STANDARD TENDER DOCUMENT

[Insert Name of Description of Procurement]

Procurement of Health Sector Goods
(Pharmaceuticals, Vaccines, and Condoms)

[Insert Package No. as provided in Procurement Plan]

Public Procurement Authority

Accra, Ghana

Issued on: [Insert date]

Issued Date: 2019
INTRODUCTION AND INSTRUCTIONS

These Standard Tender Documents (STD) have been prepared by the Public Procurement Authority for use by the Ministry of Health and all Public Health Institutions in the procurement of pharmaceuticals, vaccines, and condoms through international competitive tendering (ICT) in accordance with the Public Procurement Act, 2003 (Act 663) as amended. For the purpose of these documents, pharmaceuticals also include nutritional supplements and oral and injectable hormonal forms of contraception.

The procedures and practices presented in these documents have been developed through broad experience.

As shown in the table below, this STD is arranged into two Sections: those that must be used unchanged, and those that should be customized specifically for each procurement. An electronic version of these STD is available on disk from the Public Procurement Authority. This can be used to customize the Invitation for Tenders and Sections II, V, VI, and VII to meet the requirements of the specific procurement. Sections I, III, and IV, however, must be incorporated unchanged in the Tender Documents.

The Sample Technical Specifications Section, as well as some specific provisions of the Tender Data Sheet and Special Conditions of Contract, are applicable to pharmaceuticals, vaccines, and condoms. Care should be taken to ensure that these additional specific provisions are incorporated into the body of the Tender Document and that changes or additions made to one of the customized sections are reflected in the other customized sections when appropriate.

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<td>Technical Specifications</td>
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<td>Section VIII</td>
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<td>Sample Forms</td>
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<td>(including the Form of</td>
<td></td>
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<tr>
<td>Contract Agreement)</td>
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</table>

Additional Instructions to Tenderers and the contract-specific details needed for the tendering and evaluation process to be properly carried out must be made through the Tender Data Sheet only. Amendments to the General Conditions of Contract must be made through the Special Conditions of Contract. The Technical Requirements section of the Tender Documents should not be used to modify any of the subjects covered by Sections I or III.

Clauses included in the Special Conditions of Contract of these STD should be modified as
appropriate to reflect the specific needs of each procurement. Because such modifications prevail over the General Conditions of Contract, major changes should be avoided unless absolutely necessary.

Some of the language presented in the Technical Specifications Section of these STD, as well as certain Sample Forms (so identified), are also illustrative. Appropriate modifications should be made to match the requirements of a particular procurement.

Specific details, such as the “name of the Purchaser” and “address for tender submission,” should be furnished in the Invitation for Tenders, in the Tender Data Sheet, and in the Special Conditions of Contract. The final documents should contain neither blank spaces nor options.
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INVITATION FOR TENDERS
Invitation for Tenders (IFT)

Republic of Ghana

[ insert: name of project]

[ insert: the Health Sector Goods to be procured]

1. This invitation for tenders follows the general procurement notice for this project, which was published in [insert newspaper, bulletin name or official Gazette], issue no. [insert number] of [insert date] and in the Public Procurement Bulletin of the Public Procurement Authority of the Republic of Ghana, issue no. [insert number] of [insert date].

2. The [ insert name of Procurement Entity], Ghana hereinafter referred to as the Purchaser, intends using part of its budgetary allocation to fund the procurement of [specify goods] to support its programme.

3. The Purchaser now invites sealed tenders from eligible manufacturers or their authorized representatives for the supply of the said goods listed in the Schedule of Requirement, Section VI of this Tender Document.

4. Tendering will be conducted through the [insert the appropriate tendering procedure] specified in the Republic of Ghana’s 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.

5. Interested eligible tenderers may obtain further information from [insert name of Procurement Entity] and procure a copy of the tender documents at the address given below [state physical address at end of document] from [insert office hours].

6. A complete set of tender documents may be purchased by interested eligible tenderers on the submission of a written application to the address below and upon payment of a non-refundable fee of [insert amount in local currency] or its equivalent in freely convertible currency. The method of payment will be [insert method of payment]. If requested, the documents will be promptly dispatched by courier, but no liability can be accepted for loss or late delivery.
7. Sealed tenders must be delivered to the address below on or before [insert time and date]. All tenders must be accompanied by a tender security of [insert amount in local currency] or an equivalent amount in a freely convertible currency or [insert minimum percentage of the tender price]. The tender security shall be valid for at least [insert number of days] from the date of the tender opening.

8. Late tenders will not be accepted. Tenders will be opened in the presence of the tenderers’ representatives who choose to attend at the address stated below at [specify time and date].

9. A register of potential tenderers who have purchased the tender documents may be inspected at the address below.

[insert: name of procurement entity] [insert: postal address]

and/or

[insert: street address]

[insert: telephone number, indicate country and city code] [insert: facsimile, telex number, and e-mail address]

10. For Ghanaian Tenderers, it is mandatory that Tenderers include in their tender the underlisted statutory requirements.

- Valid GRA Tax Clearance Certificate.
- Valid SSNIT Clearance Certificate.
- Valid VAT Registration Certificate (if applicable).
- Valid Business Registration Certificate
- Valid Certificate of Incorporation
- Valid Certificate of Commencement.
- Valid Registration Certificate from PPA

1 The date to be inserted shall be fixed in accordance with minimum period for tenders set out in guidelines published by the Public Procurement Authority or set out under the Applicable Law
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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 The Government of the Republic of Ghana requires that Tenderers under the contracts financed from public funds, observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the following terms shall be interpreted as indicated:

(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;

(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, non-competitive levels and to deprive the Purchaser of the benefits of free
Section I. Instructions to Tenderers

and open competition; and

(iii) “coercive practice” means harming or threatening to harm, directly or indirectly, persons or their property to influence their participation in the procurement process or affect the execution of a contract.

(iv) “Collusion” means an agreement between tenderers designed to influence the outcome of the tender and/or for the purpose of fixing by Tenderers of non-competitive prices of a tender.

(b) the Government of Ghana, acting by the appropriate Tender Review Board or the Public Procurement Authority and in accordance with Ghana’s Public Procurement Act, 2003 (Act 663) as amended will reject a Purchaser’s proposal for award if it determines that the tenderer recommended for award has engaged in corrupt, fraudulent, collusive or coercive practices in competing for the Contract in question.

