BIDDING DOCUMENTS

TENDER NO: CHAZ/GF/HEC/ICB1/19

TENDER FOR THE SUPPLY AND DELIVERY OF 300 RE-USABLE AND 75,000 DISPOSABLE MALE CIRCUMCISION KITS–CHURCHES HEALTH ASSOCIATION OF ZAMBIA (CHAZ)

Churches Health Association of Zambia
Plot 2882/B/5/10, Meanwood Drive, Meanwood Ibex
P.O. Box 34511
Lusaka
Zambia
Telephone: 260-1–428000/428001/428002/428016

Financing Agent: Global Fund – HEC

December 2018

B I D D I N G D O C U M E N T S

For

Procurement of
Re-Usable and Disposable Male Circumcision Kits

CHAZ/GF/HEC/ICB1/19

Project: Global Fund - HIV/TB Epidemic Control (HEC)

Purchaser: Churches Health Association of Zambia

Invitation for Bids (IFB)

TENDER No. CHAZ/GF/HEC/ICB1/19

TENDER FOR THE SUPPLY AND DELIVERY OF RE-USABLE AND DISPOSABLE MALE CIRCUMCISION KITS

The Churches Health Association of Zambia has provided funds under the Global Fund HIV/TB Epidemic Control (HEC) application and intends to apply part of the funds to payments under the contract for the supply and delivery of **Re-Usable and Disposable Male Circumcision Kits.**

The tender will be processed on International Competitive Bidding (ICB) procedure.

The Churches Health Association of Zambia now invites sealed bids from eligible and qualified bidders for the Supply and Delivery of Disposable Male Circumcision Kits.

The delivery period is as shown in the table below:

Lot No.	Item Description	Quantity	Delivery Period
1	Re-Usable Male Circumcision Kits	300	8 – 12 Weeks
2	Disposable Male Circumcision Kits	75,000	12 – 16 Weeks

Interested eligible bidders may obtain further information for inspection of the Bidding Documents from CHAZ Website: www.chaz.org.zm **or** the Office of the Manager – Procurement for the Executive Director, CHAZ Complex, Plot 2882/B/5/10, Meanwood Drive, Meanwood Ibex, P.O. Box 34511, Lusaka, Zambia. The Telephone number is 260 - 211 – 428000, 428001 and 428002.

Note Telefax and E-mail bids will not be accepted.

A complete set of Bidding Documents may be **inspected from the CHAZ website**: **www.chaz.org.zm.** However, a complete set of the Bidding Documents may be purchased by any interested eligible bidder upon payment of **a non-refundable fee of K1000.00 o**r its equivalent in any freely convertible currency at the prevailing exchange rate, in cash or by bank certified cheque. Purchase and collection of Tender Documents shall be on Monday to Friday from 08.00 hours to 16.30 hours starting on 7th January, 2019.

Bids must be delivered and deposited in the Tender Box located at the main reception of CHAZ Complex at the address below on or before **Tuesday 12th February, 2019 at 14:30 hour's Central African Time (CAT).** Late bids will be rejected. Bids will be opened in the presence of the bidders

and/or their representatives who choose to attend in person at CHAZ Complex, Plot 2882/B/5/10, Meanwood Drive, Meanwood Ibex, P.O. Box 34511, Lusaka, Zambia

All bids must be accompanied either by a Bid Security (**Bank Guarantee**) of 2% (two percent) of the bid sum or an equivalent amount in a freely convertible currency **or** a **Bid-Securing Declaration** (Declaration Form) which will take T**hree (3) years** suspension period if the bid-securing declaration is not complied with by the bidder withdrawing its bid.

The Purchaser (CHAZ) reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to Bidders. The Purchaser (CHAZ) is under no obligation to accept the lowest bid.

The Procurement Manager for the
The Executive Director
Churches Health Association of Zambia
CHAZ Complex
Plot No. 2882/B/5/10 Meanwood Drive, Meanwood Ibex
P.O Box 34511, Lusaka, Zambia

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Time table

ITEM DESCRIPTION	DATE	TIME
Deadline for request for any clarifications from bidders	**22nd January, 2019**	**16:00 hours**
Last date on which clarifications are issued by CHAZ	**29th January, 2019**	**16:00 hours**
Deadline for submission of Bids	**12th February, 2019**	**14:30 hours**

SECTION I. INSTRUCTIONS TO BIDDERS

Table of Clauses

Instructions to Bidders

A. INTRODUCTION

1. Scope of Bid

1.1 The Purchaser, as specified in the **Bid Data Sheet** and in the Special Conditions of Contract (SCC), invites bids for the supply of **300 RE-USABLE AND 75,000 DISPOSABLE MALE CIRCUMCISION KITS (MC Kits)** described in the Schedule of Requirements. The name and identification number of the Contract is provided in the **Bid Data Sheet** and in the SCC.

1.2 Throughout these bidding 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 **Bid Data Sheet** has received Funding from the Global Fund. The Purchaser intends to apply this grant to eligible payments under the Contract for which these bidding documents are issued.

2.2 Payment by CHAZ will be made only in accordance with CHAZ financial regulations.

3. Fraud and Corruption

3.1 It is CHAZ's policy to require that the Bidders/Suppliers/Contractors observe the highest standard of ethics during the procurement and execution of such Contracts. In pursuance of this policy, CHAZ:

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

(i) "corrupt practice" means the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official in the procurement process or in Contract execution; and

(ii) "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a Contract to the detriment of the Purchaser; it includes collusive practices among bidders (prior to or after bid submission) designed to establish bid prices at artificial, non-competitive levels and to deprive the Purchaser of the benefits of free and open competition.

(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;

(b) will not accept a bid for award if it determines that the bidder recommended for award has engaged in corrupt or fraudulent practices in competing for the Contract in question.

(c) will cancel the portion of the funds allocated to a contract if it determines at any time that representatives of the Purchaser engaged in corrupt, fraudulent, collusive or coercive practices during the procurement or the execution of that contract.

(d) will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Contract if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing contract.

e) will have the right to require that a provision be included in Bidding Documents and in contracts financed by Funding Agency, requiring bidders, suppliers, contractors and consultants to permit the Funding Agency to inspect their accounts and records and other documents relating to the Bid submission and contract performance and to have them audited by

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

4. Eligibility

4.1 This bidding process is Open to all local and foreign suppliers of RE-USABLE AND DISPOSABLE MALE CIRCUMCISION KITS.

4.2 Pursuant to ITB Sub-Clause 14.1, the Bidder shall furnish, as part of its bid, documents establishing, to the Purchaser's satisfaction, the Bidder's eligibility to bid.

4.3 Bidders shall provide such evidence of their continued eligibility satisfactory to the Purchaser, as the Purchaser shall reasonably request.

5. Eligible Goods and Services

5.1 For purposes of this clause, the term "Goods" includes any Goods that are the subject of this Invitation for Bids

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

6.1 Pursuant to ITB Clause 14, the Bidder shall furnish, as part of its bid, 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 Bidding 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 **Bid Data Sheet.**

6.4 Unless the **Bid Data Sheet** stipulates otherwise, the Goods to be supplied under the Contract shall be registered with the relevant authority in the Purchaser's country. A Bidder who has already registered its Goods by the time of bidding should submit a copy of the Registration Certificate with its bid. Otherwise, the successful Bidder, by the time of Contract signing, shall submit to the Purchaser either:

(a) a copy of the Registration Certificate of the Goods for use in the Purchaser's country.

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

(b) Evidence establishing to the Purchaser's satisfaction that the Bidder has complied with all the documentary requirements for registration as specified in the Bid Data Sheet.

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

6.4.2 If the Goods of the successful Bidder have not been registered in the Purchaser's country at the time of Contract signing, then the Contract shall become effective upon such date as the Certificate of Registration is obtained.

6.5 For purposes of the commentary to be furnished pursuant to ITB Clause 6.3 (b) above, the Bidder 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 Bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, 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 Bidder

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

(a) the Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the **Bid Data Sheet,** and has a successful performance history in accordance with criteria specified in the **Bid Data Sheet.** If a pre-qualification process has been undertaken for the Contract, the Bidder shall, as part of its bid, update any information submitted with its application for pre-qualification.

(b) in the case of a Bidder offering to supply Health Sector Goods, identified in the Bid Data Sheet, that the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the manufacturer or producer of such Goods to supply the Goods in the Purchaser's country;

(c) The Bidder meets the qualification criteria listed in the **Bid Data Sheet** (see additional clauses of Bid Data Sheet for pharmaceuticals and vaccines).

8. One Bid per Bidder

8.1 A firm shall submit only one bid either individually or as a partner of a joint venture (other than in cases of alternatives pursuant to ITB Clause 20). A firm that submits either individually or, as a member of a joint venture, more than one bid will cause all the proposals with the firm's participation to be disqualified.

9. Cost of Bidding

9.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

B. THE BIDDING DOCUMENTS

10. Content of Bidding Documents

10.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITB Clause 12.

