s) is/are: **Delivery At Place (DAP) (MOH Temporary Central Medical Stores, Spintex Road, Accra)**
2. Application (GCC Clause 2)	
GCC 2	There are no Special Conditions of Contract applicable to GCC Clause 2
3. Country of Origin (GCC Clause 3)	
GCC 3.1	The Ghana Public Procurement Authority maintains a list of countries whose Tenderers, Goods, and Services are not eligible to participate in public procurement in Ghana. This list is updated regularly, and it is available at: www.ppbghana.org
4. Standards (GCC Clause 4)	
GCC 4	The Goods supplied under this Contract shall be in accordance with the provisions of GCC4.
5. Use of Contract Documents and Information (GCC Clause 5)	
GCC 5	The use of Contract Documents and Information shall be in accordance with GCC 5
6. Certification of Goods in Accordance with Laws of Ghana (GCC Clause 6)	
GCC 6.1	Evidence of registration of product with the Ghana Food and Drugs Authority.

GCC 6.2	The Effective Date of the Contract is the date of Contract signed by both parties and is valid for 14 Months from the date of contract signing.
GCC 6.3	The time period shall be 30 days.
	7. Patent Rights (GCC Clause 7)
GCC 7	The Indemnity provisions in GCC 7 shall apply.
	8. Performance Security (GCC Clause 8)
GCC 8.1	**Performance Security**, in favour of the Ministry of Health, shall be for an amount equal to **Ten percent (10%) of the Contract Price** and shall be valid till 30 days after the date of completion of contractual obligations.
GCC 8.4	Discharge of the Performance Security shall take place in accordance with GCC Sub-Clause 8.4
	9. Inspections and Tests (GCC Clause 9)
GCC 9.1	There are no Special Conditions of Contract applicable to GCC Sub-Clause 9.
	10. Packing (GCC Clause 10)
GCC 10.2	Containers of Pharmaceuticals must conform with any of the latest of internally recognised Pharmacopoeia Standards, such as British, United States or European. The size of the container should be proportional to its content, with the addition of appropriate padding to prevent damage to the product during transport. Container should be tamper-proof. The packing, marking and documentation within and outside the packages shall be made using the right packaging material to prevent damage or deteriorations during transit to final destination. Packages to be marked with the project name: MOH Temporary Central Medical Stores, Spintex Road In addition to provisions mentioned in GCC clause 10, the outside of each packing carton (i.e. bigger side of both inner and outer) must be boldly marked: **MOH, GHANA, TEMPORARY CENTRAL MEDICAL STORES, SPINTEX ROAD, ACCRA** and also clearly indicate the following: 1) International Non-proprietary Name of the item in the packing case. 2) Pharmacopoeial standard

	3) Strength of Active Ingredient(s) in metric units 4) Special Instructions for storage 5) Dosage Form e.g. Syrup, Tablet, Cream. 6) Basic Unit e.g. Vial, Bottle. 7) Date of Manufacture 8) Expiry Date 9) Batch Number 10) Quantity of items in each Packing carton e.g. 10 x 100 VIALS. 11) Country of Manufacture 12) Name and address of Manufacturer. **Each Packing case must contain the same items, under no circumstances should any package contain an assortment of items** **In addition, packaging should indicate the following information in** ENGLISH**:** (1) The number of boxes of product should be stated on the outer carton (2) Clearly defined labels on the outer carton (3) Batch numbers of product on the labels (4) Writing on outer carton should be legible with a minimum font size of 8cm x 12cm (5) Labeling should be done according to labeling requirements (6) Strength of the carton (should comply with GMP specification; Purchaser will not accept cartons of inferior quality), minimum of 7 ply Expiry date must be indicated on both the inner and outer cartons

	11. Delivery and Documents (GCC Clause 11)
GCC 11.1 & 11.3	***For Goods supplied from abroad:*** Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. The Supplier shall fax and then send by courier the following documents to the Purchaser, with a copy to the insurance company: (i) three originals and two copies of the Supplier's invoice, showing Purchaser as *MINISTRY OF HEALTH, GHANA;* the Contract number, Goods description, Origin of goods, quantity, unit price, and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal; (ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as *MINISTRY OF HEALTH, GHANA* and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements; (iii) four copies of the packing list identifying contents of each package; (iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied; (vi) one original of the Supplier's Certificate of Origin covering all items supplied; (vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required);

(viii) Certificate of quality control test results for each lot (original copy not later than 6 months). Or Batch Number and Certificate of Quality Control Test Results. Whichever is applicable

For the product assurance during contract execution it is recommended that: manufacturers submit the results of the manufacturer's own quality control laboratory test for each lot.

For Goods from within Ghana:

Upon or before delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser:

(i) two originals and two copies of the Supplier's invoice, showing Purchaser, the Contract number, Goods' description, Origin of goods, quantity, unit price, and total amount. Invoices must be signed in original and stamped or sealed with the company stamp/seal;

(ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as *MINISTRY OF HEALTH, GHANA* and delivery through to final destination as stated in the Contract;

(iii) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;

(iv) four copies of the packing list identifying contents of each package;

(v) one original of the manufacturer's or Supplier's Warranty certificate covering all items supplied;

(vi) one original of the Supplier's Certificate of Origin covering all items supplied;

(vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required)

(viii) other procurement-specific documents required for delivery/payment purposes.

Note: In the event that the documents presented by the Supplier are not in accordance with the Contract, then payment will be made against issue of the Acceptance Certificate, to be issued in

	accordance with SCC 9 (GCC 9) above. B) The Supplier shall inform the Consignee in advance at least 7 days before the dispatch of Goods the expected date of arrival of Goods along with quantity of Goods. Along with each consignment the Supplier shall provide the Consignee one set of the documents mentioned below: a) Copies of the Supplier's invoice showing Goods' description, Origin of goods, quantity, unit price, and total amount; b) Original and three (3) copies of the negotiable, clean, on-board bill of lading marked "freight prepaid" and three (3) copies of nonnegotiable bill of lading; c) Supplier's Delivery note, indicating Goods' description, quantity, batch number, date of expiry etc Delivery note must be signed in original and stamped or sealed with the company stamp/seal; d) Packing list identifying contents of each package e) Manufacturer's or Supplier's Warranty certificate covering all items supplied.
12. Insurance (GCC Clause 12)	
GCC 12.1	The insurance shall be in an amount equal to 110 percent of the DAP Value. (This implies that under DAP transport mode, insurance is the responsibility of the supplier and therefore you must show evidence by proof of Certificate).
13. Transportation (GCC Clause 13)	
GCC 13	DAP INCOTERMS 2010
14. Incidental Services (GCC Clause 14)	
GCC 14.1	Incidental services to be provided are: (a) The Supplier shall provide all necessary licenses and permissions for use of the Goods in Ghana that may be required for the Goods. The cost shall be deemed included in the Contract Price. (b) The Supplier shall provide such other services as are stated in the Technical Specifications.
15. Warranty (GCC Clause 15)	

GCC 15.1	Without limitation of any other warranties stated in or arising under this Contract, the Supplier warrants and represents that the goods, drugs, equipment and/or services supplied are of the quality, quantity and description required by the Contract. 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.
GCC 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.

GCC 15.4	The period for the replacement of defective goods is: 30days.
	16. Payment (GCC Clause 16)
GCC 16.1 & 16.4	The method and conditions of payment to be made to the Supplier under this Contract shall be as follows: **<u>OPTION 1:</u>** **(i) 20% of contract sum shall be paid as Advance against an Advance Payment Guarantee of the same amount and valid for the period of the contract. (Refer to Page 140 for sample of Advance Payment Guarantee)** **(ii) Remaining 80% of Contract sum after delivery, receipt and acceptance of the Goods upon submission of an invoice (showing Purchaser's name; the Contract number, Origin of Goods, 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.** **OR** **<u>OPTION 2:</u>** **100% of Contract sum shall be paid after delivery, receipt and acceptance of the Goods upon submission of an invoice (showing Purchaser's name; the Contract number, Origin of Goods, 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.** **NOTE: Suppliers are requested to choose one of the above options. Suppliers are not required to change their selected option as accepted by the purchaser**

17. Prices (GCC Clause 17)	
GCC 17.1	Prices shall be fixed and firm for the duration of the Contract.
18. Change Orders (GCC Clause 18)	
GCC 18	There are no Special Conditions of Contract applicable to GCC 18.
19. Contract Amendments (GCC Clause 19)	
GCC 19	There are no Special Conditions of Contract applicable to GCC 19.
20. Assignment (GCC Clause 20)	
GCC 20	There are no Special Conditions of Contract applicable to GCC 20.
21. Delays in the Supplier's Performance (GCC Clause 21)	
GCC 21	There are no Special Conditions of Contract applicable to GCC 21.
22. Liquidated Damages (GCC Clause 22)	
GCC 22.1	Applicable rate is 0.5% of Contract Price per week. Maximum deduction is 10% of Contracted Price.
23. Termination for Default (GCC Clause 23)	
GCC 23	There are no Special Conditions of Contract applicable to GCC 23.
24. Force Majeure (GCC Clause 24)	
GCC 24	There are no Special Conditions of Contract applicable to GCC 24.
25. Termination for Insolvency (GCC Clause 25)	
GCC 25	There are no Special Conditions of Contract applicable to GCC 25.