(c) the Government of Ghana acting by the Public Procurement Authority 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, fraudulent, collusive or coercive 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 if it at any time determines that corrupt, fraudulent, collusive or coercive 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 Authority in the Tender Sheet, where a prequalification process has been undertaken for the Contract(s) for which these Tender Documents have been issued, or

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

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. Such evidence shall be depended on mandatory requirement of the following if Tenderer is Ghanaian:

- Valid GRA Tax Clearance Certificate.
- Valid SSNIT Clearance Certificate.
- Valid VAT Registration Certificate (if applicable).
- Valid Business Registration Certificate (if applicable).
- Valid Certificate of Incorporation (if applicable).
- Valid Certificate of Commencement (if applicable).
- Valid Registration Certificate from PPA.
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.

6.1 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 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 Ghana.

OR, if such Registration Certificate has no type to be obtained, PPA must engage FDA on this provision

(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 Ghana. The agency and contact person able to provide additional information about registration are identified in the Tender Data Sheet.

6.4.2 If the goods of the successful Tenderer have not been registered in Ghana at the time of Contract signing, then the Contract shall not become effective until such date as the Certificate of Registration is obtained.

6.5 For purposes of the commentary to be furnished pursuant to ITT Clause 6.3 (b) above, the Tenderer shall note that standards as well as references to brand names designated by the Purchaser in its Technical Specifications are intended to be descriptive only and not restrictive. The Tenderer may substitute alternative standards, brand names, and/or 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.

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<th>Section I.</th>
<th>Instructions to Tenderers (ITT)</th>
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<td>Section V.</td>
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<td>Section VII.</td>
<td>Technical Specifications</td>
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<tr>
<td>Section VIII.</td>
<td>Sample Forms (including Contract Agreement)</td>
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</table>

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**

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<th>13. Language of Tender</th>
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<tr>
<td>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.</td>
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<tr>
<th>14. Documents Constituting the Tender</th>
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<tr>
<td>14.1 The tender submitted by the Tenderer shall comprise the following:</td>
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<td>(a) duly filled-in Form of Tender and Price Schedule, in accordance with the forms indicated in Section VIII;</td>
</tr>
<tr>
<td>(b) original form of tender security in accordance with the provisions of ITT Sub-Clause 19 (Tender Security);</td>
</tr>
<tr>
<td>(c) alternative offers, at the Tenderer’s option, when permitted;</td>
</tr>
<tr>
<td>(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;</td>
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<tr>
<td>(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;</td>
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<tr>
<td>(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;</td>
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<td>(g) documentary evidence establishing to the Purchaser’s</td>
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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 tender, 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:

(i) the price of the Goods quoted EXW (ex works, ex factory, ex warehouse, ex showroom, or off-the-shelf, is 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
Section I. Instructions to Tenderers

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 and Tender Securing Declaration

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

19.2 The tender security shall remain valid for a period of 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 Purchaser’s option the following forms:

(a) a cashier’s or certified cheque;

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

(c) 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;

(d) an insurance bond from a reputable bank or insurance or bonding company acceptable to the purchaser, from an eligible country.

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-Claususes 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 initialled 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

25.1 The Tenderer may modify or withdraw its tender after submission, provided that written notice of the modification,
**Tenders** 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 or reservation is one which:

a. affects in any substantial way the Scope, Quality, or Performance of the Contract; the following shall constitute such material deviations

i. failure to sign the Tender Form and Price Schedules by authorised person or persons.

ii. inability to meet the critical delivery schedule or work
schedule clearly specified in the tender document, where such schedule is a critical condition with which tenderer must comply;

iii. subcontracting in a substantially different amount or manner than that permitted;

iv. failure to submit the required Manufacturer Authorization (if applicable) for equipment not manufactured by the Tenderer/Agent.

b. which limits in any substantial way, inconsistent with the Tender documents, the Purchaser’s rights or the Tenderer’s obligations under the contract; material deviations include the following:

i. failure to submit documents establishing the Tenderer’s eligibility to Tender.

ii. failure to submit its qualifications to perform the contract if its Tender is accepted.

iii. failure to submit a tender security as specified in the tender document.

iv. failure to satisfy the tender validity period

v. failure to comply with minimum experience criteria as specified in the tender document;

vi. conditional tenders such as conditions in a tender which limit the tenderer’s responsibility to accept an award; For example

• inability to accept the price adjustment formulae of the tendering documents;

• stipulating price adjustment when fixed price tenders were invited;

c. whose rectification would affect unfairly the competitive position of other Tenderers presenting 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 incorporate or to be incorporated in the Goods, and the CIF named port 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) or 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
Section I. Instructions to Tenderers

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 deviate 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.
Environmental Factors 32.6 Environmental & Social Consideration: Tenders shall be evaluated taking into account compliance with environmental protection, policies, laws and regulations applicable in Ghana as well as policies for the promotion of sustainable development.

32.7 The Purchaser may specify in its evaluation criteria (a method to determine or assess how Tenders promote general as well as specific policies and programmes for sustainability and environmental protection.

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 non-exempt 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 non-exempt 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. Post qualification 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.
Section I. Instructions to Tenderers

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 not 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 a 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 fourteen (14) days of receipt of the Contract Form, the successful Tenderer shall sign and date the Contract Form and return it to the Purchaser.

39.3 The signing of the contract shall be subject to negotiations between the Purchaser and Tenderer of any issue that in the view of the Purchaser, end user or beneficiary entity ought to be fully clarified and the outcome of such discussion or negotiation shall be recorded in the form of minutes and a record of it kept.