Section I. Instructions to Bidders (ITB)
Section II. Bid Data Sheet (BDS)
Section III. General Conditions of Contract (GCC)
Section IV. Special Conditions of Contract (SCC)
Section V. Schedule of Requirements
Section VI. Technical Specifications
Section VII. Sample Forms (including Contract Agreement)

10.2 The "Invitation for Bids" does not form part of the Bidding Documents and is included as a reference only. In case of discrepancies between the Invitation for Bid and the Bidding Documents listed in 10.1 above, said Bidding Documents will take precedence.

11. Clarification of Bidding Documents

11.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the Purchaser in writing or by cable (for these ITB, the term "cable" is deemed to include electronic mail, telex, or facsimile) at the Purchaser's address indicated in the Bid Data Sheet. The Purchaser will respond in writing to any request for clarification received no later than twenty one (21) days calendar days prior to the deadline of submission of bids. Copies of the Purchaser's response shall be sent to all prospective Bidders who have purchased the Bidding Documents, including a description of the inquiry but without identifying its source.

12. Amendment of Bidding Documents

12.1 At any time prior to the deadline for submission of bids, the Purchaser may amend the Bidding Documents by issuing Addenda.

12.2 Any addendum thus issued shall be part of the Bidding Documents pursuant to ITB Sub-Clause 10.1 and shall be communicated in writing to all purchasers of the Bidding Documents and will be binding on them. Bidders are required to immediately acknowledge receipt of any such amendment, and it will be assumed that the information contained in the amendment will have been taken into account by the Bidder in its bid.

12.3 To give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the Purchaser shall extend, at its discretion, the deadline for submission of bids, in which case, the Purchaser will notify all Bidders by cable confirmed in writing of the extended deadline.

C. PREPARATION OF BIDS

13. Language of Bid

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

14. Documents Constituting the Bid

14.1 The bid submitted by the Bidder shall comprise the following:

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

(b) original form of bid security in accordance with the provisions of ITB Sub-Clause 19 (Bid Security);

(c) alternative offers, at the Bidder's option, when permitted;

(d) written power of attorney authorizing the signatory of the bid to commit the Bidder;

(e) in the absence of pre-qualification, documentary evidence in accordance with ITB Sub-Clause 4.4 establishing to the Purchaser's satisfaction the Bidder's eligibility to bid including but not limited to documentary evidence that the Bidder is legally incorporated in a territory of an eligible source country as defined under ITB Clause 4;

(f) documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITB Clause 6 that the Goods and ancillary services to be supplied by the Bidder are eligible Goods and Services, pursuant to ITB Clause 5, and that they conform to the Bidding Documents;

(g) documentary evidence establishing to the Purchaser's satisfaction, and in accordance with ITB Clause 7 that the Bidder is qualified to perform the Contract if its bid is accepted. In the case where pre-qualification of Bidders has been undertaken, and pursuant to ITB Paragraph 7.1 (a) the Bidder must provide evidence on

any changes in the information submitted as the basis for pre-qualification, 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 **Bid Data Sheet.**

15. Bid Form

15.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule furnished in the Bidding 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, bids will be classified in one of three groups, as follows:

(a) **Group A:** Bids offering Health Sector Goods manufactured in the Purchaser's country, for which (i) labour, raw materials, and components from within the Purchaser's country 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 bid submission.

(b) **Group B:** All other bids offering Health Sector Goods from within the country of the Purchaser.

(c) **Group C:** Bids 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 Bidder shall complete whichever version of the Price Schedule furnished in the Bidding Documents is appropriate provided, however, that the completion of an incorrect version of the Price Schedule by the Bidder will not result in rejection of its bid, but merely in the Purchaser's reclassification of the bid into its appropriate bid group.

16. Bid Prices

16.1 The Bidder shall indicate on the appropriate Price Schedule, as applicable, the unit prices of each item, total prices of each lot, and the total Bid 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 the Purchaser's country:

(i) the price of the Goods quoted EXW (ex-works, ex-factory, ex warehouse, ex showroom, or off-the-shelf, as applicable), including all customs duties and sales 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 Purchaser country sales and other taxes that will be payable on the Goods 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 **Bid Data Sheet.**

(iv) the price of other incidental Services, if any, listed in the **Bid 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 the Purchaser's country, as specified in the **Bid Data Sheet.** In quoting the price, the Bidder shall be free to use transportation through carriers registered in any eligible countries. Similarly, the Bidder 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 **Bid Data Sheet.**

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

(v) the price of incidental Services, if any, listed in the **Bid 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 Bidder's separation of price components in accordance with ITB Clause 16.2 above will be solely for the purpose of facilitating the comparison of bids 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 **Bid Data Sheet,** prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and will be rejected, pursuant to ITB Clause 29. If, however, in accordance with the **Bid Data Sheet,** prices quoted by the Bidder shall be subject to adjustment during the performance of the Contract, a bid 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 **Bid Data Sheet,** bids are being invited for one or more items, or for individual Contracts (lots) each comprising at least eighty percent (80%) of the total number of items required under the lot. In both cases, each item offered must comprise the full quantity required under that item. Bidders wishing to offer any price reduction for the award of more than one Contract shall specify in their bid the price reductions applicable to each package or, alternatively, to individual Contracts within the package. Price reductions may be submitted as an amount or a percentage to be applied to the bid prices.

17. Currencies of Bid

17.1 Prices shall be quoted in the following currencies:

(a) The Bidder shall express the bid price of the Health Sector Goods to be supplied from outside the Purchaser's Country entirely in the currency of United States Dollars or other freely convertible currency.

(b) Unless otherwise specified in the **Bid Data Sheet,** the Bidder shall express its prices for such goods to be

supplied from within the Purchaser's country in the currency of the country.

18. Period of Validity of Bids

18.1 Bids shall remain valid for the period stipulated in the **Bid Data Sheet** after the date of bid submission specified in ITB Clause 23. A bid valid for a shorter period shall be rejected by the Purchaser as non-responsive.

18.2 In exceptional circumstances, prior to expiry of the original bid validity period, the Purchaser may request that the Bidders extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. A Bidder may refuse the request without forfeiting its bid security. Except as provided in ITB Clause 18.3, a Bidder agreeing to the request will not be required or permitted to modify its bid, but will be required to extend the validity of its bid 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 bid 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. Bid Security

19.1 Unless otherwise specified in the **Bid Data Sheet,** the Bidder shall furnish, as part of its bid, a bid security in the amount stipulated in the **Bid Data Sheet** in the currency of the Purchaser's country, or the equivalent amount in a freely convertible currency.

19.2 The bid security shall remain valid for a period of 28 days beyond the validity period for the bid and beyond any extension subsequent requested under sub clause 18.2.

19.3 The bid security shall be denominated in the currency of the Purchaser's country, or in a freely convertible currency, and shall be, at the Bidder's option, in one of the following forms:

(a) a bank certified cheque;

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

(c) a bank guarantee, duly signed and sealed, issued by a reputable bank selected by the Bidder. The format of the (bank) guarantee shall be in accordance with the form of bid security included in Section VII;

(d) a bond issued by a surety selected by the Bidder and located in any country. If the institution issuing the bond is located outside the Purchaser's country, it shall have a correspondent financial institution located in the purchaser's country to make it enforceable. The format of the bank guarantee/bond shall be in accordance with the forms included in the bidding documents; other formats may be permitted, subject to the prior approval of the Purchaser.

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

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

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

19.7 The bid security may be forfeited

(a) if the Bidder withdraws its bid, except as provided in ITB Sub-Clauses 18.2 and 25.3; or

(b) if the Bidder does not accept the correction of its bid price, pursuant to ITB Clause 30; or

(c) in the case of a successful bidder, if the Bidder fails within the specified time limit to:

(i) sign the agreement, or

(ii) furnish the required performance security.

20. Alternative Proposals by Bidders

20.1 Unless **specified in the Bid Data Sheet,** alternative bids shall not be accepted.

21. Format and Signing of Bid

21.1 The Bidder shall prepare an original and the number of copies/sets of the bid indicated in the **Bid Data Sheet,** clearly marking each one as "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern.

21.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 14.1, shall be typed or

written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the Contract. The later authorization shall be indicated by written power of attorney, which pursuant to ITB Sub-Clause 14.1 (d) shall accompany the bid.

21.3 Any interlineations, erasures, or overwriting to correct errors made by the Bidder should be initialled by the person or persons signing the bid.

21.4 The Bidder shall furnish in the Bid Form (a sample of which is provided in the Sample Forms Section of the Bidding Documents) information regarding commissions or gratuities, if any, paid or to be paid to agents relating to this bid and to the execution of the Contract if the Bidder is awarded the Contract.