26. Termination for Convenience (GCC Clause 26)	
GCC 26	There are no Special Conditions of Contract applicable to GCC 26.
27. Settlement of Disputes (GCC Clause 27)	
GCC 27.2.2	The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 27.2.2 shall be as follows: ***(a) Contracts with foreign Supplier:*** Any dispute, controversy, or claim arising out of or relating to this Contract, or breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force. ***(b) Contracts with Ghanaian Supplier:*** In the case of a dispute between the Purchaser and a Supplier who is a national of Ghana, the dispute shall be referred to adjudication or arbitration in accordance with the laws of Ghana.
28. Limitation of Liability (GCC Clause 28)	
GCC 28	There are no Special Conditions of Contract applicable to GCC 28.
29. Governing Language (GCC Clause 29)	
GCC 29.1	The governing language is English.
30. Applicable Law (GCC Clause 30)	
GCC 30.1	The Contract shall be interpreted in accordance with the laws of the Republic of Ghana.
31. Notices (GCC Clause 31)	

GCC 31.1	The Purchaser's address for notification is as follows: **THE PROCUREMENT UNIT (ROOM NO.5)** **MINISTRY OF HEALTH** **28TH FEBRUARY ROAD,** **NEAR DEPARTMENT OF NATIONAL LOTTERIES** **P.O. BOX MB-44, ACCRA, GHANA** Tel: -+ 233-(050 122 8029/050 122 8051 E-mail: **procurementmohghana@gmail.com (for queries only).** **Attn: Mrs. Joycelyn Azeez**
32. Taxes and Duties (GCC Clause 32)	
GCC 32	In fulfillment of the obligation of the supplier in accordance with Section 86 of the Internal Revenue Act,2000; (Act 592) of Ghana as amended by Acts 622, 628,644,669,700 & 710 to Section 81, all successful tenderers will be subjected to the required tax obligation where applicable.

Special Conditions of Contract

PHARMACEUTICALS

11. Delivery and Documents (GCC Clause 11)	
GCC 11.1 & 11.3	***For Goods supplied from abroad**:* (ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied. (x) Certificate of quality control test results in conformity with the World Health Organization/UNFPA for lot 3&4 "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods. (xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

Special Conditions of Contract

VACCINES

11. Delivery and Documents (GCC Clause 11)	
GCC 11.1 & 11.3	***For Goods supplied from abroad:*** (ix) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped. (x) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods. (xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies. ***For Goods from within Ghana:*** (x) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.
15. Warranty (GCC Clause 15)	
GCC 15.1	The Purchaser reserves the right to request evidence of bio-availability and/or bio-equivalence data and/or evidence of the basis for expiration dating and other stability data concerning the Goods to verify shelf life claimed for the Goods. If an adverse event following immunization (AEFI) occurs in Ghana and the cause of such event cannot be immediately established, the Purchaser will, with all urgency and in accordance with the procedures laid down by the NCA of Ghana, take steps to advise the Supplier in order that an investigation may be launched immediately. If the vaccine has been supplied through an agency of the United Nations, the most current procedures laid down by the WHO for such situations will be used.

SECTION VI. SCHEDULE OF REQUIREMENTS

Lot No	Product Description	Dosage form	Strength	Pack Size	Quantity	Delivery
1	Medroxyprogesterone Acetate (DMPA)	Injection	150mg/mL	25 Vials	55,500	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing
2	Etonogestrel (Implant)	rod	68mg	1 set	54,300	Deivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing
3	Male Condom (MOH Brand)			144 condoms (48 strips of 3)	96,000	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing
4	Male Condom (Private Sector Brand)			144 condoms (48 strips of 3)	14,600	Delivery shall be within 90 days after receipt of an Advance payment OR within 90 days after contract signing

EVALUATION WILL BE CARRIED OUT ON LOT-BY-LOT BASIS AND TENDERERS ARE REQUIRED TO QUOTE FOR COMPLETE QUANTITIES UNDER A GIVEN LOT.

SECTION VII. TECHNICAL SPECIFICATIONS

Technical Specifications for Lot 1

Lot No.	**1**
Product Description	Medroxyprogesterone Acetate (DMPA)
Strength	150mg/mL
Volume	1mL
Product Use	Contraceptive
Dosage Form	Vial
Presentation	Injectable Suspension
Route of Administration	Administered by deep, intramuscular (IM) injection in the gluteal or deltoid muscle.
Regimen	Administered every 3 months
Shelf Life	The Supplier shall further warrant that all products supplied under the contract shall have remaining a minimum of three-quarters (3/4) of the specified shelf life upon delivery at port of entry).
Storage Conditions	• Store between 15 and 25°C. Do not store above 25°C • All vials must be transported in refrigerated (reefer) containers • Do not freeze, protect from light; this is valid for both storage and transport • Store vials upright
Quality Standard	Approved by Stringent Drug Regulatory Authority or **WHO Prequalified**
Accessories	980,000 (4,900 x 200) auto disable syringes (1ml) with 1 inch 22-gauge needles; bundled with 9,800 (4 x 2,450) sharp containers. The needles must conform to the current standard according to CE or ISO 9001 or AFNOR
Product Insert	Each package must be accompanied by an appropriate packaging written in English

Technical Specifications for Lot 2

Lot No.	**2**
Product Description	Etonogestrel
Strength	68mg Implant Etonogestrel (1 **Rod** implant)
Product Use	Contraceptive
Presentation	The implant consists of radiopaque rods detectable on conventional x-Rays, non-biodegradable, white to off-white, progestogen-only, soft, flexible rod with a length of 4cm and 2mm in diameter preloaded in a sterile, disposable applicator
Route of Administration	Implanted sub dermally in the upper arm
Shelf Life	The Supplier shall further warrant that all products supplied under the contract shall have remaining a minimum of three-quarters (3/4) of the specified shelf life upon delivery at port of entry).
Insertion Life	Up to 36 months
Storage Conditions	• Store at room temperature not above 30°C • Store away from excess heat and moisture
Quality Standard	Approved by Stringent Drug Regulatory Authority or **WHO Prequalified**
Client's Card	Should provide client cards that will provided basic information on the client and the product (Information must be in English Language)
Product Insert	Each package must be accompanied by an appropriate packaging insert written in English

Technical Specifications for Lot 3

Description	Minimum Technical Requirements
Product Description	**Latex Male Condom (BE SAFE LOGO)**
Features	Natural Colour, Reservoir Tip, Lubricated, Non-Spermicidal
Unit Pack	Box
Pack Size	144 condoms (48 strips of 3).
Flavour	Lime Scented (Mild)- Light Lemon
Texture	Smooth
Shelf Life	3 to 5 Years (The Supplier shall further warrant that all products supplied under the contract shall have remaining a minimum of three-quarters (3/4) of the specified shelf life upon delivery at port of entry).
Dimension	Length ≥ 180mm
Width	53.0 ± 1mm
Thickness:	0.05- 0.07mm
Foil Artwork	**See Sample on Page 105**

Technical Specifications for Lot 4

Description	Minimum Technical Requirements
Product Description	**Latex Male Condoms (BAZUKA CONDOMS)**
Features	Natural Colour, Reservoir Tip, Lubricated, Non-Spermicidal
Unit Pack	Box
Pack Size	144 condoms (48 strips of 3).
Flavour	Lime Scented (Mild)- Light Lemon
Texture	Smooth
Shelf Life	3 to 5 Years (The Supplier shall further warrant that all products supplied under the contract shall have remaining a minimum of three-quarters (3/4) of the specified shelf life upon delivery at port of entry).
Dimension	Length ≥ 180mm
Width	53.0 ± 1mm
Thickness:	0.05- 0.07mm
Foil Artwork	**See Sample on Page 106**

Check from page 98 to 113 for more detailed technical specifications for Lots 3 & 4

TECHNICAL SPECIFICATIONS CONT'D

1. ALL ORAL SOLID DOSAGE FORMS MUST CONFORM TO THE UNITED STATES PHARMACOPOEAL (USP) DISSOLUTION TESTS.

2. All items offered must conform to particular Strength, Dosage form, Unit size, and all other specifications for each item in the Schedule of Requirements.

3. All Primary packaging example vial, bottle, and collapsible bag must clearly indicate in English the following:

1. International Non-proprietary Name
2. Strength of Active Ingredient(s)
3. Applicable Pharmacopoeial standard
4. Date of Expiry
5. Batch Number

4. In addition to the above, all outer packages should be appropriately labeled to meet all the requirements in Section 2 (labeling Instructions) of the Detailed Technical Specifications.

5. All items must include Inserts containing vital information on dosage Instructions, route of administration, contraindications and any other relevant information on the pharmacological and pharmacokinetic properties of the medicine being offered.

6. Special Instructions: All Primary Packaging as well as inner carton and nested cartons to have the instructions indicated on Page 104 of this Tender Document printed on them

Technical Specifications

PHARMACEUTICALS

1. Product and Package Specifications

1.1 The Goods to be purchased by the Purchaser under this Invitation for Tenders are included in the Purchaser's *current* 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.")

1.2 Product specifications indicate dosage form (e.g., tablet, *capsules*, *dry syrup*, liquid, *ointment*, injectable, emulsion, suspension, etc.) and the drug content (exact number of mg *or international units* [IU] or % v/v, *w/w or v/w* acceptable range). The Goods should conform to standards specified in the following compendia: [The Purchaser should specify an acceptable pharmacopoeia standard from one of the following: the *British Pharmacopoeia*, the *United States Pharmacopoeia*, the *French Pharmacopoeia*, the *International Pharmacopoeia*, or the *European Pharmacopoeia*, the latter particularly for raw materials.] *The standards will be the latest edition unless otherwise stated by the Purchaser or other if applicable.* In case the pharmaceutical product is not included in the specified compendium, *but included in the Purchaser's national essential drug list, the Purchaser should clearly indicate acceptable limits and* the Supplier, upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing.

1.3 Not only the pharmaceutical item, but also the packaging and labeling components (e.g., bottles, closures, and *labeling*) should also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in Ghana. All packaging must be properly sealed and tamper-proof, *and packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national regulatory authority (RA). The Purchaser should specify any additional special requirements*.