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

<table>
<thead>
<tr>
<th>ITT 1.1</th>
<th>Name of Purchaser: ____________________________</th>
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<tbody>
<tr>
<td></td>
<td>Type of goods: ____________________________</td>
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<tr>
<td></td>
<td>Name and identification number of the Contract: __</td>
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<tr>
<td>ITT 2.1</td>
<td>Source of Funds: ____________________________</td>
</tr>
<tr>
<td></td>
<td>Name of Project: ____________________________</td>
</tr>
<tr>
<td>ITT 4.1 &amp; 5.1</td>
<td>Applicable edition of the Published List of Eligible Countries as issued by the Public Procurement Authority of the Republic of Ghana</td>
</tr>
<tr>
<td>ITT 6.3 (c)</td>
<td>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:</td>
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<td></td>
<td>• ___________________________________</td>
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<td></td>
<td>• ___________________________________</td>
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<tr>
<td>ITT 6.4</td>
<td>Health sector Goods to be supplied under the contract shall be registered with the Food &amp; Drugs Board of the Republic of Ghana.</td>
</tr>
<tr>
<td>ITT 6.4 (b)</td>
<td>By the time of Contract signing, the successful Tenderer should have complied with the necessary documentary requirements as required by the Food &amp; Drugs Board of the Republic of Ghana, in order to register the Goods to be supplied under the Contract.</td>
</tr>
<tr>
<td>ITT 6.4.1</td>
<td>For the purpose of obtaining additional information about the requirements for registration, Tenderers may contact:</td>
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<tr>
<td></td>
<td>Food &amp; Drugs Authority</td>
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<td></td>
<td>Ministries Area (Adjacent Public Services Commission)</td>
</tr>
<tr>
<td></td>
<td>P. O. Box CT 2783</td>
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<tr>
<td></td>
<td>Cantonments, Accra, Ghana</td>
</tr>
<tr>
<td></td>
<td>Tel: (233 21) 661248; 673090</td>
</tr>
<tr>
<td></td>
<td>Fax: (233 21) 660389</td>
</tr>
<tr>
<td></td>
<td>Website: <a href="http://www.fdaghana.gov.gh">www.fdaghana.gov.gh</a></td>
</tr>
<tr>
<td>ITT 7.1 (a)</td>
<td>Qualification requirements for Tenderers are:</td>
</tr>
<tr>
<td></td>
<td>_____________________________________________</td>
</tr>
<tr>
<td></td>
<td>_____________________________________________</td>
</tr>
</tbody>
</table>
The following documents must be included with the tender:

Documentary evidence of the Tenderer’s qualifications to perform the Contract if its tender is accepted:

(i) that, in the case of a Tenderer offering to supply Goods under the Contract that the Tenderer manufactures or otherwise produces 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;

(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;

(ii) that, in the case of a Tenderer offering to supply Goods under the Contract that the Tenderer does not manufacture or otherwise produce,

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

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 three fiscal years;

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

(d) list of major supply contracts conducted within the last five years.
### B. THE TENDER DOCUMENTS

<table>
<thead>
<tr>
<th>ITT 11.1</th>
<th>Purchaser’s/duly authorized Purchasing Agent’s address is:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mailing Address: ___________________________________</td>
</tr>
<tr>
<td></td>
<td>Street Address: ________________________________</td>
</tr>
<tr>
<td></td>
<td>________________________________</td>
</tr>
<tr>
<td></td>
<td>Floor/Room Number: ________________________________</td>
</tr>
<tr>
<td></td>
<td>City/Town: ________________________________, Ghana.</td>
</tr>
<tr>
<td></td>
<td>Telephone: (233 - )________________________________</td>
</tr>
<tr>
<td></td>
<td>Facsimile Number: (233 - )________________________</td>
</tr>
<tr>
<td></td>
<td>Electronic Mail Address: ____________________________</td>
</tr>
<tr>
<td></td>
<td>Contact Person: ________________________________</td>
</tr>
</tbody>
</table>

### C. PREPARATION OF TENDERS

<table>
<thead>
<tr>
<th>ITT 13.1</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT 14.1 (i)</td>
<td>In addition to the documents stated in Paragraphs 14.1 (a) through (h), the following documents must be included with the Tender</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>ITT 16.2 (a) (iii), (iv)</td>
<td>The price quoted for Goods offered from within Ghana shall be EXW, ____________________________________________</td>
</tr>
<tr>
<td>ITT 16.2 (b) (i) (ii), (iii), (iv), (v)</td>
<td>Prices for Goods offered from abroad shall be quoted as CIF Tema or KIA, Accra.</td>
</tr>
<tr>
<td>ITT 16.5</td>
<td>Prices quoted by the Tenderer shall be fixed</td>
</tr>
<tr>
<td>ITT 16.6</td>
<td>Tenders are being invited for one or more items</td>
</tr>
<tr>
<td>ITT 17.1 (a)</td>
<td>Tender prices may be expressed in the currency of the tenderers’ country or in US dollars</td>
</tr>
<tr>
<td>ITT 17.1 (b)</td>
<td>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 Ghanaian Cedi:</td>
</tr>
<tr>
<td>ITT 18.1</td>
<td>The tender validity period shall be [insert number of days] after the deadline for tender submission, as specified below in reference to ITT Clause 23. Tender security must be valid [insert number of days] after the end of the tender validity period. Accordingly, a tender with a tender security that expires before [insert number of days] after the end of the tender validity period shall be rejected as nonresponsive.</td>
</tr>
<tr>
<td>ITT 19.1</td>
<td>The amount of tender security required is not less than [insert amount or percentage] of tender value.</td>
</tr>
<tr>
<td>ITT 20.1</td>
<td>Alternative tenders [insert number] be accepted.</td>
</tr>
<tr>
<td>ITT 21.1</td>
<td>Required number of copies of the tender shall be [insert number]</td>
</tr>
</tbody>
</table>
D. SUBMISSION OF TENDERS

<table>
<thead>
<tr>
<th>ITT 22.2 (b)</th>
<th>The address for tender submission is:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Street/Location Address: ________________________________</td>
</tr>
<tr>
<td></td>
<td>_______________________________________________</td>
</tr>
<tr>
<td></td>
<td>Floor/Room Number: _____________________________</td>
</tr>
<tr>
<td></td>
<td>City/Town: ________________________________, Ghana.</td>
</tr>
<tr>
<td></td>
<td>Contact Person: ________________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ITT 22.2 (c) &amp; (d)</th>
<th>See the above data for ITT 1.1 for the name of the Contract.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The Invitation for Tenders title and number are: ________________</td>
</tr>
<tr>
<td></td>
<td>See below data for ITT 23.1 for the deadline for tender submission.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ITT 23.1</th>
<th>See the above data for ITT Sub-Clause 22.2 (b) for the address.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Deadline for tender submission is: ___________________________</td>
</tr>
</tbody>
</table>

| 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

<table>
<thead>
<tr>
<th>ITT 26.1</th>
<th>Time, date, and place for tender opening are:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date &amp; Time: ________________________________</td>
</tr>
<tr>
<td></td>
<td>Street Address: ______________________________</td>
</tr>
<tr>
<td></td>
<td>_______________________________________</td>
</tr>
<tr>
<td></td>
<td>Floor/Room Number: __________________________</td>
</tr>
<tr>
<td></td>
<td>City/Town: ________________________________, Ghana.</td>
</tr>
</tbody>
</table>
ITT 31.3  The currency chosen for the purpose of converting to a common currency is Ghana Cedi.
The source of exchange rate is: Bank of Ghana
The date of exchange rate determination is the date of opening of tenders