D. SUBMISSION OF BIDS

22. Sealing and Marking of Bids

22.1 The Bidder shall enclose the original and each copy of the bid including alternative bids, if permitted in accordance with ITB Clause 20, in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." 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 Bidder;

(b) be addressed to the address given in the **Bid Data Sheet;**

(c) bear the specific identification of this bidding process indicated in the **Bid Data Sheet,** the Invitation for Bids title and number indicated in the **Bid 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 Bid Data Sheet relating to ITB Sub-Clause 23.1.

22.3 If the outer envelope is not sealed and marked as required by ITB Sub-Clause 22.2, the Purchaser will assume no responsibility for the misplacement or premature opening of the bid.

23. Deadline for Submission of Bids

23.1 Bids must be received by the Purchaser at the address specified in the **Bid Data Sheet** relating to ITB Sub-Clause 22.2 (b) no later than the time and date specified in the **Bid Data Sheet.**

23.2 The Purchaser may, at its discretion, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITB Sub-Clause 12.3, in which case all rights and obligations of the Purchaser and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

24. Late Bids

24.1 Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser in the **Bid Data Sheet** pursuant to ITB Clause 23 will be rejected and returned unopened to the Bidder.

25. Modification and Withdrawal of Bids

25.1 The Bidder may modify or withdraw its bid after submission, provided that written notice of the modification, or withdrawal of the bids duly signed by an authorized

representative, is received by the Purchaser prior to the deadline prescribed for submission of bids.

25.2 The Bidder's modification shall be prepared, sealed, marked, and dispatched as follows:

(a) The Bidder shall provide an original and the number of copies specified in the **Bid Data Sheet** of any modifications to its bid, clearly identified as such, in two inner envelopes duly marked "BID MODIFICATION-ORIGINAL" and "BID MODIFICATION-COPIES." The inner envelopes shall be sealed in an outer envelope, which shall be duly marked "BID MODIFICATION."

(b) Other provisions concerning the marking and dispatch of bid modifications shall be in accordance with ITB Sub-Clauses 22.2 and 22.3.

25.3 A Bidder wishing to withdraw its bid shall notify the Purchaser in writing prior to the deadline prescribed for bid submission. A withdrawal notice shall be received prior to the deadline for submission of bids. The notice of withdrawal shall:

(a) be addressed to the address named in the **Bid Data Sheet,**

(b) bear the specific identification of the bidding process (Contract name), the Tender title and Tender number, and the words "BID WITHDRAWAL NOTICE," and

(c) be accompanied by a written power of attorney authorizing the signatory of the withdrawal notice to withdraw the bid.

25.4 Bids requested to be withdrawn in accordance with ITB Sub-Clause 25.3, shall be returned unopened to the Bidders.

25.5 No bid may be withdrawn in the interval between the bid submission deadline and the expiration of the bid validity period specified in ITB Clause 18. Withdrawal of a bid during this interval may result in the forfeiture of the Bidder's bid security, pursuant to ITB Sub-Clause 19.7.

E. OPENING AND EVALUATION OF BIDS

26. Bid Opening

26.1 The Purchaser will open all bids, including withdrawal notices and modifications, in public, in the presence of Bidders' representatives who choose to attend, at the time, on the date, and at the place specified in the **Bid Data Sheet.** Bidders' 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 bid shall not be opened but returned to the Bidder. No bid withdrawal notice shall be permitted unless the corresponding withdrawal notice is read out at bid opening. Envelopes marked "MODIFICATION" shall be read out and opened with the corresponding bid.

26.3 Bids shall be opened one at a time, reading out: the name of the Bidder and whether there is a modification; the bid price of each item or lot, as the case may be, including discounts and alternative offers, if allowed in the Bid Data Sheet; the presence or absence of a bid security, if required; the presence or absence of requisite powers of attorney; and any other such details as the Purchaser may consider appropriate. No bid shall be rejected at bid opening except for late bids pursuant to Sub-Clause 24.1.

26.4 Bids (and modifications sent pursuant to ITB Sub-Clause 25.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances.

26.5 The Purchaser will prepare minutes of the bid opening at the end of the opening session, including, as a minimum: the name of the Bidder and whether there was a withdrawal or modification; the bid price; including any discounts or alternatives offered if permitted in the Bid Data Sheet; the presence or absence of a bid security; the presence or absence of requisite powers of attorney.

The Bidder's representatives who are present shall be requested to sign the minutes. The omission of a Bidder's signature on the minutes shall not invalidate the content and effect of the minutes. The minutes should be distributed to all Bidders who request them.

27. Clarification of Bids

27.1 During evaluation of the bids, the Purchaser may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing and no change in the prices or substance of the bid shall be sought, offered, or permitted, except to correct arithmetic errors identified by the Purchaser in the evaluation of the bids, in accordance with ITB Sub-Clause 30.1.

28. Confidentiality

28.1 Information relating to the examination, clarification, evaluation, and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the notification of Contract award is made to all Bidders.

28.2 Any effort by the bidder to influence the Purchaser in the Purchaser's bid evaluation, bid comparison, or contract award decisions may result in the rejection of the Bidder's bid.

28.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Purchaser on any matter related to its bid, it should do so in writing.

29. Examination of Bids and Determination of Responsiveness

29.1 The Purchaser will examine the bids 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 bids are generally in order. In the case where a pre-qualification process has been undertaken for the Contract(s) for which these Bidding Documents have been issued, the Purchaser will ensure that each bid is from a pre-qualified Bidder.

29.2 The Purchaser may waive any minor informality, nonconformity, or irregularity in a bid that does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

29.3 Prior to the detailed evaluation, pursuant to ITB Clause 32, the Purchaser will determine whether each bid is of acceptable quality, is complete, and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionality, or reservations. A material deviation, exception, objection, conditionality, or reservation is one: (i) that limits in any substantial way the

scope, quality, or performance of the Goods and related Services; (ii) that limits, in any substantial way that is inconsistent with the Bidding Documents, the Purchaser's rights or the successful Bidder's obligations under the Contract; and (iii) that the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids.

29.4 If a bid is not substantially responsive, it will be rejected by the Purchaser and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Purchaser's determination of a bid's responsiveness is to be based on the contents of the bid itself, and any written clarification submitted by the Bidder in accordance with ITB 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 Bidder does not accept the correction of errors, its bid will be rejected and its bid security may be forfeited.

31. Conversion to Single Currency

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

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

or

(b) in U.S. Dollars, at the selling rate of exchange published in the international press for the amount payable in foreign currency; and at the selling exchange rate established for similar transactions by the Central Bank in the Purchaser's country for the amount payable in the currency of the Purchaser's country.

31.2 The currency selected for converting bid prices to a common base for the purpose of evaluation, along with the source and

date of the exchange rate, are specified in the **Bid Data Sheet.**

32. Evaluation and Comparison of Bids

32.1 The Purchaser will evaluate and compare the bids that have been determined to be substantially responsive, pursuant to ITB Clause 29.

32.2 The Purchaser's evaluation of a bid will exclude and not take into account:

(a) in the case of Goods manufactured in the Purchaser's country or Goods of foreign origin already located in the Purchaser's country, sales and other similar taxes, that will be payable on the Goods if a contract is awarded to the Bidder;

(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 Bidder; and

(c) any allowance for price adjustment during the period of execution of the Contract, if provided in the bid.

The evaluation shall include and take into account:

(d) any direct taxes levied on the Bidder, or the Bidder's employees, subcontractor, or the subcontractor's employees.

(e) any indirect taxes on the Goods required as inputs to the Goods supplied under the Contract.

32.3 The comparison shall be between the EXW price of the Goods offered from within the Purchaser's country, such price to include all costs, as well as duties and taxes paid or payable on components and raw material incorporated or to be incorporated in the Goods, and the CIF named port of destination (or CIP border point, or CIP named place of destination) price of the Goods offered from outside the Purchaser's country.

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

(a) cost of inland transportation, insurance, and other costs within the Purchaser's country incidental to delivery of the Goods to their final destination;

(b) delivery schedule offered in the bid;

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

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

32.5 For factors retained in the **Bid Data Sheet** pursuant to ITB Sub-Clause 32.4, one or more of the following quantification methods will be applied, as detailed in the **Bid 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 **Bid Data Sheet** will be computed for each bid 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, Bidder shall furnish in its bid 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 Bidding 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 bid after allowing for reasonable international and inland transportation time. A delivery "adjustment" will be calculated for and added to each bid by applying a percentage, specified in the **Bid Data Sheet,** of the EXW/CIF/CIP price for each week of delay beyond the expected time of arrival specified in the Bidding Documents for evaluation purposes. No credit shall be given to early delivery.

Or

(ii) The Health Sector Goods covered under these Bidding 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 bids offering delivery beyond this range will be treated as non-responsive. Within this acceptable range, an adjustment per week, as specified in the **Bid Data Sheet,** will be added for evaluation to the bid price of bids 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. Bids offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the bid price a factor equal to a percentage, specified in the **Bid Data Sheet,** of EXW/CIF/CIP price per week of variation from the specified delivery schedule.