1.4 All labeling and packaging inserts shall be in the language requested by the Purchaser or English if not otherwise stated.

1.5 Goods requiring refrigeration or freezing *or those that should not fall below a certain minimum temperature* for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.

1.6 Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the tender of the prescriber's information for any specific goods the Purchaser may request.

2. Labeling Instructions

2.1 The label of the primary container for each pharmaceutical and vaccine products shall meet the W210 GMP standard and include:

(a) The international nonproprietary name (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;

(b) dosage form, e.g., tablet, ampoule, syrup, etc.;

(c) the active ingredient "per unit, dose, tablet or capsule, etc.";

(d) the applicable pharmacopoeial standard;

(e) the Purchaser's logo and code number and any specific color coding if required;

(f) content per pack;

(g) instructions for use;

(h) special storage requirements;

(i) batch number;

(j) date of manufacture and date of expiry (in clear language, not code);

(k) name and address of manufacture;

(l) any additional cautionary statement.

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

3. Case Identification

3.1 All cases should prominently indicate the following:

(a) Purchaser's line and code numbers;

(b) the generic name of the product;

(c) the dosage form (tablet, ampoule, syrup);

(d) date of manufacture and expiry (in clear language not code);

(e) batch number;

(f) quantity per case;

(g) special instructions for storage;

(h) name and address of manufacture;

(i) any additional cautionary statements.

3.2 No case should contain pharmaceutical products from more than one batch.

4. Unique Identifiers

4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the *labels of the containers* used for packaging and in certain dosage forms, such as tablets, *and ampoules* and this will be in the Technical Specifications. The design *and detail will be clearly indicated at the time of tendering, and confirmation of the design of such logo shall be provided to the Supplier at the time of contract award.*

5. Standards of Quality Control for Supply

5.1 The successful Supplier will be required to furnish to the Purchaser:

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

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

(c) Evidence of bio-availability and/or bio-equivalence for certain critical Goods upon request. *This information*

would be supplied on a strictly confidential basis only.

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

5.2 The Supplier will also be required to provide the Purchaser with access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality control mechanisms.

Technical Specification

VACCINES

1. Product Qualification Requirements

Option A

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

(a) licensing based on published set of requirements

(b) surveillance of vaccine field performance

(c) system of lot release for vaccines

(d) use of laboratory when needed

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

(f) evaluation of clinical performance

Or state the following:

Option B

1.1 The Goods under this Invitation for Tenders should be purchased from WHO-approved sources only.

1.2 The Goods to be purchased by the Purchaser under this Invitation for Tenders must be produced in accordance with the GMP recommendations of WHO for biological products.

1.3 The Goods to be purchased by the Purchaser under this Invitation for Tenders must be registered by the National Control Authority (NCA) of the Ghana.

2. Product Specifications

2.1 Dosage form (e.g.: oral or injectable; liquid or freeze dried with sterile diluent packed separately, etc.).

2.2 Type (e.g.: “live attenuated,” “manufactured from purified inactivated (...) obtained from human plasma or manufactured using recombinant DNA technology,” etc.).

2.3 Administration (e.g.: “intended for intramuscular injection,” etc.).

2.4 Description of intended use (e.g.: “immunization of newborn infants,” etc.).

2.5 Dosage size (if not restrictive), or expected immunogenic reaction (e.g.: each dose shall contain that amount of Hbsag protein with micrograms/ml specified by the manufacturer for newborn dosage, that when given as part of a primary immunization series [3 doses] is capable of producing specific humoral antibody [anti HBs] at a level of at least 10 milli international units in >-90 percent of recipients,” etc.).

2.6 Dose package (e.g.: “5 infant dose sterile glass vials,” etc.).

2.7 Filling volume (e.g.: “final product should contain 15% overfill,” etc.).

2.8 Closures (e.g.: “vaccine vials shall be fitted with closures that conform to ISO standard 8362-2”).

2.9 Storage temperature (e.g.: “2–8 degrees C. Do not freeze,” or as appropriate, etc.).

2.10 The product should remain stable up to the indicated test expiry date if kept according to the required storage temperature.

2.11 Standards (e.g.: “The vaccine should conform to standards established by the Ghana or, where no standard has been adopted, meet current requirements published by the WHO Expert Committee on Biological Standardization, or requirements of an established body of equivalent stature such as the *U.S. Pharmacopoeia, the British Pharmacopoeia, the French Pharmacopoeia, or the International Pharmacopoeia*”).

3. Labeling Requirements

3.1 Each vial or ampoule shall carry the manufacturer’s standard label in the language of Ghana, if available at no extra charge; otherwise, the label shall be in English.

3.2 Each vial or ampoule label shall state the following:

(a) name of the vaccine;

(b) name of the manufacturer;

(c) place of manufacture;

(d) lot number;

(e) composition;

(f) concentration;

(g) dose mode for administration;

(h) expiration date;

(i) storage temperature;

(j) any other information that is appropriate.

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

4. Packing Requirements

4.1 Inner boxes: Inner Boxes shall contain not more than (*number*) individual vials/ampoules and shall be constructed of sturdy white cardboard outfitted with individual segments for protecting and separating each vial/ampoules.

4.2 Printed materials: Each inner box shall contain at least (*number*) manufacturer's standard package inserts in the language of Ghana if available at no extra charge; otherwise, package insert shall be in English.

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

4.4 Exterior shipping cartons: Product and printed materials, packaged as described above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1,900 kPa. The overall

dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

No shipping carton should contain vaccine from more than one lot.

4.5 Cold chain monitor cards: Each insulated shipping container must include appropriate temperature-monitoring devices designated by the Purchaser.

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

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

5. Marking Requirements

5.1 All containers and invoices must bear the following information:

(a) the name of the vaccine;

(b) expiration date of the vaccine;

(c) appropriate storage temperature.

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

(a) Generic name and trade name of the vaccine;

(b) Manufacturer’s name and trade registered address;

(c) Manufacturer’s national registration number;

(d) Lot or batch number;

(e) Composition and concentration;

(f) Number of vials contained in box;

(g) Expiration date (month and year in clear language, not code);

(h) Instructions for storage and handling;

(i) Place of manufacture (Made in _____).

5.3 Exterior Shipping Cartons: The following information shall be stenciled or labeled on the exterior shipping cartons on

two opposing sides in bold letters at least 30mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser.

(a) Generic name and trade name of the vaccine;

(b) Lot or batch number;

(c) Expiration date (month and year in clear language, not code);

(d) Manufacturer's name and registered address;

(e) Manufacturer's national registration number;

(f) Destination airport and routing;

(g) Consignee's name and address in full;

(h) Consignee contact name and telephone number;

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

(j) Gross weight of each carton (in kg);

(k) Carton #____ of _____;

(l) Instructions for storage and handling;

(m) Contract number;

(n) Place of manufacture (Made in_____).

6. Quality Control for Supply

6.1 All goods must:

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

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

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

(d) be fit for the purposes expressly made known to the Supplier by the Purchaser;

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

(f) be certified by a competent authority in the manufacturer's country according to resolution WHA 28-65(2), of the WHO release certificate.

6.2 The Supplier will be required to furnish to the Purchaser with each consignment;

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

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

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

6.3 Preshipment inspection and testing: The Supplier will be required to provide the Purchaser or his representative with access to the product as packed for shipment at the sellers' factory and/or warehouse at a mutually agreeable time prior to shipment of the product.

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

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

DETAILED TECHNICAL SPECIFICATIONS – MALE CONDOMS

SPECIFICATION FOR LATEX RUBBER CONDOMS (Lots 3 & 4)

(Based on WHO/UNFPA Specification, Prequalification and Guidelines, 2010 and ISO 4074:2015

This Specification describes the performance, design, and general requirements for condoms purchased in accordance with the WHO/UNFPA Specification, Prequalification and Guidelines for Condom procurement, published in 2010.

Compliance with this Specification will be verified by the laboratory testing of batches arriving in the country on lot-by-lot basis. Suppliers are required to get from the manufactures a copy of the pre-testing result from an independent quality control laboratory before shipment to enable us inform the FDA accordingly. Unless otherwise stated, the method of verification for each attribute and performance requirement will be that specified by ISO 4074:2015 and ISO 4074:2015 Corrigendum 2: 2008.

1. GENERAL REQUIREMENTS

1.1 Materials

The condoms shall be made of natural rubber latex, and shall be capable of meeting all requirements and passing all tests specified herein. The rubber latex shall be free from embedded solid impurities and discoloration. The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing or otherwise harmful to the user of the condom under normal conditions of use, and shall be in strict compliance with ISO 10993.

Biocompatibility assessments shall be conducted in accordance with ISO10993-1. Specifically, tests shall be conducted for cytotoxicity according to ISO 10993-5 and for irritation and sensitization according to ISO 10993-10. Manufacturers should use accredited toxicologists or other suitably qualified expert.

*Manufacturers shall take steps to minimise the level of water-extractable proteins in the condoms. The recommended levels for soluble proteins, as determined by the modified Lowry method, should be less than **200 µg/g.** Manufacturers should take steps not to exceed this level and should monitor production periodically.*

A suitable dusting powder (e.g. cornstarch, magnesium and calcium carbonate) should be used to improve the “feel” of the condom, to prevent the condoms from sticking together during manufacture and facilitate unrolling.
Talc or lycopodium spores must not be used.

The quantity of powder used should not exceed 50 mg per condom.

The condoms and their packaging shall be free of defects that affect their durability, detract from their appearance, or impair their serviceability.

1.2 Minimum Stability Requirements

Condoms shall comply with the minimum stability requirements defined in ISO 4074.

1.3 Sampling

Condoms shall be sampled from three Manufacturing Lots in accordance with Annex B of ISO 4070.

1.4 Conditioning

Condoms shall be conditioned at 30 ± 5°C in *a*ccordance with the relevant Annex of ISO 4074.