ITT 32.4 (d)  The evaluation will take into account_________________________
____________________________________________________________
__________________________________________________

ITT 32.5  The factors retained pursuant to ITT Sub-Clause 32.4 and the quantification methods are:
_____________________________________________________
_______________________________________________________

ITT 32.5 (a)  Inland transportation from port of entry to ___________________ insurance and incidentals.
Tenderer shall furnish estimated dimensions and shipping weight of each package and approximate CIF value of each package.

ITT 32.5 (b)  Delivery schedule.
Relevant parameters in accordance with option selected:

(i)  The adjustment per week for delivery delays beyond the time specified in the Schedule of Requirements is ____________.
Or

(ii) The adjustment per week for delivery delays beyond the range of weeks specified in the Schedule of Requirements is ____________.
Or

(iii) The adjustment for partial shipments is ________ for early deliveries and ________% for late deliveries.

ITT 32.5 (c) (ii)  The Purchaser will not accept deviations in the payment schedule in the SCC.

ITT 32.5 (d)  Other factors to be used in the evaluation and their evaluation method.
Evaluation criteria for items/lots

Tenderers may tender for any one or more items. Tenders will be evaluated for each item and the Contract will comprise the item(s) awarded to the successful Tenderer.
Or

Tenderers can tender for one or more lots. Tenders will be evaluated lot
by lot. Tenderers must quote for the entire quantity of each item and at least [insert percentage] of the number of items in the lot to be treated as substantially responsive.

Tender evaluation of such tenders will be carried out as per the following procedures. The average price of an item quoted by substantially responsive Tenderers will be added to the tender price of those who did not quote for that item and the equivalent total cost of the tender so determined will be used for tender comparison, evaluation, and award.

| ITT 33.1 | A margin of domestic preference will apply. |

---

**F. AWARD OF CONTRACT**

| ITT 37.1 | Percentage for increase or decrease of quantity of Goods and Services originally specified shall not be more than 15%. |
## Tender Data Sheet

### PHARMACEUTICALS

(Additional Clauses)

| 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) (a) has a Good Distribution Practice (GDP) Certificate where appropriate.  

The Tenderer will submit the following additional information:  
(b) list of pharmaceuticals being manufactured by the Tenderer with product registration/license number and date.  
(c) a Certificate of Pharmaceutical Product as recommended by the WHO for each item offered. |
Tender Data Sheet

VACCINES

(Additional Clauses)

A. GENERAL

<table>
<thead>
<tr>
<th>ITT 6.3 (c)</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITT 7.1 (a) &amp; (d)</td>
<td>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.</td>
</tr>
<tr>
<td>ITT 7.1 (a) &amp; (d)</td>
<td>Documentary evidence of the Tenderer’s qualifications to perform the Contract if its tender is accepted:</td>
</tr>
<tr>
<td>ITT 7.1 (a) &amp; (d)</td>
<td>(a) 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.</td>
</tr>
<tr>
<td>ITT 7.1 (a) &amp; (d)</td>
<td>The Tenderer will submit the following additional information:</td>
</tr>
<tr>
<td>ITT 7.1 (a) &amp; (d)</td>
<td>(b) list of vaccines being manufactured by the Tenderer with product registration/license number and date.</td>
</tr>
</tbody>
</table>
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

As of ___.__. ___ 20__.  

For the information of Tenderers, and in accordance with ITT Clause 5, set forth below is a 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:
SECTION IV. GENERAL CONDITIONS OF CONTRACT
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<th></th>
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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.
Section IV. General Conditions of Contract

(l) “SCC” means the Special Conditions of Contract.

(m) “The Services” means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.

(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.
Section IV. General Conditions of Contract

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. Intellectual Property Rights 7.1 The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, copyrights, 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 Documents

11.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in the SCC.

11.2 For purposes of the Contract, “EXW,” “FOB,” “FCA,” “CIF,” “CIP,” 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 Contract 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 the Contract to deliver the Goods CIF or CIP, no restriction shall be placed on the choice of carrier. Where the Supplier is required under the 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 ….. days after submission of an invoice or claim by the Supplier.

16.4 The Purchaser shall pay to the Supplier interest on any outstanding amount at the prevailing interbank rate where the Purchaser has received an invoice from the Supplier but has failed to make payment within the number of days stated in the Data Sheet and where such period is not stated payment remains outstanding for more than …..days after the agreed due date.

16.6 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.

16.7 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 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:

(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.

(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, 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 from abroad shall comply with the Income Tax Act, 2015 (Act 896) As Amended

32.3 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
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<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
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<td>Condoms</td>
<td>79</td>
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<tr>
<td>9.</td>
<td>Inspections and Tests (GCC Clause 9)</td>
<td>79</td>
</tr>
<tr>
<td>11.</td>
<td>Delivery and Documents (GCC Clause 11)</td>
<td>79</td>
</tr>
</tbody>
</table>
# 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)

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCC 1.1 (f)</td>
<td>The End User is: ____________________________________________</td>
</tr>
<tr>
<td>GCC 1.1 (i)</td>
<td>The Purchaser is: ___________________________________________</td>
</tr>
<tr>
<td>GCC 1.1 (o)</td>
<td>The Supplier is: ____________________________________________</td>
</tr>
<tr>
<td>GCC 1.1 (n)</td>
<td>The Site(s) is/are __________________________________________</td>
</tr>
</tbody>
</table>

## 2. Application (GCC Clause 2)

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCC 2</td>
<td>The following clauses/provisions supersede the GCC: ____________________________</td>
</tr>
</tbody>
</table>

Or

There are no Special Conditions of Contract applicable to GCC Clause 2

## 3. Country of Origin (GCC Clause 3)

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCC 3.1</td>
<td>The Public Procurement Board 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 from the Board. A copy of this list is contained in the section of the Tender Documents entitled “Eligibility for the Provision of Goods, Works and Services Financed with Public Funds of the Republic of Ghana”</td>
</tr>
</tbody>
</table>