(c) Deviation in payment schedule.

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

or

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

invitation, at the rate per annum specified in the **Bid Data Sheet.**

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

33. Domestic Preference

33.1 If indicated in the **Bid Data Sheet** and for the purpose of bid comparison, the Purchaser will grant a margin of preference to Goods manufactured in the Purchaser's country. This margin of preference will be granted in accordance with the procedures outlined in subsequent paragraphs, provided the Bidder shall have established to the satisfaction of the Purchaser that its bid complies with the criteria specified in ITB Paragraph 15.2 (a).

33.2 The Purchaser will first review the bids to confirm the appropriateness of, and to modify if necessary, the bid group classification to which Bidders assigned their bids in preparing their Bid Forms and Price Schedules.

33.3 All evaluated bids in each group will then be compared among themselves to determine the lowest evaluated bid of each group. The lowest evaluated bid of each group will next be compared with the lowest evaluated bids of the other groups. If this comparison results in a bid 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 bid is from Group C, all Group C bids will then be further compared with the lowest evaluated bid from Group A, after adding to the evaluated bid price of the imported Goods offered in each Group C bid, 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 bid*;*

or

(b) fifteen (15) percent of the CIF (or CIP border point or CIP named place of destination, as the case may be) bid 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 bid in the further comparison is the lowest, it will be selected for award. If not, the lowest evaluated bid from Group C, as determined from the comparison under ITB Sub-Clause 33.3 above, will be selected for award.

F. AWARD OF CONTRACT

34. Post qualification

34.1 In the absence of pre-qualification, the Purchaser will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITB Sub-Clause 7.1 and any additional post qualification criteria stated in the **Bid Data Sheet.** If a pre-qualification process was undertaken for the Contract(s) for which these Bidding Documents were issued, the Purchaser will determine in the manner described above that no material changes have occurred after the pre-qualification that negatively affect the ability of the Bidder that has submitted the lowest evaluated bid to perform the Contract.

34.2 The determination will evaluate the Bidder's financial, technical, and production capabilities. It will be based on an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB 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 Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Purchaser will proceed to the next-lowest evaluated Bidder to make a similar determination of that Bidder's capabilities to perform satisfactorily.

35. Award Criteria

35.1 Pursuant to ITB Clauses 32, 33, and 38, the Purchaser will award the Contract to the Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily, pursuant to ITB Clause 34.

36. Purchaser's Right to Accept Any Bid and to Reject Any or All Bids

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

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 **Bid 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 bid validity, the Purchaser will notify the successful Bidder in writing by registered letter or by cable, to be subsequently confirmed in writing by registered letter, that its bid has been accepted.

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

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

38.5 The Purchaser shall publish in publication(s) named in the **Bid Data Sheet** the results identifying the bid and lot numbers and the following information: (i) name of each Bidder who submitted a Bid; (ii) bid prices as read out at bid opening; (iii) name and evaluated prices of each Bid that was evaluated; (iv) name of bidders whose bids were rejected and the reasons for their rejection; and (v) name of the winning Bidder, and the price it offered, as well as the duration and summary scope of the contract awarded. After publication of the award, unsuccessful bidders may request in writing to the Purchaser for a debriefing seeking explanations on the grounds on which their bids were not selected. The Purchaser shall promptly respond in writing to any unsuccessful Bidder who, after Publication of contract award, requests a debriefing.

39. Signing of Contract

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

39.2 Within twenty-eight (28) days of receipt of the Contract Form, the successful Bidder shall sign and date the Contract Form and return it to the Purchaser.

40. Performance Security

40.1 Within twenty-eight (28) days of the receipt of notification of award from the Purchaser, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, using the Performance Security Form provided in the Bidding Documents, or in another form acceptable to the Purchaser.

40.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 39 or ITB Sub-Clause 40.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Purchaser may make the award to the next-lowest evaluated bid submitted by a qualified Bidder or call for new bids.

SECTION II. BID DATA SHEET

Bid Data Sheet

The following specific data for the Goods to be procured shall complement, supplement, or amend the provisions in the Instructions to Bidders (ITB). Whenever there is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

A. GENERAL

ITB 1.1	Name of Purchaser: **CHURCHES HEALTH ASSOCIATION OF ZAMBIA (CHAZ).** Type of goods**: RE-USABLE AND DISPOSABLE MALE CIRCUMCISION KITS.** Name and identification number of the Contract: Name**: Supply and Delivery of 300 Re-Usable and 75,000 Disposable Male Circumcision Kits.** Number**: TENDER NO: CHAZ/GF/HEC/ICB1/19** Bidders may bid for **one** Lot or **both** Lots. The CHURCHES HEALTH ASSOCIATION OF ZAMBIA will evaluate the bids for each Lot and award the contract(s) accordingly. Bids not quoting for all required quantities for an item in a lot will be considered **non-responsive**.
ITB 7.1 (a)	Qualification requirements for Bidders are: The following documents must be included with the bid: Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted: (i) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Bidder: (a) is incorporated in the country of manufacture of the Goods; *(b)* has manufactured and/or marketed the specific goods covered by this bidding Document, for at least two (two) years, (ii) that, in the case of a Bidder offering to supply Goods under the Contract that the Bidder does not manufacture or otherwise produce, (a) that the Bidder has been duly authorized by a manufacturer of the Goods that meets the criteria under (i) above to supply the Goods in the Purchaser's country; and

	The bidder shall also submit the following additional information: (a) list of major supply contracts conducted within the last three years

B. THE BIDDING DOCUMENTS

ITB 11.1	**Purchaser's address:** CHURCHES HEALTH ASSOCIATION OF ZAMBIA CHAZ Complex Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex P.O Box 34511 Lusaka Zambia. Tel: **260-211-428000/428001/428002** **Address to seek clarifications:** The CHURCHES HEALTH ASSOCIATION OF ZAMBIA CHAZ Complex Procurement Unit Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex P.O Box 34511 Lusaka Zambia. Tel: **260-211-428000/428001/428002**

C. PREPARATION OF BIDS

ITB 13.1	The language of all correspondence and documents related to the bid is: **English.** Moreover, the key passages of all accompanying printed literature in any other language must be translated into the above language.
ITB 15.1	A Bidder who submits a Bid Form that is not signed shall be considered non-responsive
ITB 16.2 (a) (iii)	The price quoted shall be EXW (ex works, ex-factory, ex warehouse, ex showroom and off the shelf) Prices for inland transportation, insurance and price of incidental local costs incidental to the delivery of goods offered from within the Purchaser's country shall be quoted in addition to EXW or ex-factory

	or ex warehouse or ex showroom or off the shelf CHAZ Warehouse, AT Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex P.O Box 34511 Lusaka Zambia. Tel: **260-211-428000/428001/428002**
ITB 16.2 (b) (i)	Prices for Goods offered from abroad shall be quoted as: CIP CHAZ Warehouse, **AT** Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex P.O Box 34511 Lusaka Zambia. Tel: **260-211-428000/428001/42800**
ITB 16.5	Prices quoted by the Bidder shall be **fixed.**
ITB 17.1 (b)	BDS – 17.1(b)The currency to be used for quoting prices of the Goods and Services components of the Goods offered from within the Purchaser's country, as well as local currency expenditures for local technical support, training, maintenance, transportation, insurance, and other local costs incidental to delivery is: **Zambian Kwacha for local suppliers.** **NOTE: Foreign suppliers - Contract will be drawn in the currency used for quoting prices of the goods but preferably US Dollars.**
ITB 18.1	The bid validity period shall be **ninety (90)** days after the deadline for bid submission, as specified below in reference to ITB Clause 23.
ITB 19.1	Manufacturer's authorization is: **APPLICABLE.**
ITB.19.2	a) The bid security (Bank Guarantee) must be valid up to twenty-eight (28) days after the end of the bid validity period. Accordingly, a bid with a bid security that expires before twenty-eight (28) days after the end of the bid validity period shall be rejected as non-responsive. b) Similarly, the Bid Securing Declaration form signed and submitted for less than Three (3) years duration shall be rejected as non-responsive.
ITB 20.1	Alternative bids will not be accepted.
ITB 21.1	Required number of copies of the bid: **one (1No.) original and (3No.) four copies.**

D. SUBMISSION OF BIDS

ITB 22.2 (b)	Churches Health Association of Zambia CHAZ Complex Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex P.O Box 34511 Lusaka Zambia. Tel: **260-211-428000/428001/428002**
ITB 22.2 (c) & (d)	The Invitation for Bids title and number are: Title**: Tender for the supply and delivery of 300 Re-Usable and 75,000 Disposable Male Circumcision Kits.** Number: **TENDER NO: CHAZ/GF/HEC/ICB1/19**
ITB 23.1	Deadline for bid submission is: **Tuesday, 12th February, 2019 at 14:30 hours Central African Time (CAT)**
ITB 24.1	Any bid submitted after **14:30 hours Central African Time (CAT) on Tuesday, 12th February, 2019** will be rejected and returned unopened to the Bidder.
ITB 25.2 (a)	Required number of copies of bid modifications is : **One (1No.) Original and four (3No.) Copies.**