2. PERFORMANCE REQUIREMENTS

2.1 Bursting Volume and Pressure

Sampling

The Manufacturer shall assess compliance with the requirements for bursting properties, freedom from holes and packaging integrity in accordance with relevant clause of ISO 4074 at least annually for the full shelf life of the product.

All three Lots of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and package integrity

In accordance with: ISO 2859-1 General Inspection Level 1.

Testing

In accordance with the test method in the relevant Annex of ISO 4074and the relevant clause of ISO 4074.

Minimum Bursting Requirement is as listed below:

AQL: 1.5

Volume: *16.0 dm^3 for condom widths less than 50.0 mm*
18.0 dm^3 for condoms with widths from 50.0 mm up to but not including 56.0 mm

Pressure: 1.0 kPa (for all widths)

The width is defined as the mean lay flat width of 13 condoms measured in accordance with the relevant Annex of ISO 4074: at a point 75 ± 55 mm from the closed end, rounded to the nearest 0.5 mm.

.

2.2 Freedom from Holes and Visible Defects Sampling

In accordance with ISO 2859-1 General Inspection Level 1, at least code letter M.

Testing

The Manufacturer shall test samples in accordance with Annex B of ISO 4074 using at least Code Letter M.

Requirement

Freedom from holes: **AQL 0.25.**

Critical visible defects: **AQL 0.4**

Non- critical visible defects: **AQL 2.5**

The most common visible defects, both critical and non-critical, are described in ISO 4074:

Critical defects are those which will affect the performance of the condom. These defects include: Pleats/Creases, Blisters/Bubbles, Visible holes, Coagulum (>0.2mm), Embedded particles (>1mm), Faulty bead, Crack marks, Delamination and Thin spots.

Non-critical defects may not cause the condom to fail but are undesirable for the user. These defects include Coagulum (<0.2mm), Embedded particles (<0.1mm), Irregular teat, Surface discoloration/Streaks.

2.3 Package (Seal) Integrity

Sampling

In accordance with ISO 2859-1 Inspection Level S-2.

Testing

The test shall be carried out in accordance with ISO 4074:

3. DESIGN REQUIREMENTS

The following design requirements should be adhered to.

3.1 Shape and Texture

The surface of the condoms shall be smooth (non-textured) throughout. The condoms shall have straight and parallel sides, without constrictions, and with a visible shoulder leading to a reservoir pouch at the tip.

3.2 Integral Bead

The open end of the condom shall have a thickened rolled ring of latex, called an integral bead.

3.3 Colour and Clarity

The condoms shall be translucent (clear) and without added colouring.

3.4 Odour and Taste (Scents and Flavourings)

The condoms shall not give off any unpleasant odour when the package is opened at any time after manufacture and during the stated shelf-life of the product.

The purchaser or the purchaser's agent will retain and store 350 condoms from each lot as reference samples for use in resolving disputes.

The Bazuka Condoms (Lot 4) shall have a mild Lime scented Flavour

Any masking agent used must be non-toxic and non-irritating and must not degrade the rubber according to biocompatibility studies conducted to ISO 10993.

3.5 Length

Sampling

In accordance with ISO 2859-1, Inspection Level S-2

Testing

According to the length measurement procedures in ISO 4074.

Requirement:

A minimum of 165 mm for condoms with widths less than 50 mm

A minimum of 180 mm for condoms with widths from 50.0 mm up to 55.5 mm

A minimum of 190 mm for condoms with widths equal to or greater than 56.0mm

AQL 1.0

3.6 Width

Sampling

In accordance with ISO 2859-1, Special Inspection Level S-2

Testing

According to the width measurement procedure in ISO 4074.

Requirement

Limits: Individual condom 52 ± 2mm
Mean Batch (LOT) average: ± 1 mm

AQL 1.0

3.7 Thickness:

Sampling

In accordance with ISO 2859-1, Special Inspection Level S-2

Testing

According to the thickness measurement procedure in ISO 4074.

Requirement

The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points.

The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.05 - 0.07 mm (that is, the average of the thickness measurements of each condom must fall within the limits 0.050 – 0.070 mm).

The thickness measurements obtained on textured condoms should be used with caution since they may be the average of the textured and smooth portions of the condom.

AQL 1.0

3.8 Lubricant Quantity (including Powder)

Sampling

In accordance with ISO 2859-1 Special Inspection Level S-2.

Testing

In accordance with the test method in ISO 4074.

Requirement

The condoms shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 Centistokes (Cs). The quantity of lubricant, including powder used should not exceed 50 mg per condom.
The quantity of lubricant, including powder, in the package shall be
(550 $\pm$ 150) mg.

AQL 4.0

Other lubricants such as glycol and water-based lubricants may be used.

Oil-based lubricants must NOT be used.

Minimum recommended quantity of lubricant is 250 250mg

Condoms falling outside the limits of any of the Design requirements are considered as Non-compliers.

3.9 Primary Pack – materials and markings

Sampling

In accordance with ISO 2859, Inspection level S-2.

Requirement

The condoms shall be sealed in square, individual packages constructed of a laminate that shall include a layer of suitable impermeable flexible aluminium foil of minimum 8 micrometers thickness, and layers of plastic materials suitable for the mechanical protection of the foil, and for printing and sealing. The packages shall be hermetically sealed and impermeable to oxygen, ozone, water vapour, ultraviolet and visible light, and shall have sufficient internal volume to avoid damaging the rolled condom.

Below is the artwork for LOT 3 and LOT 4 for the colour.

The packages shall be provided in strips of three (3), perforated or otherwise designed to facilitate separation by hand without interfering with the seals. The packages must be easy to open, without damaging the condom, and can have a notch or serration to assist in opening.

- **Below is the artwork for LOT 3 for the colour. (BE SAFE)**

- **Below is the artwork for LOT 4 for the colour. (BAZUKA)**

Any batch (LOT) number on the package *must be printed at the time of packaging* - not pre-printed.

In addition, the packages shall conform to the following requirements:

- There shall be no evidence of leakage
- The outside surface of the package shall be clean
- There shall be no separation of the layers of laminate
- The packages must be easy to open without damaging the condom

The packages shall have the following markings (printed on the reverse side (back).

- Manufacturer's name.
- Batch (LOT) number or Lot identification code (printed at the time of packaging, not pre-printed)
- Month and year of expiry, in numerical form, *mm/yyyy*, marked *Expiry date.*

4. PACKAGING FOR DELIVERY

4.1 Secondary Packs

The secondary pack shall be a box of white-lined cardboard, at least 375g/m^2, with a loose plastic liner, each box to contain 144 condoms (48 strips of 3).
The box shall be of sufficient strength and rigidity to retain its shape through every stage of the distribution chain.

Each box shall be printed, legibly, with the following information

- Number of condoms in the box.
- Batch (LOT) number or identification code.
- Month and year of manufacture (including the words Date of Manufacture, Month, Year), in English. The year will be written as a four digit number and the month as a two digit number. i.e. *mm/yyyy*
- Month and year of expiry, in numerical form, *mm/yyyy*, including the words: *Expiry date.*
- Manufacturers name and registered address.

- Nominal width (in millimetres).
- Number of condoms in each box
- Instructions for storage.

Each secondary pack shall have the following inscribed on it:

"When used correctly, every time you have sex, condoms greatly reduce the risk of unintended pregnancy, HIV/AIDS and some other sexually transmitted infections. Use a new condom every time you have sex and follow the instructions carefully".

ALL MARKINGS SHALL BE IN ENGLISH

4.2 Tertiary (Shipment) Pack

The tertiary pack is a shipment carton holding 50 gross shipping cartons with white boxes, which are to be packed into plastic or other waterproof lining bags before being placed in the shipment carton. The carton is to be constructed of three-wall weather-resistant corrugated fibreboard, with a bursting strength of at least 1900 kPa (275 lbs/in^2).

The carton flaps shall be sealed with water-resistant tape at least 75 mm wide, applied to the full length of the centre seams and extending over the end by not less than 75 mm.

The cartons will be secured by plastic strapping at not less than two positions.

The cartons must be capable of being stacked to a height of at least 6 metres.

In some countries, the three-wall corrugated fibreboard available is not of sufficient strength and rigidity to meet the stacking requirements or to resist being cut at the corners when the plastic strapping is applied. In such cases, an inner carton of two-wall corrugated fibreboard shall be inserted into the shipping carton before packing the condoms.

The carton shall be marked and printed, in a clearly legible manner, on both end-walls of the carton, with the following information:-

- Batch (LOT) number or identification code.
- Month and year of manufacture, in numerical form, *mm/yyyy*, including the words: *Date of Manufacture.*

- Month and year of expiry, in numerical form, *mm/yyyy*, including the words: *Expiry date.*
- Manufacturer's name and registered address.
- Nominal width (in millimetres).
- Number of condoms in the carton.
- Instructions for storage and handling.
- Name and address of consignee

To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each discrete LOT shall be assembled and shipped together.

LOT traceability: Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.

These efforts must include the use of very large font sizes for LOT codes on the exterior shipping cartons; colour coding; using one pallet per LOT; physically linking all exterior shipping cartons from discrete LOTS; and issuing instructions to this effect to shippers and warehouse personnel.

5. TESTS FOR PACK CONDITIONS AND MARKINGS

5.1 Primary Pack

Sampling

In accordance with ISO 2859-1 Special Inspection Level S-2

Testing

By visual inspection

Requirement

- There shall be no evidence of leakage
- The outside surface of the package shall be clean and free from lubricant
- The laminate shall be intact, and there shall be no separation of the layers of laminate

- The individual packages shall be separated by perforations or other means which allow the packages to be separated by hand without interfering with the seals

- The package shall be easy to open (they may have a notch or serration to assist in opening)

- The identification marking shall be complete, correct and legible, as specified in Section 3.9

AQL 2.5

5.2 Secondary and Tertiary Packs

Sampling

ISO 2859-1 Special Inspection Level S-2

The batch size for the inspection of inner boxes is the number of inner boxes, and the sample unit is one inner box. For the inspection of exterior shipping cartons, the batch size is the number of exterior shipping cartons, and the sample unit is one shipping carton.