## 4. Standards (GCC Clause 4)
### Section V. Special Conditions of Contract

#### 5. Use of Contract Documents and Information (GCC Clause 5)

<table>
<thead>
<tr>
<th>GCC 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following provisions shall apply to the use of Contract Documents and Information:</td>
</tr>
<tr>
<td>____________________________________________</td>
</tr>
<tr>
<td>Or:</td>
</tr>
<tr>
<td>The use of Contract Documents and Information shall be in accordance with GCC 5</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>GCC 6.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence of registration of product with the Food and Drugs Board of Ghana</td>
</tr>
<tr>
<td>GCC 6.2</td>
</tr>
<tr>
<td>The Effective Date of the Contract is ___________________________</td>
</tr>
<tr>
<td>GCC 6.3</td>
</tr>
<tr>
<td>The time period shall be ___________________________ days.</td>
</tr>
</tbody>
</table>

#### 7. Patent Rights (GCC Clause 7)

<table>
<thead>
<tr>
<th>GCC 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following indemnity provisions against all third-party claims shall apply:</td>
</tr>
<tr>
<td>____________________________________________</td>
</tr>
<tr>
<td>Or:</td>
</tr>
<tr>
<td>The Indemnity provisions in GCC 7 shall apply.</td>
</tr>
</tbody>
</table>

#### 8. Performance Security (GCC Clause 8)

<table>
<thead>
<tr>
<th>GCC 8.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance security shall be for an amount equal to ____% of Contract Price</td>
</tr>
<tr>
<td>GCC 8.4</td>
</tr>
<tr>
<td>Discharge of the Performance Security shall take place in accordance with GCC Sub-Clause 8.4</td>
</tr>
<tr>
<td>[ insert: any additional requirement related to the discharge of the performance security. ]</td>
</tr>
</tbody>
</table>
9. Inspections and Tests (GCC Clause 9)

<table>
<thead>
<tr>
<th>GCC 9.1</th>
<th>/ insert: any additional requirement related to the inspections and tests /</th>
</tr>
</thead>
<tbody>
<tr>
<td>Or state:</td>
<td></td>
</tr>
<tr>
<td>There are no Special Conditions of Contract applicable to GCC Sub-Clause 9.</td>
<td></td>
</tr>
</tbody>
</table>

10. Packing (GCC Clause 10)

<table>
<thead>
<tr>
<th>GCC 10.2</th>
<th>/ insert: any necessary additional requirement with respect to packing and marking /</th>
</tr>
</thead>
<tbody>
<tr>
<td>Or state:</td>
<td></td>
</tr>
<tr>
<td>Additional requirements are indicated in the Technical Specifications.</td>
<td></td>
</tr>
</tbody>
</table>
### 11. Delivery and Documents (GCC Clause 11)

<table>
<thead>
<tr>
<th>GCC 11.1 &amp; 11.3</th>
<th>For Goods supplied from abroad:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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:</td>
</tr>
<tr>
<td></td>
<td>(i) three originals and two copies of the Supplier’s invoice, showing Purchaser as [enter correct description of Purchaser for customs purposes]__________________; the Contract number, Goods description, quantity, unit price, and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal;</td>
</tr>
<tr>
<td></td>
<td>(ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked “freight prepaid” and showing Purchaser as [enter correct name of Purchaser for customs purposes]__________________ 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;</td>
</tr>
<tr>
<td></td>
<td>(iii) four copies of the packing list identifying contents of each package;</td>
</tr>
<tr>
<td></td>
<td>(iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;</td>
</tr>
<tr>
<td></td>
<td>(v) one original of the manufacturer’s or Supplier’s Warranty Certificate covering all items supplied;</td>
</tr>
<tr>
<td></td>
<td>(vi) one original of the Supplier’s Certificate of Origin covering all items supplied;</td>
</tr>
<tr>
<td></td>
<td>(vii) original copy of the Certificate of Inspection furnished to Supplier by the nominated inspection agency and six copies (where inspection is required);</td>
</tr>
<tr>
<td></td>
<td>(viii) any other procurement-specific documents required for delivery/payment purposes.</td>
</tr>
</tbody>
</table>

*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, 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 [enter correct name of Purchaser for customs purposes] 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.

12. Insurance (GCC Clause 12)

GCC 12.1 The insurance shall be in an amount equal to 110 percent of the CIF or CIP value of the Goods from “warehouse” to “warehouse” on “All Risks” basis, including war risks and strikes (only if contract placed on CIF or CIP basis).

13. Transportation (GCC Clause 13)

GCC 13 [insert: necessary and appropriate clauses], or state:

There are no Special Conditions of Contract applicable to GCC 13.

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)

<table>
<thead>
<tr>
<th>GCC 15.1</th>
<th>[ insert: necessary and appropriate clauses, ]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Or state:</td>
</tr>
<tr>
<td></td>
<td>There are no Special Conditions of Contract applicable to GCC 15.</td>
</tr>
</tbody>
</table>
The period for the replacement of defective goods is ___________ days.

### 16. Payment (GCC Clause 16)

The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

**Payment for Goods supplied from abroad:**

Payment of foreign currency portion shall be made in [insert: currency of the Contract Price] ___________ in the following manner:

(i) **Advance Payment:** An Advance Payment ___[shall / shall not]__ be made. If an Advance Payment is allowed, it shall be Ten (10) percent of the Contract Price and it shall be paid within thirty (30) days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing Purchaser’s name; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Section VIII, Advance Payment Bank Guarantee.

(ii) **On Shipment:** Eighty (80) percent of the Contract Price of the Goods shipped shall be paid where an advance payment has been made, and where no advance payment has been made ninety (90) percent of the Contract Price of Goods shipped shall be paid. In either case, payment shall be effected through irrevocable confirmed letter of credit opened in favor of the Supplier in a bank in its country, upon submission of documents specified in GCC Clause 11 or, alternatively, at the Supplier’s option, within thirty (30) days of submission of documents specified in GCC Clause 11 above by direct bank transfer to the Supplier’s nominated bank account. Opening charges and charges for amendment of the letter of credit at the request of or due to a fault or default of the Purchaser are for the account of the Purchaser. Confirmation charges and charges for amendment to letters of credit at the request of or due to a fault or default on behalf of the Supplier are for the account of the Supplier.