E. BID OPENING AND EVALUATION

ITB 26.1	Time, date, and place for bid opening are: Time: Immediately after closing at 14.30 hours local time Date: **Tuesday, 12th February, 2019.** Place*:* CHURCHES HEALTH ASSOCIATION OF ZAMBIA CHAZ Complex Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex P.O Box 34511 Lusaka Zambia. Tel: **260-211-428000/428001/428002**
ITB 31.2	The currency chosen for the purpose of converting to a common currency is **Zambian Kwacha:** The source of exchange rate is: **Standard Chartered Bank Plc** The date of exchange rate determination is **Tuesday, 12th February, 2019.**
ITB 32.4	**The evaluation will take into account the following; (a), (b) , (d) and ITB 7.1 (a), ITB 15.1, ITB 18.1**
ITB 32.5	The factors retained pursuant to ITB Sub-Clause 32.4 and the quantification methods are: as specified in BDS, ITB 32.5 (a), (b), (ii)
ITB 32.5 (a)	Inland transportation from EXW/port of entry/border point to **CHAZ Warehouse, AT Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex in Lusaka, Zambia, insurance and incidentals.**
ITB 32.5 (b)	Delivery schedule: Ex- Stock or Indicate the earliest delivery period. Delivered **CIP - CHAZ Warehouse including customs, clearing, insurance and incidentals for local costs of transportation to the Warehouse, AT Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex, P.O Box 34511, Lusaka** **Zambia. Tel: 260-211-428000/428001/428002** The adjustment per week for delivery delays beyond the time specified in the Schedule of Requirements is **0.5% up to a maximum of 10%**
ITB 32.5 (c) (ii)	The Purchaser will not accept deviations in the payment schedule in the SCC. However, payment terms and conditions for payment can be negotiated at the award of contract stage.

F. POST-QUALIFICATION AND AWARD OF CONTRACT

ITB 34.1	The Bidder must demonstrate that it has successfully completed at least 2 similar or larger contracts during the last 3 years.
ITB 37.1	Percentage for increase or decrease of quantity of Goods and Services originally specified: **Thirty per cent (30%).**

SECTION III. GENERAL CONDITIONS OF CONTRACT

TABLE OF CLAUSES

General Conditions of Contract

1. Definitions

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

(a) "The Contract" means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

(b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.

(c) "Day" means calendar day.

(d) "Effective Date" means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.

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

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

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

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

(i) "The Purchaser's country" is the country **named in the SCC.**

(j) "Registration Certificate" means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser's country in accordance with the Applicable Law.

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

(l) "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other

such obligations of the Supplier covered under the Contract.

(m) "The Site," means the place or places of delivery named in the **SCC.**

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

2. Application

2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

3. Country of Origin

3.1 Bidders shall specify the country of origin for each item to be supplied under the Contract(s)

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

3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.

4. Standards

4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

5. Use of Contract Documents and Information

5.1 The Supplier shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The Supplier shall not, without the Purchaser's prior written consent, make use of any document or information enumerated in GCC Sub-Clause 5.1 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC Sub-Clause 5.1 shall remain the property of the Purchaser and shall be returned (all copies) to the Purchaser on completion of the Supplier's performance under the Contract if so required by the Purchaser.

5.4 The Supplier shall permit the Funding Agency 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 Funding Agency, if so required by the Funding Agency.

6. Certification of Goods in Accordance with Laws of the Purchaser's Country

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

6.2 Unless otherwise specified in the SCC, the Contract shall become effective on the date ("the Effective Date") that the Supplier receives written notification from the relevant authority in the Purchaser's country that the Goods have been registered for use in the Purchaser's country.

6.3 If thirty (30) days, or such longer period **specified in the SCC,** elapse from the date of Contract signing and the Contract has not become effective pursuant to Sub-Clause 6.2 above, then either party may, by not less than seven (7) days' written notice to the other party, declare this Contract null and void. In such event, the Supplier's performance security shall be promptly returned.

7. Patent Rights

7.1 The Supplier shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in the Purchaser's country.

8. Performance Security

8.1 Within Twenty Eight (28) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Purchaser the performance security in the amount **specified in the SCC.**

8.2 The proceeds of the performance security shall be payable to the Purchaser as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

8.3 The performance security shall be denominated in the currency of the Contract and shall be in one of the following forms:

(a) a bank guarantee issued by a reputable bank located in the Purchaser's country or abroad, acceptable to the Purchaser, in the format provided in the Bidding Documents or another format acceptable to the Purchaser.

8.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than twenty eight (28) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless **specified otherwise in the SCC.**

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 FCA 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 FCA, transport of the Goods and delivery into the custody of the carrier at the place named by the Purchaser or other agreed point shall be arranged and paid for by the Supplier, and the cost thereof shall be included in the Contract Price.

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

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

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

14. Incidental Services

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

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

15. Warranty

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

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

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

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

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

15.5 *Recalls.* In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly

replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfil 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 fulfilment of other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Purchaser, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.

16.4 The currency or currencies in which payment is made to the Supplier under this Contract shall be **specified in the SCC** subject to the following general principle: Payment will be made in the currency or currencies in which the payment has been requested in the Supplier's bid.

16.5 All payments shall be made in the currency or currencies specified in the SCC pursuant to GCC 16.4.

17. Prices

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

18. Change Orders

18.1 The Purchaser may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:

(a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Purchaser;

(b) the method of shipment or packing;

(c) the place of delivery; and/or

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

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both,

and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Purchaser's change order.

19. Contract Amendments

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

20. Assignment

20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Purchaser's prior written consent.

21. Delays in the Supplier's Performance

21.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

21.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Purchaser in writing of the fact of the delay, its likely duration, and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

21.3 Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of liquidated damages.

22. Liquidated Damages

22.1 Subject to GCC Clause 24, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage **specified in the SCC** of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage **specified in the SCC.** Once the maximum is reached, the Purchaser may consider termination of the Contract pursuant to GCC Clause 23.

23. Termination for Default

23.1 The Purchaser, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

(a) if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser pursuant to GCC Clause 21; or

(b) if the Goods do not meet the Technical Specifications stated in the Contract; or

(c) if the Supplier fails to provide any registration or other certificates in respect of the Goods within the time specified in the Special Conditions.

(d) if the Supplier, in the judgment of the Purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

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

"fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a Contract to the detriment of the Purchaser, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Purchaser of the benefits of free and open competition.

"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;

(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 wilful misconduct, and in the case of infringement pursuant to Clause 7,

(a) the Supplier shall not be liable to the Purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Purchaser and

(b) the aggregate liability of the Supplier to the Purchaser, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

29. Governing Language

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

30. Applicable Law

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

31. Notices

31.1 Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex, or facsimile and confirmed in writing to the other party's address **specified in the SCC.**

31.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.

32. Taxes and Duties

32.1 A Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, licence fees, and other such levies imposed outside the Purchaser's country.

32.2 A Supplier supplying Goods offered locally shall be entirely responsible for all taxes, duties, licence fees, etc., incurred until delivery of the contracted Goods to the Purchaser.

SECTION IV. SPECIAL CONDITIONS OF CONTRACT

SPECIAL CONDITIONS OF CONTRACT

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.	
1. Definitions (GCC Clause 1)	
GCC 1.1 (h)	The Purchaser is: **CHURCHES HEALTH ASSOCIATION OF ZAMBIA**
GCC 1.1 (i)	The Purchaser's country is: **Zambia**
GCC 1.1 (m)	The Site is: **CHAZ Warehouse, AT Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex, P.O Box 34511, Lusaka Zambia. Tel: 260-211-428000/428001/428002**
GCC 1.1 (n)	The Supplier is:
GCC 1.1 (e)	**The end user is: CHURCHES HEALTH ASSOCIATION OF ZAMBIA**
6. Certification of Goods in Accordance with Laws of the Purchaser's Country (GCC Clause 6)	
GCC 6.1	Details of registration and other certification necessary to prove registration in the Purchaser's country: **Product Registration certificate and Retention Fees certificate for 2019 from the Zambia Medicines Regulatory Authority in Zambia (ZAMRA) – APPLICABLE** **** Bids without Product registration and retention certification with ZAMRA shall be rendered non – responsive**
GCC 6.2	The Effective Date of the Contract is: **Date of Contract signing by both parties.**
Performance Security (GCC Clause 8)	
GCC 8.1	Performance security shall be for an amount equal to: **Ten (10) percent of the Contract Price.**
10. Packing (GCC Clause 10)	
GCC 10.2	The necessary requirements with respect to packing and marking are as specified in the Technical Specifications.
	11. Delivery and Documents (GCC Clause 11)
GCC 11.1 & 11.3	***For Goods supplied from abroad:*** Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment,

	mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. The Supplier shall fax and then send by courier the following documents to the CHURCHES HEALTH ASSOCIATION OF ZAMBIA (CHAZ) with a copy to CHAZ Warehouse and the insurance company: (i) three originals of the Supplier's invoice, showing Purchaser as CHURCHES HEALTH ASSOCIATION OF ZAMBIA*;* 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; (ii) one original and two copies of the negotiable, clean, on-board through bill of lading marked "freight prepaid" and showing Purchaser as CHURCHES HEALTH ASSOCIATION OF ZAMBIA and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements; (iii) three copies of the packing list identifying contents of each package; (iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied; (vi) one original of the Supplier's Certificate of Origin covering all items supplied; (vii) any other procurement-specific documents required for delivery/payment purposes. (viii) Certificate of Analysis (CoA) **The above documents shall be received by the Purchaser before arrival of the Goods and, if not received, the Supplier will be responsible for any consequent expenses.**