Examination of inner boxes is done on boxes selected at random from sample shipping cartons. Examination of defects of closure is done on randomly selected shipping cartons fully prepared for delivery.

Testing

Testing of pack conditions and markings will be by visual inspection, and will be carried out by the purchaser's own inspectors.

Requirements

The individual requirements for the secondary and tertiary packs are set out below. The AQL for these inspections is 2.5.

5.3 Classification of Defects

Defects found in the packaging and the marking of packages for delivery should be recorded in accordance with the following table:

Classification of Defects in Packaging and Marking of Packages for Delivery

Examine	Defects
Contents	Number of condoms not as specified; packages or strips not as specified
Marking	Omitted; incorrect; illegible; of an improper size, (Exterior, Interior) location, sequence, or method of application
Materials	Packaging/packing materials not as specified, missing, damaged or non-serviceable
Workmanship	Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted intermediate packages

6. WORKMANSHIP

The supplier is required to follow an appropriate code of Good Manufacturing Practice for the manufacture and packaging of condoms. The condoms and their packaging must be free of defects that affect their durability.

7. BATCH TRACEABILITY

To facilitate monitoring of batch (LOT) quality during shipping and storage, it is essential that all exterior shipping cartons for each discrete batch (LOT) are assembled and shipped together.

Efforts must be made to ensure that shipments remain organised as discrete batches (LOTS) and that these batches (LOTS) remain intact as far down the distribution system as possible.

These efforts may include the use of very large lettering for batch (LOT) codes on the exterior shipping cartons, colour coding, palleting of discrete batches (LOTS) or otherwise physically linking all exterior shipping cartons from discrete batches (LOTS), Instructions to this effect shall be issued to shippers and warehouse personnel.

8. PLACING OF WAHO LABEL

Suppliers are required to label all shipping boxes. The boxes should be arranged in the container such that labels remain legible until the container reaches its final destination. Suppliers must use the label in page 154 with dimension 15cm x 10cm on each of the two (2) widest sides of the shipping boxes.

GHANA MOH CONDOM SPECIFICATIONS

SUMMARY SPECIFICATION FOR LUBRICATED, NATURAL CONDOMS

This summary specification is included for quick reference to the test Requirements for each test parameter, and should be read in conjunction with the main specification on pages 96 to 109.

Specification	Limits	Test Method (ISO 4074:2015	Inspection Level (ISO 2859-1)	AQL
Performance Requirements				
Burst volume and pressure				
Before Oven Conditioning				
Burst Volume (individual condom)	≥18.0L	Annex G and general requirement clause 6.1.	G-1	1.5
Burst Pressure for all widths	≥ 1.0 kPa		G-1	1.5
Freedom from Holes	No Leakage	Annex L	G-1 (at least code N)	0.25
Visible defects		Annex L	G-1 (at least code N)	0.4 (critical) 2.5 (non-critical)
Package (Seal) Integrity	No air leakage or visible test fluid	Annex M	S-2	2.5
Design Requirements				
Length	≥180mm	Annex D	S-2	1.0
Width (individual)	53.0 ± 1mm	Annex E	S-2	1.0
Width (batch mean)	53.0 ± 1mm			
Thickness	0.05 - 0.07mm	Annex F	S-2	1.0
Lubricant Quantity	550 ± 150mg	Annex C	S-2	4.0

Specification	**Limits**	**Test Method (ISO 4074:2015**	**Inspection Level (ISO 2859-1)**	**AQL**
Performance Requirements				
Lubricant Viscosity	200-350Cs			
Package Condition & Marking	Free from defects	Visual inspection	S-2	2.5

NOTES TO TENDERERS ON THE PREPARATION OF SAMPLE FORMS

The Purchaser has prepared the forms in this section of the Tender Documents to suit the specific requirements of the procurement. In its tender, the Tenderer **MUST** use these forms. If the Tenderer has a question regarding the meaning or appropriateness of the contents or format of the forms and/or the instructions contained in them, these questions should be brought to the Purchaser's attention as soon as possible during the tender clarification process, by addressing them to the Purchaser in writing pursuant to ITT Clause 11.

The Purchaser has provided explanatory text and instructions to help the Tenderer prepare the forms accurately and completely. The instructions that appear directly on the forms themselves are indicated by use of typographical aides such as italicized text within square brackets.

In preparing its tender, the Tenderer **MUST** ensure all such information is provided and that the typographical aides are removed.

SAMPLE FORMS

1. Tender Form

Date: _____

IFT No.:_____

Name of Contract_____

To: _____

_____

_____

_____

Dear Sir or Madam:

Having examined the Tender Documents, including Addenda Nos. _____, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said Tender Documents for the sum of:

	[insert: ***amount of local currency in words*** *]*	*([insert:* ***amount of local currency in figures*** *])*
plus	*[insert:* ***amount of foreign currency A in words*** *]*	*([insert:* ***amount of foreign currency A in figures*** *])*
[as appropriate, include the following]		
plus	*[insert:* ***amount of foreign currency B in words*** *]*	*([insert:* ***amount of foreign currency B in figures*** *])*
plus	*[insert:* ***amount of foreign currency C in words*** *]*	*([insert:* ***amount of foreign currency C in figures*** *])*

(hereinafter called "the Total Tender Price") or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this tender.

We undertake, if our tender is accepted, to deliver the Goods in accordance with the delivery schedule specified in the Schedule of Requirements.

If our tender is accepted, we undertake to provide an advance payment security and a performance security in the form, in the amounts, and within the times specified in the Tender Documents.

We agree to abide by this tender, for the Tender Validity Period specified in Clause 18.1 of the Tender Data Sheet and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final Contract is prepared and executed between us, this tender, together with your written acceptance of the tender and your notification of award, shall constitute a binding Contract between us. We understand that you are not bound to accept the lowest or any tender you may receive.

Commissions or gratuities, if any, paid or to be paid by us to agents relating to this tender, and to contract execution if we are awarded the Contract, are listed below:

Name and Address of Agent	Amount and Currency	Purpose of Commission or Gratuity

(if none, state "none")

Dated this ____ *[insert:* ***number*** *]* day of _____ *[insert:* ***month*** *]*, 20___ *[insert:* ***year*** *]*.

Signed: _____

Date: _____

In the capacity of _____ *[insert:* ***title or position*** *]*

Duly authorized to sign this tender for and on behalf of

_____*[insert:* ***name of Tenderer*** *]*

2. Price Schedule for Goods Offered from Abroad

(Group C tenders)

Name of Tenderer _____. IFT Number _____. Page of ___.

1	2	3	4	5	6	7				8	9	10	11	12	13
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices				Total unit price DAP (MOH Temporary Central Medical Stores, Spintex Road [b+c+d]	Total price per Item (DAP) [6 x 8]	Shipment weight and volume	Name of manufac-turer	Country. of origin	Pharma-copoeial standard
						[a] Unit price **FOB** or FCA port or place of loading	[b] **DAP** (MOH Temporary Central Medical Stores, Spintex Road)	[c] Inland transp., insurance & other local costs incidental to delivery if specified	[d] Other incidental costs as defined in the SCC						

Total Tender Price (DAP WITHOUT VAT& NHIL at MOH Temporary Warehouse, Spintex Road, Accra):
Currency:
In figures:
In words:

Signed: _____

Dated: _____

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

3. Price Schedule for Domestic Goods Offered from within the Ghana

(Group A and Group B tenders)

Name of Tenderer _____. IFT Number _____. Page . of ___.

1	2	3	4	5	6	7			8	9	10	11	12	13
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices			Total unit price [a+b+c]	Total price per item [6 x 8]	Sales and other taxes payable if contract is awarded	Name of manufacturer	Pharma-copoeial standard	Local input in the cost as % of ex-factory price in column 7[a]
						[a] Ex-factory Ex-warehouse Ex-showroom Off the shelf	[b] Inland transp., insurance & other local costs incidental to delivery	[c] Other incident-al costs as defined in the SCC						

Note:

(i) Column 7[b] is optional and it will be applicable only when required in accordance with ITT Sub-Clause 16.2 (a) (iii) and (iv) and the related provisions in the Tender Data Sheet.

(ii) For column 9, pursuant to ITT 30.1 in the case of discrepancy between unit price and total price, the unit price shall prevail.

(iii) For column 13, a breakdown of the cost of local labor, local raw materials, and local components provided from within the country should also be indicated separately as specified in ITT Sub-Clause 27.1 along with adequate proof to substantiate each of these local inputs.

Total Tender Price (DAP WITHOUT VAT& NHIL at MOH Temporary Warehouse, Spintex Road, Accra):
Currency:
In figures:
In words:

Signed: _____

Dated: _____

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

Domestic Value Added Calculation Form

Name of Tenderer:	Factory Location:

IFT Number:_____

- To be completed by manufacturers located in Ghana only.
- To be completed for Goods manufactured in Ghana, which have at least 20 per cent domestic value added in the ex-factory tender price.
- Manufacturers may be required to provide further evidence to verify domestic value-added claims, the amount of customs duty on finished Goods, and details about any associations established with foreign or local firms that would affect the manufacturing process.