(iii) **On Acceptance:** Ten (10) percent of the Contract Price of Goods received shall be paid within thirty (30) days of receipt of the Goods upon submission of an invoice (showing Purchaser’s name; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

Payment of local currency portion shall be made in Ghana Cedis (¢) within thirty (30) days of presentation of an invoice (showing Purchaser’s name; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

**Payment for Goods and Services supplied from within Ghana:**

Payment for Goods and Services supplied from within Ghana shall be made in Ghana Cedis (¢) as follows:
Section V. Special Conditions of Contract

(i) **Advance Payment:** An Advance Payment ___[shall / shall not]__ be made. If an Advance Payment is allowed, it shall be Ten (10) percent of the Contract Price shall be paid within thirty (30) days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing Purchaser’s name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Section VIII, Advance Payment Bank Guarantee.

(ii) **On Shipment:** Eighty (80) percent of the Contract Price of the Goods shipped shall be paid where an advance payment has been made, and where no advance payment has been made ninety (90) percent of the Contract Price of Goods shipped shall be paid. In either case, payment shall be effected within 30 days of submission of documents specified in GCC Clause 11 above by direct bank transfer to the Supplier’s nominated bank account.

(iii) **On Acceptance:** Ten (10) percent of the Contract Price of Goods received shall be paid within thirty (30) days of receipt of the Goods upon submission of an invoice (showing Purchaser’s name; the Contract number, description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.
<table>
<thead>
<tr>
<th>17. Prices (GCC Clause 17)</th>
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<tbody>
<tr>
<td>GCC 17.1</td>
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<tr>
<th>18. Change Orders (GCC Clause 18)</th>
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<tr>
<td>GCC 18</td>
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<tr>
<th>19. Contract Amendments (GCC Clause 19)</th>
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<tr>
<td>GCC 19</td>
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<tr>
<th>20. Assignment (GCC Clause 20)</th>
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<tbody>
<tr>
<td>GCC 20</td>
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<tr>
<th>21. Delays in the Supplier’s Performance (GCC Clause 21)</th>
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<tbody>
<tr>
<td>GCC 21</td>
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<table>
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<tr>
<th>22. Liquidated Damages (GCC Clause 22)</th>
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</thead>
<tbody>
<tr>
<td>GCC 22.1</td>
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<table>
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<tr>
<th>23. Termination for Default (GCC Clause 23)</th>
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<tbody>
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<td>GCC 23</td>
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<tr>
<th>24. Force Majeure (GCC Clause 24)</th>
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<tbody>
<tr>
<td>GCC 24</td>
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<table>
<thead>
<tr>
<th>25. Termination for Insolvency (GCC Clause 25)</th>
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</thead>
<tbody>
<tr>
<td>GCC 25</td>
</tr>
</tbody>
</table>
### 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)

<table>
<thead>
<tr>
<th>GCC 27.2.2</th>
<th>The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 27.2.2 shall be as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Contracts with foreign Supplier:</td>
<td>GCC 27.2.2 (a)–Any dispute, controversy, or claim arising out of or relating to this Contract, or breach, termination or invalidity thereof, shall be settled by arbitration in accordance with the UNCITRAL Arbitration Rules as at present in force.</td>
</tr>
<tr>
<td>(b) Contracts with Ghanaian Supplier:</td>
<td>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.</td>
</tr>
</tbody>
</table>

### 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 Supplier’s address for notification purposes is as follows:

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

### 32. Taxes and Duties (GCC Clause 32)

GCC 32

There are no Special Conditions of Contract applicable to GCC 32.
Special Conditions of Contract

PHARMACEUTICALS

(Additional Clauses)

11. Delivery and Documents (GCC Clause 11)

<table>
<thead>
<tr>
<th>GCC 11.1 &amp; 11.3</th>
<th>For Goods supplied from abroad:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied.</td>
</tr>
<tr>
<td></td>
<td>(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.</td>
</tr>
<tr>
<td></td>
<td>(xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.</td>
</tr>
</tbody>
</table>
### Special Conditions of Contract

#### VACCINES

(Additional Clauses)

<table>
<thead>
<tr>
<th>11. Delivery and Documents (GCC Clause 11)</th>
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<tbody>
<tr>
<td>GCC 11.1 &amp; 11.3</td>
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<tr>
<td><strong>For Goods supplied from abroad:</strong></td>
</tr>
<tr>
<td>(ix) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.</td>
</tr>
<tr>
<td>(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.</td>
</tr>
<tr>
<td>(xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.</td>
</tr>
<tr>
<td><strong>For Goods from within Ghana:</strong></td>
</tr>
<tr>
<td>(x) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.</td>
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<tr>
<th>15. Warranty (GCC Clause 15)</th>
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<tbody>
<tr>
<td>GCC 15.1</td>
</tr>
<tr>
<td>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.</td>
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<tr>
<td>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.</td>
</tr>
</tbody>
</table>
### Special Conditions of Contract

**CONDOMS**

#### 9. Inspections and Tests (GCC Clause 9)

<table>
<thead>
<tr>
<th>GCC 9</th>
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<tbody>
<tr>
<td>(d)</td>
<td>The Supplier shall test batches of Goods ready for shipment in accordance with the WHO specification. The size of the sample for testing will be calculated by reference to ISO2859-1. With each consignment, the Supplier must provide a certificate of quality control test results in conformity with the standards laid down in ISO 2859-1 and in accordance with the general sampling levels appropriate to each feature as necessary. The Supplier will bear the cost of such tests.</td>
</tr>
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</table>

#### 11. Delivery and Documents (GCC Clause 11)

<table>
<thead>
<tr>
<th>GCC 11.1 &amp; 11.3</th>
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<tbody>
<tr>
<td><em>For Goods supplied from abroad:</em></td>
<td></td>
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<tr>
<td>(ix)</td>
<td>original copy of quality control tests for each consignment as stated in SCC 9 above.</td>
</tr>
<tr>
<td>(x)</td>
<td>original copy of the certificate of inspection furnished to Supplier by nominated inspection agency and six copies [where separate inspection is required].</td>
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</table>

*For Goods from within Ghana:*

| (ix)  | certificate of in-house analysis. |
SECTION VI. SCHEDULE OF REQUIREMENTS
### Schedule of Requirements

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Unit Size</th>
<th>Name &amp; Brief Description of Good or Related Service</th>
<th>Quantity</th>
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# Delivery Schedule

<table>
<thead>
<tr>
<th>Item No</th>
<th>Description</th>
<th>Strength</th>
<th>Quantity</th>
<th>Delivery Schedule (Shipment) In weeks from</th>
<th>Mode of Shipment</th>
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</table>
SECTION VII. TECHNICAL SPECIFICATIONS
### Sample 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.
Sample 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 \((\text{number})\) 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 \((\text{number})\) 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.
Sample Technical Specifications

CONDOMS

1. Product and Package Specifications

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

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

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

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

2. Labeling

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

(a) Manufacturer’s name;
(b) Batch number (printed at the time of packaging);
(c) Month and year of expiry; and
(d) Any other information as requested by the Purchaser.