	NOTE: CHAZ will facilitate the Pre-clearance only and ALL payments related to pre-clearance fees with ZAMRA shall be settled/or paid by the supplier/or supplier representative agent to ZAMRA.
	For Goods from within the Purchaser's country: Upon or before delivery of the Goods, the Supplier shall notify the Purchaser in writing and deliver the following documents to the Purchaser: (i) three originals 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 CHURCHES HEALTH ASSOCIATION OF ZAMBIA and delivery through to final destination as stated in the Contract; (iii) copy of the Insurance Certificate, showing the Purchaser as the beneficiary; (iv) three 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; (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 CIP value of the Goods from "warehouse" to "warehouse" on "All Risks" basis, including war risks and strikes.
	14. Incidental Services (GCC Clause 14)
	15. Warranty (GCC Clause 15)
GCC 15.4	The period for the replacement of defective goods is: **Four (4) weeks from the date of official notification of such defects**.
	16. Payment (GCC Clause 16)
GCC 16.1 & 16.4	The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

	Payment for Goods supplied from abroad: Payment shall be made in *[currency **of the Contract Price (preferably US Dollars)]*** in the following manner: (i) On **delivery and Acceptance:** One Hundred (100) percent of the Contract Price of the Goods shipped shall be paid through by Bank Transfer within 30 days after delivery. . **Payment for Goods and Services supplied from within the Purchaser's country:** Payment for Goods and Services supplied from within the Purchaser's country shall be made in **Zambian Kwacha**, as follows: (i) **On Delivery and Acceptance:** One Hundred (100) percent of the Contract Price of the Goods delivered shall be paid through by Bank Transfer within 30 days. **NOTE: ADVANCE PAYMENT**: Any Advance Payment, if negotiated with the Purchaser, shall be paid against an Advance Payment Guarantee for the equal amount as requested **(The Advance Guarantee MUST be obtained from any Zambian Local commercial Bank)** ***The advance payment shall NOT have any bearing whatsoever on the commencement of procurement of goods by the Supplier and as such the Supplier shall diligently commence and proceed with the supply of goods on the date stated in the Agreement even before advance payment is made.***
	22. Liquidated Damages (GCC Clause 22)
GCC 22.1	Applicable rate shall be one-half **(0.5)** percent per week and the maximum shall not **exceed ten (10)** percent of the Contract Price.
	27. Settlement of Disputes (GCC Clause 27)
GCC 27.2.2	The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 27.2.2 shall be as follows: **(a) Contracts with foreign Supplier:** 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. **(b) Contracts with Supplier from within the Purchaser's country:**

	In the case of a dispute between the Purchaser and a Supplier from within the Purchaser's country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's country.
29. Governing Language (GCC Clause 29)	
GCC 29.1	The governing language shall be**: English**
30. Applicable Law (GCC Clause 30)	
GCC 30.1	The Contract shall be interpreted in accordance with the laws of the: **Government of the Republic of Zambia**.
31. Notices (GCC Clause 31)	
GCC 31.1	The Purchaser's address for notice purposes is: CHURCHES HEALTH ASSOCIATION OF ZAMBIA, CHAZ Complex Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex P.O Box 34511 Lusaka Zambia. Tel: **260-211-428000/428001/428002** Contact Person: **Shadreck Malupenga (Mr)** **Manager - Procurement.**

SECTION V. SCHEDULE OF REQUIREMENTS

Schedule of Requirements

The delivery schedule expressed as weeks stipulates hereafter a delivery date that is the date of delivery to the first carrier when the Contract is placed on CIP terms. To determine the correct date of delivery hereafter specified, the Purchaser has taken into account the additional time that will be needed for international or national transit to the site or to another common place.

The named destination for delivery CIP is:

CHAZ Warehouse
CHAZ Complex
Plot No. 2882/B/5/10, Meanwood Drive, Meanwood Ibex
P.O Box 34511
Lusaka
Zambia. Tel: **260-211-428000/428001/428002**

SCHEDULE OF REQUIREMENTS MALE CIRCUMCISION KITS

Lot No.	Description of Item	Delivery Period	Total
1	Re-Usable MC Kits	8 – 12 Weeks	300
2	Disposable MC Kits	12 – 16 Weeks	75,000

Shelf Life:

All Health Products are expected to have 80% of their Shelf life remaining at the time of delivery. Health Products with less than 80% of the Shelf life shall be rejected and a replacement shall be called at the supplier's expense.

All pharmaceuticals, Paracetamol 500mg, plain Lignocaine 2% and Betadine Solution/bottle (Povidone Iodine Solution) should be packaged separately from the other items in a Kit and must be licensed and registered by the Zambian Medicines Regulatory Authority (ZAMRA)

Both the pharmaceuticals and other items for the kits MUST be delivered on pallets.

Both pharmaceuticals and surgicals MUST be delivered at the same time. Kits will only be considered complete when both pharmaceuticals and surgicals are delivered at same time.

IMPORTANT NOTES (APPLICABLE)

a) **Samples:** The bidder MUST submit as part of the bid samples for the Re-Usable and Disposable MC –Kits.
b) With the Manufacturer's duly signed authorisation letter as per sample form contained in this bidding documents and Registration/Retention certification from **ZAMRA** for the pharmaceuticals

SECTION VI. TECHNICAL SPECIFICATIONS

The Technical Specifications for the Male Circumcision Kits (MC- Kits) are as follows:

LOT 1: Re-Usable MC Kits

Item Description	Measurement	Quantity
Scissors, dissecting, Curved	12cm – 15cm	2
Suture scissors	12cm – 15cm, working surface approximately 20mm	1
Needle holder	12 – 14 cm, working surface 20mm	1
Toothed Dissecting forceps	12- 13cm, working surface 15mm serrated	1
Non-Toothed Dissecting forceps	12- 13cm, working surface 15mm serrated	1
Sponge holding forceps	20 – 25cm	1
Mosquito clamp straight	Length 12 – 14 cm,	2
Mosquito clamp curve	Length 12 – 14 cm, working surface 20 – 30 mm	4
Scapel	Size 4	1
Gallipot	150 ml	1
Kidney Dish	25cm, 825 ml, stainless steel	1

LOT 2: Disposable MC Kits

Item Description	Sterile	Measurement	Quantity
Multipurpose Container tray	✓	Stable plastic recycle tray to conduct procedure, minimum 700 micron virgin plastic, with 4 compartments (compartments 1 = 13 cm x 26 cm, compartment 2 = 5 cm x 8 cm, compartment 3 = 5cm x 5 cm and compartment 4 = 5 cm x 13 cm.	1
Surgical gloves, size 8	✓	Pair	1
Surgical gloves, size 7.5	✓	Pair	1
Scalpel w/handle, retractable – disposable, retractable and lockable; blade type 23; total length 11 – 11.2 cm	✓	No. 23	1

Surgical blade (size 21)	✓	Each	1
Gauze swabs, plain	✓	100 x 100mm (12 ply)	10
Sterile syringe	✓	10ml	1
Sterile needle	✓	21G, 1.5 inch	1
Sterile needle	✓	23G, 1.5 inch	1
1st Option: Polyglycolic Acid sutures **NOTE: (Where the 1st Option cannot be found 2nd Option can be used)** - **2nd Option:** Catgut chromic suture w/needles (pack size 26mm)	✓	Suture, 3/0 braided/absorbable, 75cm on reverse cutting needle (w/needle 26mm)	2
O-drape, hole diameter 5cm	✓	Disposable 100 cm x 75cm (one side absorbable and one side impermeable. The two different sides are fused together and not lint applied)	1 piece
Gauze, Petroleum jelly impregnated	✓	Para net gauze 10cm x 10cm (1 Ply)	1
Disposable Plastic apron	✓	Trash bag quality - 80cm x 130cm	2
Isopropyl alcohol swabs	✓	1 1/4" x 2 1/2", isopropyl alcohol 70%	2
Zinc Oxide adhesive tape (Surgical tape - Self-stick tape of pressure-sensitive adhesive coated onto a backing material **cotton**)	✓	Micro pore 12 mm, 1 – 3 meter in length	1 piece
Examination gloves		Large	1 pair
Cotton wool-balls	✓		10 balls
Disposable Incontinent sheet	✓	80cm x 50cm	1
To be Packaged Separately			
Paracetamol		500mg tablet	10 tabs
Plain Lignocaine 2%		10ml vial	1 vial
Betadine 10% Solution/bottle (Povidone Iodine 10% Solution)		30ml	1 bottle