Product: _____

Strength: _____

Dose: _____

Pack Size: _____

Ex-Factory Tender Price: _____

	Component Cost			
	Imported	Local	Total	% OF local Component Cost to Ex-Factory Tender Price
Product Component				
Active Raw Material				
Excipients				
Packaging				
Local Materials				
Local Labour				
Cost of Capital				
Estimated Duties & Taxes				
Overhead				
Profit				
Other				
TOTAL				

Signature of Tenderer: _____

Date: _____

4. Tender Security Form

Date: _____*[insert: **date**]*

IFT: _____*[insert **name and number of IFT**]*

Contract: _____*[insert: **name and number of Contract**]*

To: _____

_____

_____

_____

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 Bank this _____ *[insert: **number**]* day of *[insert: **month**]*, *[insert: **year**]*.

THE CONDITIONS of this obligation are the following:

1. If, after the tender submission deadline, the Tenderer

   (a) withdraws its tender during the period of tender validity specified by the Tenderer in the Tender Form, or

   (b) does not accept the Purchaser's corrections of arithmetic errors in accordance with the Instructions to Tenderers; or

2. If the Tenderer, having been notified of the acceptance of its tender by the Purchaser during the period of tender validity

   (a) fails or refuses to sign the Contract Agreement when required; or

   (b) fails or refuses to issue the performance security in accordance with the Instructions to Tenderers.

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

This guarantee will remain in full force up to and including _____ *[insert:* ***the date that is 28 days after the period of tender validity*** *]*, and any demand in respect thereof must reach the Bank not later than the above date.

For and on behalf of the Bank

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

Common Seal of the Bank

5. Form of Contract Agreement

CONTRACTING ORGAN'S letter header

City, date..... ..

CONTRACTING ORGAN

(Full address)

SUPPLIER

(Full address)

SUBJECT: Procurement No. ..... Contraceptives

Your ref: Your tender No. ....

Sir/Madam,

We refer to your proposal in response to the invitation to tender ***(to be specified: "Limited Consultation", "International Bid" or "National Bid")*** No. .... xx xx xx ***(date advert was placed)*** by..... ***(Procurement organ)*** for the procurement of..... ***(List the products)*** **to be financed by the West African Health Organization (**ECOWAS No. 2014 68 289**) on behalf of.....** ***(mention the beneficiary)***, with WAHO's notice of No-Objection dated xx xx xxxx (***the NO date***), approving the contract award for the said

Consultation *(or: the international / national bid)*, we are pleased to notify you of this Contract for the supply of the products listed on the order form *(or in the absence of the order form: "the invoice slip")* dated .....copy of which is attached.

The terms set out below shall govern this Bid. **Kindly read through very carefully and indicate your acceptance of the terms by signing the contract.**

Article 1 Purpose of the Contract

The aim of this Contract is to supply..... *(Indicate the product(s) and quantity)* **and unit price** to the … *(procurement organ)*, on behalf of..... *(Indicate the beneficiary)*, as indicated on the order form *(or in the absence of the order: "the invoice slip")* annexed.

Delivery will be in ... *(to be specified, for example "in a single tranche," or "in two tranches by this date and that date" etc.).*

Article 2 Contract documentation

The documentation consist of:

• the Contract,

• the invoice slip,

• the contract award notification letter,

• the bidding dossier,

• the Purchase Order issued for the Contract,

• Any documentation proving product compliance with technical specifications,

• All documents and correspondences exchanged between the parties during the course of Procurement.

Article 3 Contract Type and Duration

3.1. Contract Type

This is a purchase order contract *(when purchase orders are issued. Otherwise: "This Contract is ...")* based on unit price of..... *(Indicate the product(s)).*

3.2. Contract Duration

The Contract shall take effect from the date of notification and be concluded within a period of ..... month(s).

Article 4 Value of the Contract:

4.1. The total value of the Procurement excluding tax in ... *(State the INCOTERMS)* delivered to..... *(Final delivery destination)* in..... *(Specify the city)* is *amount in words* and *figures*.

4.2. Prices are **fixed and non-reviewable and may not vary on any item** throughout the duration of the Contract, and shall include transport and delivery costs to the location indicated **in article 7 hereunder**.

Article 5: Payment Procedure

5.1. KfW shall be directly responsible for the payments, to be effected as follows:

100% of the Procurement costs: *amount in words* and *figures*, xx (xx) **days after** the complete and satisfactory delivery of products and on submission of the invoice along with a delivery note

confirming that the Supplies have been delivered.

(Or for payment in installments, for example):

- **XX% advance** upon presentation of duly formulated corresponding surety and valid for 30 days after the deadline for delivery,
- **the balance of XX% no later than XX days after the date** goods are delivered **in store** based on the purchase order.

5.2. In order to receive payments, the Supplier shall submit a claim to the xxx *(Procurement Organ)* accompanied by original invoices for the payment.

Each invoice shall indicate the following:
- The name and address of the Holder.
- The bank details of the Holder, as specified on the Contract (Bank account details).
- Contract Date and number.
- Purchase order date and number set by the Beneficiary for the Contract.
- For each item delivered:
o The full description, as indicated on the order form.
o The unit quantity delivered as indicated on the delivery note and packing list.
o The unit price and in the currency indicated on the order form (xxx *(specify currency)*).
o The total amount in the same currency.
- The total amount on the invoice, in the same currency.
- The origin of the product delivered
- The signature of the person authorized *(or: qualified)*, to represent the Holder, and the company stamp.

5.3. The cost of the Goods procured shall be paid in **xxx** ***(specify currency)*** directly by KfW once the invoice and confirmation of receipt is dispatched.

5.4. Any correspondence or document relating to this Procurement shall cite the references of the said Procurement.

Article 6 Receiving Payments

Payments will be made by bank transfer to account No .....
..... [1]
within xxx ***(xxx)*** days after complete and satisfactory delivery and upon presentation of the request for payment along with requisite documents stipulated in article 5.2 of the said Contract.

Article 7 Place of Delivery and Verification

7.1. The supplies shall be delivered by the supplier to the stores of the xxx ***(Procurement Organ)*** in xxx ***(specify the city)*** at the address below:

"INDICATE FULL ADDRESS"

7.2. All checks provided for in Article 8 below shall be conducted randomly in the stores of the..... ***(Procurement Organ)*** in xxx ***(specify the city)*** and concluded with a report signed by parties involved (Beneficiary Program, Procurement Organ, Supplier or the representative) or failing which, a report to be drawn up by a bailiff or any sworn officer.

[1] Indicate your RIB *(full bank details)*

7.3. All invoices, delivery slips and packing lists must bear the related Procurement references.

7.4. The Supplier shall be responsible for transporting supplies to the delivery location specified in the Contract. Cost of transportation, insurance, handling and warehousing will be borne by the supplier. The products being delivered XXXXX *(Specify the INCOTERMS and their designated final destination)*.
In the event of a "DDP - Delivered Duty Paid" delivery, the Holder must take prompt measures to complete the formalities for removal within the time required in order to deliver the products within the agreed deadlines. In any event, the responsibility for demurrage rests with the Holder.

7.5. The goods delivered shall become the property of the beneficiary once received in full, which should be 30 days after delivery to the store.

7.6. In case of shipment by sea or air, the supplier shall provide comprehensive insurance covering at least all the risks and perils as defined by the clause "Institute Cargo" (comprehensive), including the risk of war and strikes, where obtainable. The insurance cost must be 110% of the price charged for delivery to destination. Transportation from the factory of the Supplier in the country of manufacture, to the Purchaser's designated location *(specify the final destination)* pursuant to clause xxx of the Special Conditions of Contract (CCP) should be covered by the insurance, that is to say, a warehouse to warehouse insurance (EAE). Unless otherwise indicated in the CCP, losses will be payable in Euros to KfW, Frankfurt Account (BIC: KFWIDEFF, BLZ 500 204 00), account no. 38000000 00 (IBAN: DE53 5002 0400 3800 0000 00).

Article 8 Quality Assurance

8.1. For each batch delivered a record of the tests conducted (or analysis report) in the

manufacturer's laboratory must be provided. The record of analysis shall specify the methods (pharmacopoeia or internal) used.

The xxx *(procurement organ)* reserves the right to reject all batches without an analysis report.

The supplier shall take appropriate steps to register the products in the country of the beneficiary. He must provide the xxx *(Procurement Organ)* a copy of the marketing authorization (AMM) or a copy of the warehouse release record papers for products still without marketing authorization in the country of the Beneficiary. *(Section to be adapted to country regulations)*

8.2. The expiry date of the delivered products may not be less than X / X *(to be specified: for instance, 3/4 or 5/6 for certain products depending on the shelf life)* of the total lawful duration for the use of each product when received in the stores of xxx *(Procurement Organ)*.

8.3. Supplies that are sub-standard, unusable, destroyed or degraded will be replaced by the supplier within an agreed stipulated timeframe upon notification of the request of xxx *(Procurement Organ)*. Rejected supplies shall be removed or destroyed at the supplier's expense.

8.4. In the event of damages to supplies that emerge close to the end of the warranty period that is to say before the expiry date of the products, or from test results not compliant with the European, French, British or American pharmacopoeia, the supplier must bear the costs of replacing the damaged goods within a consensually agreed timeframe.

8.5. The manufacture and expiry dates, batch numbers and full addresses of the factories are to be printed in indelible ink on the primary and secondary packaging labels of products. These must be legible to the naked eye.

8.5.1. It is mandatory that product descriptions are written in the English language and clearly legible.

8.5.2. The boxes with labels not marked accordingly will not be accepted.

8.6. The required packaging must be strictly adhered to or otherwise rejected.

8.7. The supplier shall deliver goods matching the technical specifications proposed in the bid.

In case of non-compliance with the provisions of this Article, the xxx *(Procurement Organ)* reserves the right to reject the items delivered, which must then be replaced at no cost and within a consensually agreed timeframe.