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

(a) Batch number;
(b) Month and year of manufacture (including the words: Date of Manufacture/month/year);
(c) Manufacturer’s name and registered address;
(d) Nominal width expressed in millimeters;
(e) Number of condoms in box;
(f) Instructions for storage; and
(g) Month and year of expiry.

3. Packaging Specification

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

4. Case Identification

4.1 All cases should predominantly indicate the following:

(a) Batch number;
5. **Lot Traceability**

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

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

6. **Unique Identifiers**

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

7. **Standards of Quality Control for Supply**

7.1 The Supplier will be required to provide the Purchaser with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.
8. Quality Control Testing

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

(b) With each consignment the Supplier must provide a certificate of quality control test results in conformity with the WHO specifications and in accordance with the general sampling levels appropriate to each feature as necessary.
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 .......................................................................................................................... 102
2. Price Schedule for Goods Offered from Abroad ................................................................. 104
3. Price Schedule for Domestic Goods Offered from within Ghana .................................... 105
4. Tender Security Form or Tender Securing Declaration ...................................................... 107
5. Form of Contract Agreement ............................................................................................. 109
7. Bank Guarantee Form for Advance Payment .................................................................. 113
8. Manufacturer’s Authorization Form .................................................................................. 114
9. Specimen Certificate of a Pharmaceutical Product ........................................................... 115
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 ]

plus [ insert: amount of foreign currency A in words ]

[ as appropriate, include the following ]

plus [ insert: amount of foreign currency B in words ]

plus [ insert: amount of foreign currency C in words ]

(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:

<table>
<thead>
<tr>
<th>Name and Address of Agent</th>
<th>Amount and Currency</th>
<th>Purpose of Commission or Gratuity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(if none, state “none”)</td>
</tr>
</tbody>
</table>

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 ____.

<table>
<thead>
<tr>
<th>Product code</th>
<th>Product</th>
<th>Strength</th>
<th>Dosage form</th>
<th>Unit pack size</th>
<th>Qty. offered</th>
<th>[a] Unit price FOB or FCA port or place of loading</th>
<th>[b] CIF at port of entry or CIP named place of destination (specify one)</th>
<th>[c] Inland transp., insurance &amp; other local costs incidental to delivery if specified</th>
<th>[d] Other incidental costs as defined in the SCC</th>
<th>Total unit price [a+c+d] or [b+c+d]</th>
<th>Total price per item [6 x 8]</th>
<th>Local agent’s commissio as a % of FOB price included in quoted price</th>
<th>Shipment weight and volume</th>
<th>Name of manufacturer</th>
<th>Ctry. of origin</th>
<th>Pharma-copoeial standard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note:
(i) Column 7[c] is optional and it will be applicable only when required in accordance with ITT Sub-Clause 16.2 (b) (iv) and (v) 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) Unit pack size must conform with specifications in schedule of requirement.
(iv) Lot Nos. must conform with that of Schedule of Requirements given in the Tender Document.

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 ____.

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

#### 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.

Signed:  
Dated:  
In the capacity of: ______________ [insert: title or other appropriate designation]
# Domestic Value Added Calculation Form

<table>
<thead>
<tr>
<th>Name of Tenderer:</th>
<th>Factory Location:</th>
</tr>
</thead>
</table>

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:** ________________________________________________

<table>
<thead>
<tr>
<th>Component Cost</th>
<th>Imported</th>
<th>Local</th>
<th>Total</th>
<th>% OF local Component Cost to Ex-Factory Tender Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Component</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Raw Material</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excipients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Packaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Labour</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost of Capital</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated Duties &amp; Taxes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overhead</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Profit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Signature of Tenderer: _____________________________________________

Date: ____________________________________________________________
Tender Security Form

Date:

To [name and address of Purchaser]

Whereas [name of the Tenderer] (hereinafter called “the Tenderer”) has submitted its Tender dated [date of submission of Tender] for the supply of [name and/or description of the goods and services] (hereinafter called “the Tender”).

KNOW ALL PEOPLE by these presents that We [name of bank/insurance/bonding institutions] of [name of country], having our registered office at [address of bank] (hereinafter called “the Bank/insurance company/bonding company”), are bound unto [name of Purchaser] The Government of Ghana (hereinafter called “the Purchaser”) in the sum of [amount] for which payment well and truly to be made to the said Purchaser, the Bank/Insurance Company/Bonding Company binds itself, its successors, and assigns by these presents. Sealed with the Common Seal of the said Bank/Insurance Company/Bonding Company this _____ day of _________ [mm] 20____.

THE CONDITIONS of this obligation are:

1. If the Tenderer
   
   (a) withdraws its Tender during the period of Tender validity specified by the Tenderer on the Tender Form; or
   
   (b) does not accept the correction of 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 execute the Form of Agreement in accordance with the Instructions to Tenderers, if required; or
   
   (b) fails or refuses to furnish the performance security, in accordance with 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 him is due to him, owing to the occurrence of any of the two conditions, specifying the occurred condition or conditions.

This guarantee will remain in force up to and including twenty eight (28) days after the period of Tender validity or as it may be extended by the Purchaser, notice of which extension(s) to the Bank/Insurance Company/Bonding Company is hereby waived.

And any demand in respect thereof should reach the Bank/Insurance Company/Bonding Company not later than the above date.
Seal of the issuing Bank/Insurance Company/Bonding Company:

Witness:

Signature:

Name:

Address:

[Insert Title or other appropriate]
Tender Securing Declaration

[The Tenderer shall fill in this Form in accordance with the instructions indicated.]