IMPORTANT NOTES

- **Each sterile line item should be sealed/packaged in its ORIGINAL Manufacturers Pack to preserve sterility before being packaged with other items in the MC Kit tray.**

- **Any bidder who will NOT provide right samples in terms of quantity and /or measurements and specifications shall be considered non-responsive.**

NOTE: NO LOT WILL BE ACCEPTED WITH MORE THAN SIX (6) BATCHES

3. Technical Specifications (Applicable)

PHARMACEUTICALS AND MEDICAL SUPPLIES

Zambia regulatory requirements

Zambia Medicine Regulatory Authority (ZAMRA) is the body that governs the approval, importation and distribution of pharmaceuticals in the Zambia. It is mandatory that all the necessary documents are completed and submitted to ZAMRA for approval prior to importation of any finished pharmaceutical product (FPP). Import registration requires the following:

i. Pharmaceutical licence – the importer should be a holder of a valid pharmaceutical licence issued by the authority
ii. Products registration – the FPP or health product should be registered in Zambia or submitted for Zambia product registration to the authority
iii. Import permit - The importer should pay a hundred kwacha (K100.00) for import permit and 1.5% invoice value of the freight on board (FOB)
iv. Product registration waiver - The requirements to register medicines in Zambia for supply may be waived on application to the Authority (ZAMRA) and the applicant should pay hundred kwacha (K 100.00) for import permit and 5% invoice value of the FOB

ZAMRA does not include specific technical requirements for each FPP, but considers only the WHO registered manufacturers whose products are further subjected to quality control investigations prior to product registration approval for importation. The CHAZ technical requirements are a tool to be used as a standard for CHAZ, for selection of suppliers or bidders for Pharmaceutical and health products of good quality, efficacy and safety with packaging specifications for easy distribution to user facilities and dispensing to patients.

FINISHED PHARMACEUTICAL PRODUCT

1 Regulatory Requirements

All Finished Pharmaceutical Products (FPPs) should have evidence of registration or marketing authorization in the country of manufacture by the national regulatory authority. Where applicable, the FPP and the manufacturing site should have been prequalified by the WHO and with a Certificate of Pharmaceutical Product (CPP) issued by the national regulatory authorities.

2 Identification

Each FPP must be identified by the International Non-proprietary Name (INN) thus:

i) The Active Pharmaceutical Ingredient (API) base or the prodrug compound, salt or ester, as applicable
ii) The pharmaceutical dosage form
iii) The amount of active ingredient in each unit dosage form; where this is given in terms of the salt, ester or prodrug, the equivalent amount of active moiety must be specified
iv) Route of administration
v) Inactive ingredients or excipients of medical and/or pharmaceutical relevance and the amount in each dosage unit. Bidders must submit the complete qualitative and quantitative composition of the FPP, including active ingredient(s) and excipients.

3 Specifications

CHAZ will accept the following pharmacopoeial monographs which whenever used, the year of publishing of the pharmacopoeia must be specified:

i) The British Pharmacopoeia (BP)
ii) European Pharmacopoeia (Ph.Eur)
iii) International Pharmacopoeia (Ph.Int) or
iv) United States Pharmacopoeia (USP)

If there is no monograph, in-house specifications and validated analytical test methods must have been submitted and certified by WHO. The results of validation studies, including comments on the choice of routine tests and standards must have been submitted as well. For

all FPPs, copies of certificates of analysis for the last three production batches are a must requirement.

4 GENERAL REQUIREMENTS FOR DOSAGE FORMS

Each FPP should comply with the general requirements for dosage forms of the relevant edition of the specified pharmacopoeia. At a minimum, all dosage forms must be:

i) Packaged in a dispensable maximum adult single dose in breakable tablet or minimum adult single dose in capsule (e.g. co-trimoxazole 960mg single tablet in blister pack of 10 tablets)
ii) Packed together with the dispensing graduated plastic 10mls bottle cup for pediatric doses
iii) Packaging that promote course adherence for instance FDCs or single tablet Artemether/Lumefantrine of 480/80mg tablet
iv) Packed in rigid paperboard boxes, strong enough to resist crushing during transportation and storage.

5 Preferred Packaging

i) A primary package which will be in direct contact with the dispensable dosage form that covers a complete minimum days of the course of therapy.
ii) All packaging must be designed so as to protect the dosage form and to render it suitable for the intended use throughout the stated shelf life.
iii) Each unit pack must come with a patient information leaflet (PIL).
iv) Packs must come with oral dispensing devices if the FPP requires this for administration
v) Materials used for packaging must conform to the relevant edition of the specified pharmacopoeia with reference to the specific Active Pharmaceutical Ingredient (API) and/or FPP
vi) Packaging must be safe for use with the dosage form for the intended route of administration and be suitable for shipment, storage and worldwide use at extreme temperatures and humidity

6 Warehouse Packaging

i) Packaging must facilitate the warehouse storage and distribution to the lowest level health facilities as well as dispensing to individual patients and their subsequent adherence. Product packaging that facilitates patient adherence is much more encouraged

ii) The size of the container should be proportional to its contents with the addition of appropriate padding to prevent damage to the product during shipment

iii) Glass containers will not be accepted unless otherwise specifically authorised. Glass bottles must be separated by criss-cross partitions or be packed individually in cartons

iv) For glass ampoules, single ended -break-off necks will be required

v) Both secondary and primary packaging should be marked with a barcode label for warehouse storage and dispensing respectively

7 Labels

i) Labels must be self-adhesive and made from paper, e.g. pharmaceutical defiberised paper (80gsm), that is film or UV coated for protection against humidity and firmly affixed to be tamper proof and to prevent detachment in tropical climates.

ii) Language - English will be the primary language. Bidders should be prepared to include other language requirements for specific orders.

iii) Type - Preferably by lithography directly on container or on packaging.

iv) Ink/colour - The writing on primary and secondary packs must be in indelible ink, in black on white background.

8 Information required on labels

(Dispensable/ carton/ pallet pack) instructions

The following label information is requested for FPPs to be supplied for and on behalf of CHAZ in accordance with WHO standards:

i) International Non-proprietary Name (INN) or generic name of the FPP should be written in a bold and clearly visible font size which must not be abbreviated anywhere, including on labels and package inserts. CHAZ prefers that ONLY the International Non-proprietary Name (INN) is written on all labels and pack inserts

and that any proprietary, brand or registered trade name is not included. If included, it must not be so prominent as to mask the appearance and readability of the INN.

ii) Amount of API or active moiety per dosage unit, unit of volume or unit of weight

iii) Names and amounts of excipients of medical and/or pharmaceutical relevance, e.g. "contains 10% ethanol".

iv) Net quantity per unit pack labeled on that unit pack (primary, secondary, tertiary) in a visible manner

v) Directions for use only to be labeled on dispensable packs, there should be instructions on how to administer the dose and daily recommended frequency with duration when required

vi) Any special instructions for use e.g. "to be swallowed whole - do not chew"

vii) Recommended temperature and further requirements during transport and storage

viii) Special storage and handling instructions, including warnings and precautions

ix) If a product has a limited shelf life after the primary package is opened and manipulated, the in use period and storage condition should be indicated on the label

x) Batch identification number

xi) Manufacture date

xii) Expiry date in the recommended format of: DD/MM/YYYY. The year of expiry must be 4 digits

xiii) Name and address of manufacturer and marketing authorization holder. For contract manufacture, indicate as: manufactured by company X for company Y.

9 Layout of information on labels

i) Information 1-6 above should appear clearly and adjacent to each other

ii) The strength of the API should at all times appear next to the name of the API, e.g. Artemether 20mg + Lumefantrine 120mg

iii) Components in Fixed dose combination FPPs (FDCs) and co-packs should be written in ascending alphabetical order with reference to the first letter of the INN e.g. Artemether 20mg + Lumefantrine 120mg

iv) Co-formulated FDC products, should be denoted with a "+" or "/"sign e.g. Artemether 20mg + Lumefantrine 120mg, while co-packaged FDCs should be

denoted with an "&" sign e.g. Amodiaquine 15mg & Artesunate 50mg Another example: Co-Amoxiclav BP also the INN names of the two APIs should be stated with their full INN names i.e. Amoxicillin 500 mg & Clavulanic Acid 125 mg

v) The design of the secondary and tertiary packaging labels must allow for the important information on the manufacturer label. Dispensing information is not necessary

This desired label format is expected at the time of supply, subject to acceptable variations according to each order. The bidder is expected to confirm that they are able to do such labeling, should their samples submitted for technical evaluation be deemed different. The summary of product characteristics (SPC) as well as a detailed patient information leaflet (PIL) as per standards and norms for each FPP must be submitted.