8.8. Whenever the Supplier, upon notice, fails to rectify defect(s) within a reasonable timeframe, the Buyer may begin taking the necessary measures, at the risk and expense of the supplier and without any prejudice to the Supplier's rights in that regard, in line with the Contract Clauses.

8.9. Guaranteeing the Durability of the Products Delivered

8.9.1. The Supplier shall guarantee the durability of products delivered throughout their validity period. As such, the Supplier shall bear the cost of replacing products which have suffered any damage, making them unusable.

The Beneficiary shall take all necessary measures to ensure the preservation of products in stores in accordance with Good Distribution Practice laid down by WHO.

8.9.2. Whenever a product is seen to deteriorate even before its expiry date, the Beneficiary shall report the facts and circumstances, immediately notifying the Supplier in writing, supporting his/her finding with an adequate sample of the degraded product, taken from the remaining stock in his/her stores.

8.9.3. The Beneficiary may demand that the Supplier replace the total quantity of the batch or batches in question and still in stock in his/her stores. To this end, the beneficiary shall inform the Supplier of the affected stock.

The Supplier shall proceed to deliver the replacement batch within a reasonable timeframe from the date of notification of the remaining stock. Unless otherwise instructed by the Beneficiary, delivery will be by the fastest mode of shipment.

The specifications for the replacement batch shall match those of the original delivery under the Contract.

8.10. Assisting the supplier

The Beneficiary shall undertake to assist the Supplier to ensure the success of the contract, and more importantly prevent and resolve any problem that may occur in the institutions or national territory of the Beneficiary.

As such, the Beneficiary shall send the Supplier all documentation required for shipment, which includes:

- required authorization for the importation of drugs and other pharmaceuticals into the country of the Beneficiary,

- Specific customs arrangements, capable of expediting the removal process,

- Specific certification arrangements for the registration of drugs to be placed on the local market.

Article 9 Product Quantity

9.1. The quantity of products delivered should tally with the actual order. Consequently, shipping documents, invoices, delivery notes, packing lists must state the quantity of products ordered by the buyer. In the event of partial delivery, the quantities eventually delivered should add up to the total quantity on the order.

9.2. For loading or delivery of possible additional quantities of products ordered by the buyer, the supplier should obtain prior agreement.

9.3. In case of non-compliance with the provisions of this Article, the buyer may hand over to the Customs Administration products not ordered or delivered in excess. In addition, the supplier will be mandated to pay for the removal of products rejected by the buyer and also address customs infringements. In the event of a recurrence, the supplier may be dropped from the buyer's vendor file.

Article 10 Provisions for Product Shipping *(specify INCOTERMS)*

10.1. Before Loading:

The information below must be sent by fax, email or post to the xxx *(procurement organ)* at least two (2) working days prior to loading:

1. Invoice or part of the invoice of products to be shipped,
2. Packing list,
3. The number of palettes and their total content:
   (Example: 10 palettes = 500 cartons, number of containers, number of parcels by

shipment)

4. Weight,

5. References of the vessel (ship or air), and Air Way Bill (AWB)or bill of lading.

10.2. After Loading:

10.2.1. Shipment by Sea:

A copy of the bill of lading and the original record-keeping documents listed in Article 16 below should be forwarded by express courier to xxx *(Procurement Organ)* at the address below:

INDICATE THE FULL DELIVERY ADDRESS

10.2.2. Shipment by Air:

The Airway Bill (AWB), an original copy of the invoice and shipment packing list must accompany the products.

The original record-keeping documents listed in Article 16 below should reach the XXXX *(Procurement Organ)* by express mail or courier at the above address.

Article 11 Failed Delivery

If at any given time during the execution of the Contract, the Supplier or subcontractor(s) encounters circumstances that hinder the timely delivery of goods or services, the Supplier shall promptly notify the Buyer in writing at least one (01) month before the deadline stipulated on the Contract, of the delay, its likely duration and cause(s). Upon receipt of the Supplier's notification, the Buyer shall endeavor to promptly evaluate the situation; and shall have the power to extend the deadline for delivery of products or services, in which case the extension shall be ratified by the parties as an addendum to the Contract.

Article 12 Penalty for Late Delivery

Subject to the provisions of Article 11 above, if the Supplier fails to deliver any or all of the goods or services within deadline(s) specified in the Contract, the Buyer, without prejudice to the other provisions of the Contract, may deduct a sum equivalent to that specified in the CCP, from the cost of the order concerned, as penalty, for late delivery of goods or non-delivery of services, and for every day of delay before actual delivery of goods or services, up to a maximum of 10% of the cost of the said goods and services. Once the maximum is reached, the Buyer without prejudice to the other provisions of the Contract may consider terminating the Contract.
The formula for calculating the penalty for lateness:

$$P = \frac{V*R}{1{,}000}$$

Where: P =Penalty, V = Value of the supplies or services and R = Number of days behind schedule.

The value **V** is equal to the initial value of the supplies or services. However, where delivery of products is staggered, the value will be equal to the original value of the delayed goods.

Excepting a Force majeure (see Article 20), penalties are fully applicable on any invoice raised for an item delivered after the agreed delivery date.

The following measures may also be taken in addition to the above mentioned:

a) fall back on the performance bond;

b) suspension, for a period of 1 to 2 years,

c) Permanent withdrawal from the list of prequalified suppliers.

Article 13 Guarantee for Proper Execution

13.1. For the proper execution of the Contract, the supplier shall at his own expense and regardless of the selected mode of payment, obtain a guarantee, representing 10% (ten percent) of the Contract or xxx *(Specify the cost of the guarantee).*

13.2. A letter of Guarantee (in line with the template annexed to this Contract) by a reputable bank acceptable to xxx *(Procurement Organ)* shall serve as the guarantee. The said guarantee must be submitted within fifteen (15) days from the date of notification of the Contract by xxxx *(Procurement Organ)* and must remain valid thirty (30) days after the deadline for complete delivery of products mentioned in the Contract.

13.3. The Supplier shall be fully responsible for obtaining this guarantee.

13.3.1. Any guarantee bearing a validity date that precedes the date stipulated above will be rejected.

13.3.2. The supplier may also provide a certified cheque payable to the xxx *(Procurement Organ)*.

All reimbursements for insurance payments, guarantees, deposits or similar payments arising from transactions and paid services under the provisions of this Contract will be made to KfW, Frankfurt / Main, account no. IBAN DE53 5002 0400 3800 0000 00 BIC: KFWIDEFF.

Deadline for delivery: *(specify the delivery deadline for each product)*

Validity period of the guarantee: .... In all cases, the validity date of the guarantee should be updated taking into account the date of actual delivery.

Article 14 Taxation

Shall comply with the requirements of the beneficiary country

Article 15 Receiving Goods

The supplier shall make arrangements to be present or be represented when goods are delivered in the stores of the (**Procurement Organ**) for the signing of the acknowledgement of receipt. In the absence of the supplier and his representative, the supplier is required to acquiesce to the report of the **(Procurement Organ).**

Article 16 Records

The supplier shall send invoices, packing lists and delivery notes relating to the products in **three original copies**. All these documents should essentially bear the references of the Contract.

Article 17 Contractual Language

All memoranda relating to this contract **shall be drafted in English**.

Article 18 Termination of Contract

Where the Supplier fails to fulfill the commitments under this Contract, the XXX ***(to be adapted or added to the specific country requirements, eg "... and XXX ...")*** may, subject to the provisions of Article 11 above, terminate the contract without prejudice to sanctions and coercive measures.

This termination shall come into full effect as from XXX days after the delivery deadline.

Article 19 Dispute Settlement

Disputes that may arise under this Contract shall be settled by arbitration in line with the regulations of the United Nations Commission on International Trade Law (UNCITRAL). However any disputes that may arise under this Contract with Local Supplier(s} shall be settled by arbitration in line with the Laws of XXX ***(insert the country).***

Article 20 Force majeure

The Contractor shall not be held liable for his/her performance guarantee, or subjected to

penalties or termination for non-performance, where, and to the extent that delay in services or any other failure in fulfilling obligations under the Contract, results from a force majeure.
The term "*Force Majeure*" here refers to an unpredictable and insurmountable external event preventing the Holder from performing his/her obligations. Such events may include, but are not limited to, actions by the Beneficiary either in sovereign capacity or under the Contract, wars and revolutions, fires, floods, epidemics, quarantine measures and freight embargoes.
In the event of a force majeure, the Contractor shall notify the Beneficiary, within ten days and in writing, of the existence of a *Force Majeure* specifying its nature, likely duration and its impact on the performance of all or part of the Contract. Unless otherwise instructed by the Beneficiary, the Contractor shall continue to carry out his/her obligations under the Contract, within reasonable timeframe, and will endeavor to find other reasonable means to fulfill the contractual obligations not hampered by *force majeure*.
Once notified of the *Force Majeure*, the Buyer shall evaluate the situation, and shall have full discretion to extend the deadline for delivery or execution of the Contract or to terminate by simple written letter, without compensation or notice.

The letter of notification regarding the *Force Majeure* shall prevent penalties for late delivery.

Article 21 Correspondence

All official correspondence to either party to this Contract shall be in writing and sent to the following addresses ***(or such other address as indicated in writing by each party):***

For the supplier ...., **For *(Procurement Organ)***

....

…… General Manager

PO Box:..... PO Box:.....

Phone: ( ) ..... Phone: ....

Fax: () ..... Fax: ....

Email: ..... Email: ....

For information on logistics, guarantees and regulations, the supplier may contact the following persons ... *(Procurement Organ)*:

Logistics: XXX

Position

Phone: ...

Mail: ...

Guarantees: XXX

Position

Phone: ...

Mail: xxx

Regulations: XXX

Position

Tel: ...

Mail: xxx

Article 22 Contract Date

This Contract shall come into force and effect from ....

In witness whereof, the contracting parties have hereto signed this Contract.