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

ICT No.: [insert number of Tendering process]

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

To: [insert complete name of Purchaser]

We, the undersigned, declare that:

1. We understand that, according to your conditions, tender must be supported by a Tender Securing Declaration.

2. We accept that we will automatically be suspended from being eligible for Tendering in any contract with the Purchaser for the period of time of [insert number of months or years] starting on [insert date], if we are in breach of our obligation(s) under the bid conditions, because we:

   (a) have withdrawn our Tender during the period of tender validity specified by us in the Tendering Data Sheet; or

   (b) having been notified of the acceptance of our Tender by the Purchaser during the period of tender validity, (i) fail or refuse to execute the Contract, if required, or (ii) fail or refuse to furnish the Performance Security, in accordance with the ITB.

3. We understand this Tender Securing Declaration shall expire if we are not the successful Tenderer, upon the earlier of (i) our receipt of a copy of your notification of the name of the successful Tenderer; or (ii) twenty-eight days after the expiration of our Tender

4. We understand that if we are a Joint Venture, the Tender Securing Declaration must be in the name of the Joint Venture that submits the Tender. If the Joint Venture has not been legally constituted at the time of bidding, the Tender Securing Declaration shall be in the names of all future partners as named in the letter of intent.

Signed: [insert signature of person whose name and capacity are shown] In the capacity of [insert legal capacity of person signing the Tender Securing Declaration]

Name: [insert complete name of person signing the Tender Securing Declaration]

Duly authorized to sign the bid for and on behalf of: [insert complete name of Tenderer]

Dated on ____________ day of __________________, _______ [insert date of signing]
5. Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

The ___ [insert: number] day of __ [insert: month], 20__ [insert: year].

BETWEEN

(1) [insert: Name of Purchaser], a [insert: description of type of legal entity, for example, an agency of the Ministry of .... of the Government of [insert: country of Purchaser], or corporation incorporated under the laws of [insert: country of Purchaser] and having its principal place of business at [insert: address of Purchaser] (hereinafter called “the Purchaser”), and

(2) [insert: name of Supplier], a corporation incorporated under the laws of [insert: country of Supplier] and having its principal place of business at [insert: address of Supplier] (hereinafter called “the Supplier”).

WHEREAS the Purchaser invited tenders for certain goods and ancillary services, viz., [insert: brief description of goods and services] and has accepted a tender by the Supplier for the supply of those goods and services in the sum of [insert: contract price in words and figures] (hereinafter called “the Contract Price”).

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

2. The following documents shall constitute the Contract between the Purchaser and the Supplier, and each shall be read and construed as an integral part of the Contract:

   (a) This Contract Agreement

   (b) Special Conditions of Contract

   (c) General Conditions of Contract

   (d) Technical Requirements (including Technical Specifications)

   (e) The Supplier’s tender and original Price Schedules

   (f) The Purchaser’s Notification of Award

   (g) [Add here: any other documents]

3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to provide the Goods and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.
5. This Agreement shall not be valid unless;
(a) signed by both parties

(b) authorised in the form of a Purchase Order (PO) generated from the Ghana Integrated Financial Management Information Systems (GIFMIS) or in a form specified by the Ministry of Finance (MoF) pursuant to the Applicable Law.

(c) the fulfillment of conditions precedent such as the submission performance bond, if any, that may be required on the part of either party under the Agreement or under the Applicable law.

For and on behalf of the Purchaser

Signed: ____________________________
in the capacity of [ insert: title or other appropriate designation ]
in the presence of ____________________________

For and on behalf of the Supplier

Signed: ____________________________
in the capacity of [ insert: title or other appropriate designation ]
in the presence of ____________________________

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

BETWEEN

[ insert: name of Purchaser ], “the Purchaser”

and

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


(unconditional)

Date: __________

IFT: __________ [ insert: name or number of IFT ]

Contract: __________ [ insert: name or number of Contract ]
To: __________________________ [insert: name of Purchaser]

________________________ [insert address of Purchaser]

Dear Sir or Madam:

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

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

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

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

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

For and on behalf of the Bank

Signed: ____________________________

Date: ____________________________
in the capacity of: ____________________ [insert: title or other appropriate designation]
Common Seal of the Bank
7. Bank Guarantee Form for Advance Payment

Date: ________ [ insert: date ]

Loan/Credit Number: ________ [ insert: loan or credit number from IFT ]

IFT: ________ [ insert: name and number of IFT ]

Contract: ________ [ insert: name and number of Contract ]

To: ___________________ [ insert: name and address of Purchaser ]

Dear Sir or Madam:

In accordance with the payment provision included in the Special Conditions of Contract, which amends Clause 16 of the General Conditions of Contract to provide for advance payment, ____________________ [ insert: name and address of Supplier ] (hereinafter called “the Supplier”) shall deposit with the Purchaser a bank guarantee to guarantee its proper and faithful performance under the said Clause of the Contract in an amount of ______________________ [ insert: amount of guarantee in figures and words ].

We, the ____________________ [ insert: bank or financial institution ], as instructed by the Supplier, agree unconditionally and irrevocably to guarantee as primary obligator and not as surety merely, the payment to the Purchaser on its first demand without whatsoever right of objection on our part and without its first claim to the Supplier, in the amount not exceeding ______________________ [ insert: amount of guarantee in figures and words ].

We further agree that no change or addition to or other modification of the terms of the Contract to be performed thereunder or of any of the Contract documents which may be made between the Purchaser and the Supplier, shall in any way release us from any liability under this guarantee, and we hereby waive notice of any such change, addition, or modification.

This guarantee shall remain valid and in full effect from the date of the advance payment received by the Supplier under the Contract until _________________ [ insert: 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
8. 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 ]
9. **Specimen Certificate of a Pharmaceutical Product**

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?\textsuperscript{11} yes/no/not provided (key in as appropriate)

2A.6 Applicant for certificate, if different from license holder (name and address):\textsuperscript{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:\textsuperscript{9}

________________________________________________________________________

________________________________________________________________________

2B.3 Why is marketing authorization lacking?

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

2B.4 Remarks:\textsuperscript{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\textsuperscript{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?\textsuperscript{15}

     yes/no/not applicable\textsuperscript{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?\textsuperscript{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 non-proprietary names (INNs) or national non-proprietary 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.