Read and accepted by the Supplier (manuscript):	For the Beneficiary (manuscript):
... . (Place), on	..... (Place), on .....
Full Name (to be mentioned)	Full Name (to be mentioned)
xxxxxxx xxxxxxx	xxxxxx xxxxxx
Title of signatory	Title of signatory

CONTRACT AGREEMENT (cover page)

CONTRACT No. .....

CONTRACT VALUE: xxxxxx (Euros or US Dollars) is CFA F xxxxxxxx

FUNDING: West African Health Organisation (ECOWAS Nº 2014 68 289)

CONTRACT CONCLUDED BETWEEN:

Xxx xxxxx (Specify the Beneficiary)

AND

Xxxxx xxxxxx (Specify Supplier)

FOR: The supply of xxxxx (Specify Products)

PROCUREMENT OFFICER (To be specified)

The undersigned duly authorized representatives of parties hereby agree to the following terms and conditions and all annexes to this Contract.

LETTER HEADER OF CONTRACTING ORGAN

City, date..... ..

CONTRACTING ORGAN

(Full address)

SUPPLIER

(Full address)

No. _____ *(Reference)*

Subject: Award Notification of Contract No. xxx *(Contract Reference).*

Your ref: Your bid for xxx *(for example limited consultation)* No. xxxxx xx xx xx

Sir,

We hereby notify you of Contract No. .... which governs the execution of order (where applicable) **No** ..... .of..... ..addressed to you upon analysis of your bid for *(to be specified "Limited Consultation", " International Bid" or "National Bid")* No. xxx xx xxx launched by the *(specify the procurement organ)*.

The total value of the contract is **xxxxx** *(amount in figures and words, in Euros or US Dollars) or XXXXXX CFA F (amount in figures and words, where applicable)*.

The Contract delivery deadline is set as follows:

Xxx *(specify the delivery deadline for the supplier)* **from the date of notification of the order, no later than.....**

We ask you to take appropriate measures henceforth to ensure full delivery of the products listed on the abovementioned Contract, and within the agreed deadline.

Moreover, you are requested to read all the terms of the Contract, including those relating to the:

- *Terms of payment (Article 5);*
- *Quality Assurance (provision of analysis report of batches delivered, Marketing authorization) - (Article 8);*
- *Presentation of shipping or delivery documents (Article 10); and*
- *Penalties for delayed deliveries (Article 12).*

We present to you XXX *(in words and figures)* original copies of the Contract for you to read through and sign. You are to return same (within **fifteen days maximum** from the date of receipt of the Contract), XXX *(in words and figures)* with your name, signature and stamp on the last page *(or another if preferred)* (the other pages should be signed) along with the performance bond that is **xxx** *(specify the value of the performance guarantee),* or 10% of the total value of the Contract.

Please accept, Sir, the expression of our best regards.

The Beneficiary

xxxx xxxx

Title of Signatory

Encl: Contract No. xxx

ANNEX No 1:

PERFORMANCE GUARANTEE (KfW Template)

(Bank Guarantee)

Address of guarantor bank:

……

……

Address of beneficiary (contracting agency):

……

……..

On ..... you concluded with ..... ("Contractor") a contract for ..... (project, object of contract)

at a price of .....

In accordance with the provisions of the contract the Contractor is obligated to provide a performance bond for … % of the contract price.

We, the undersigned …….. (Guarantor), waiving all objections and defences under the aforementioned contract, hereby irrevocably and independently guarantee to pay on your first written demand an amount up to a total of ..... (in words: .....) against your written declaration that the Contractor has failed to duly perform the aforementioned contract.

In the event of any claim under this guarantee, payment shall be effected to KfW, Frankfurt am Main, BIC: KFWIDEFF, account IBAN: DE53 5002 0400 3800 0000 00, for account of ..... (project-executing agency/purchaser).

This guarantee shall expire no later than ……..

By this date we must have received any claims for payment by letter or encoded telecommunication.

It is understood that you will return this guarantee to us on expiry or after payment of the total amount to be claimed hereunder.

This guarantee is governed by the laws of ……..

....

Place, date Guarantor

ANNEX No. 2

Declaration of Undertaking

We underscore the importance of a free, fair and competitive procurement process that precludes abusive practices. In this respect we have neither offered nor granted directly or indirectly any inadmissible advantages to any public servant or other person nor accepted such advantages in connection with our bid, nor will we offer or grant or accept any such incentives or conditions in the present procurement process or, in the event that we are awarded the contract, in the subsequent execution of the contract. We also declare that no conflict of interest exists in the meaning of the kind described in the corresponding Guidelines[2].

We also underscore the importance of adhering to environmental and social standards in the implementation of the project. We undertake to comply with applicable labor laws and the Core Labor Standards of the International Labor Organization (ILO) as well as national and applicable international standards of environmental protection and health and safety standards.

We will inform our staff about their respective obligations and about their obligation to fulfil this declaration of undertaking and to obey the laws of the country of @ (name of country).

We also declare that our company/all members of the consortium has/have not been included in the list of sanctions of the United Nations, nor of the EU, nor of the German Government, nor in any other list of sanctions and affirm that our company/all members of the consortium will immediately inform the client and KfW if this situation should occur at a later stage.

We acknowledge that, in the event that our company (or a member of the consortium) is added to a list of sanctions that is legally binding on the client and/or KfW, the client is entitled to exclude our company/the consortium from the procurement procedure and, if the contract is awarded to our company/the consortium, to terminate the contract immediately if the statements made in the Declaration of Undertaking were objectively false or the reason for exclusion occurs after the Declaration of Undertaking has been issued.

[2] See : “Guidelines for the Assignment of Consultants in Financial Cooperation with Partner Countries“ and “Guidelines for Procurement of Goods, Works and associated Services in Financial Cooperation with Partner Countries”

.....	.....	....
(Place)	(Date)	(Name of company)
		.....
		(Signature(s))

6. Advance Payment Bank Guarantee

Address of guarantor bank:

……

……

Address of beneficiary (contracting agency):

……

……..

On ..... you concluded with ..... ("Contractor") a contract for ..... (project, object of contract) at a price of .....

In accordance with the provisions of the contract, the Contractor receives an advance payment in the amount of …….., which represents …… % of the order value.

We, the undersigned …….. (Guarantor), waiving all objections and defences under the aforementioned contract, hereby irrevocably and independently guarantee to pay on your first written demand any amount advanced to the Contractor up to a total of

..... (in words:

.....) against your written declaration that the

Contractor has failed to duly perform the aforementioned contract.

This guarantee shall come into force and effect as soon as the advance payment has been credited to the account of the Contractor.

In the event of any claim under this guarantee, payment shall be effected to KfW, Frankfurt am Main, BIC: KFWIDEFF, account IBAN: DE53 5002 0400 3800 0000 00, for account of

..... (contracting agency/project-executing agency).

This guarantee shall expire no later than …….

By this date we must have received any claims for payment by letter or encoded telecommunication.

It is understood that you will return this guarantee to us on expiry or after payment of the total amount to be claimed hereunder.

This guarantee is governed by the laws of …….

....

Place, date Guarantor

7. Manufacturer's Authorization Form

(Manufacturer's or Producer's letterhead)

To: _____ *[insert: **name of the Purchaser**]*

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 _____ *[insert: **title and reference number of the Invitation for Tenders**]* 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**]*

8. Specimen Certificate of a Pharmaceutical Product

Certificate of a Pharmaceutical Product[1]

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

No. of certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

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

_____

_____

_____

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

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

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

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

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

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

_____

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

_____

_____

_____

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

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

_____

_____

_____

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

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

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

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

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

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

_____

_____

_____

2B.3 Why is marketing authorization lacking?

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

2B.4 Remarks:[13]

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

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

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): _____

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

yes/no *(key in as appropriate)*

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

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

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

   yes/no *(key in as appropriate)*

If no, explain: _____

_____

Address of certifying authority: _____

Telephone number: _____ Fax number: _____

Name of authorized person:

_____

Signature:

_____

Stamp and date:

_____

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

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

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

Explanatory notes

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

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

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

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

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

6 Sections 2A and 2B are mutually exclusive.

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

8 Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;
(b) packages and/or labels a dosage form manufactured by an independent company; or
(c) is involved in none of the above.

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

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

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

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

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

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

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

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

The layout for this Model Certificate is available on diskette in WordPerfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.

SAMPLE OF INSTRUCTION ON INNER AND OUTER CARTON

Position of the marking: **on BOTH SMALL sides of the carton**
In English only

Contract No:	……
Gross weight:	A kg
NET weight:	B kg
Carton Size:	X cm x Y cm x Z cm

SAMPLE OF INSTRUCTION ON OUTER CARTON

Position of the marking:**on BOTH BIGGER sides of the carton**
Minimum font size of the marking:**8 x 12 cm**
Language of carton marking: **English only**

Consignee: CENTRAL MEDICAL STORE, TEMA, GHANA

Description of goods: International Non Proprietary Name, Strength of Active Ingredient (s) in metric units, Dosage Form, Basic Unit

Country of Manufacture:

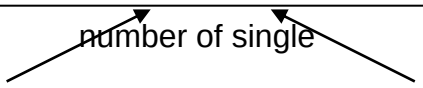
Name of Manufacturer:

Date of Manufacture:

Batch/Lot No:

Expiry Date:

Number of inner carton/bag number of single



Suppliers are required to label all shipping boxes. The boxes should be arranged in the container such that labels remain legible until the container reaches its final destination.

Suppliers should use the label below with dimension 15cm x 10cm on each of the two (2) widest sides of the shipping boxes.

Mécanisme de financement régional des produits de la Santé de la Reproduction

Mecanismo de financiamento regional de produtos de saúde da reprodução

Regional Financing Mechanism of Reproductive Health Commodities