10 Stability

i) In order to safeguard product quality throughout its entire intended shelf-life, stability studies under the conditions defined for Zone 4 Climatic Zones should have been performed and the WHO certified data submitted

ii) Stability studies, as defined by WHO, should have been carried out on at least three primary batches. This is compulsory for FDC products and new APIs. In the case of conventional dosage forms with APIs that are known to be stable, data from at least two primary batches should be provided

iii) Where the product is to be reconstituted and/or diluted before use, such as powder or concentrate for injection or a powder for oral suspension "in use" stability data must be submitted to support the recommended in-use storage conditions and duration.

11 Shelf life and Storage

i) The assigned shelf life and recommended storage conditions should reflect the outcome of stability studies, as per WHO guidelines and be printed on labels and leaflets. Acceptable temperature excursions should be specified

ii) The bidder is responsible to inform CHAZ if special transport and packaging is required for a product, such as cold storage.

12 ACTIVE PHARMACEUTICAL INGREDIENT(S) AND EXCIPIENTS

APIs and excipients should comply with the current requirements of the specified Pharmacopoeia (BP, European, International /or USP). If not described in a pharmacopoeia, a copy of the manufacturer's specification, the certificate of analysis and a description of the test methods with limits for results must be submitted.

13 Documents to submit:

i) A confirmatory certificate of analysis from the API supplier for two API batches. The certificate should be satisfactory as defined in WHO"s Good Manufacturing Practice (GMP) guidelines
ii) List of site(s) of manufacture of API as well as any alternative manufacturers
iii) A GMP certificate of the API manufacture site(s)
iv) A copy of a valid Certificate of Suitability to the European Pharmacopoeia (CEP) and it's annexes, if available

Notification of changes - CHAZ should be notified and approve of any changes in excipients, API sources, routes of synthesis and/or specifications.

14 Manufacturing status

Good Manufacturing Practice Both APIs and FPPs must be manufactured as per GMP guidelines established by WHO.

Manufacturing site(s) must be WHO approved site(s) of manufacture and CHAZ must also approve any changes in manufacturing site(s) whether it remains in line with the WHO standards.

The manufacturing site(s) where any aspect of manufacture occurs must be stated. (This includes production, sterilization, packaging and quality control.) The bidder must submit a copy of the valid Manufacturing License for the site where the FPPs of interest are manufactured as issued by the relevant authorities in the country of manufacture, stating the dosage forms authorized for manufacture at the respective site.

Bidders may be required to submit a copy of the last inspection report by the National Regulatory Authority and/or stringent regulatory authorities/international organizations, relevant to the manufacturing site. If the report is considered confidential, CHAZ will accept a summary of the key positive and negative aspects provided that contact details of a contact

person from the inspecting authority/agency, who can corroborate the information contained therein, are provided and that the detailed report can be made available under confidential cover for review on request.

15 Contract manufacture

All details regarding contracting part or all manufacture to another party as well as relations to other companies should be clearly stated. CHAZ must approve the site(s) of contract manufacture(s) and any changes thereof.

Notification of changes - CHAZ should be notified and approve of any changes of manufacturing sites and/or changes in GMP status that is if they remain in line with WHO guidelines.

16 SAMPLE SUBMISSION

Manufacturers or bidders are required to submit only a specified number of non-returnable samples to enable visual and organoleptic examination. Such samples should be in their final status and packaging as intended to be supplied on purchase orders, including pack inserts and dose measuring devices. Commercial or market samples will normally be accepted up to one week after the solicitation closes.

In cases where samples submitted are NOT commercial samples, they MUST be labeled as NON-COMMERCIAL SAMPLE. A justification why a commercial sample cannot be submitted must be included with the submitted sample.

17 Minimum requirements

i) Vendor should pay specific attention to the actual requirements in each solicitation activity.

ii) For solid oral dosage forms with several pack sizes:

iii) Submit the lowest pack size as a complete and intact sample for each packaging type e.g. HDPE bottle, blister packs;

iv) Submit subsequent pack sizes of each packaging type within the correct primary and secondary packaging, including package insert with the full number of dosage units in this pack size OR the same number of dosage units as that of the lowest pack size.

v) For parenteral and rectal preparations, submit a minimum of 5 and maximum of 10 individual units in the correct primary and secondary package and with package insert
    a. For powders for oral use and oral liquids, submit a minimum of two (2) bottles or packs
    b. Exceptions may apply for example, for controlled medicines, CHAZ may accept FPP packaging and package insert/patient information leaflet without the medicine.

NOTE: It is VERY IMPORTANT for the vendor to ensure that packages containing samples are addressed correctly with the correct reference to make sure they are delivered in time to the right person and physical location within CHAZ pharmaceutical and logistics planning division

18 COMMITMENT

Suppliers/manufacturers must be able to fulfill commitments they make regarding products technical specifications throughout the contract period. CHAZ must be notified of any changes to specification prior to shipment. The manufacturer/supplier must make a commitment to inform CHAZ immediately about any serious quality and/or safety concerns related to the manufacture, control or use of their product, including suspension or cancellation of marketing authorizations. The manufacturer should pledge to work with CHAZ to minimize potential public health risks by actively organizing product recalls of defective products and either in replacing the defective product or covering the direct and related costs related to replacing the defective product within defined timelines as specified in the contractual requirements.

SECTION VII: SAMPLE FORMS

Notes to Bidders on the Preparation of Sample Forms

The Purchaser has prepared the forms in this section of the Bidding Documents to suit the specific requirements of the procurement. In its bid, the Bidder **MUST** use these forms (or forms that present in the same sequence substantially the same information). If the Bidder 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 bid clarification process, by addressing them to the Purchaser in writing pursuant to ITB Clause 11.

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

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

SAMPLE FORMS

1. Bid Form

Date:*[insert:* ***date of bid*** *]*

[Purchaser specify: "Tender No.: [number]"]

To: *[Purchaser insert:* ***Name and address of Purchaser*** *]*

Dear Sir or Madam:

Having examined the Bidding Documents, including Addenda Nos.*[insert* ***numbers*** *]*, 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 Bidding Documents for the sum of_____

(hereinafter called "the Total Bid 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 bid.

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

If our bid 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 Bidding Documents.

We agree to abide by this bid, for the Bid Validity Period specified in Clause 18.1 of the Bid 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 bid, together with your written acceptance of the bid 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 bid you may receive.

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

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

(if none, state "none")

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

Signed: _____

Date: _____

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

Duly authorized to sign this bid for and on behalf of *[insert:* ***name of Bidder*** *]*

2. Price Schedule for Goods Offered from Abroad

(Group C bids)

Name of Bidder _____.Tender Number ____.Page _ of ___.

1	2	3	4	5	6	7				8	9	10	11	12	13	14
Product code	Product	Strength	Dosage form	Unit pack size	Qty. offered	Unit prices				Total unit price [a+c+d] or [b+c+d]	Total price per item [6 x 8]	Local agent's commission as a % of FOB price included in quoted price	Shipment weight and volume	Name of manufac-turer	Ctry. of origin	Pharma-copoeial standard
						[a] Unit price FOB port loading	[b] CIF at port of entry or CIP named place of destination (specify one)	[c] Inland transp., insurance & other local costs incidental to delivery if specified	[d] Other incidental costs as defined in the SCC							

Note:

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

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

Total Bid Price:
Currency:
In figures:
In words:

3. Price Schedule for Domestic Goods Offered from within the Purchaser's Country

(Group A and Group B bids)

Name of Bidder _____.Tender Number ____.Page _ of ___.

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

Note:

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

(ii) For column 9, pursuant to ITB 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 labour, local raw materials, and local components provided from within the country should also be indicated separately as specified in ITB Sub-Clause 27.1 along with adequate proof to substantiate each of these local inputs.

Total Bid Price:
Currency:
In figures:
In words:

4. Bid Security Form (Bank Guarantee)

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

Tender: *[insert: **name and number of Tender**]*

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

WHEREAS *[insert: **name of Bidder**]* (hereinafter called "the Bidder") has submitted its bid dated *[insert: **date of bid**]* for the performance of the above-named Contract (hereinafter called "the Bid")

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

Signed and sealed with the Common Seal of the said Bank this *[insert: **number**]* day of *[insert: **month**],[insert: **year**]*.

THE CONDITIONS of this obligation are the following:

1. If, after the bid submission deadline, the Bidder

   (a) withdraws its bid during the period of bid validity specified by the Bidder in the Bid Form, or

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

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

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

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

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

This guarantee will remain in full force up to and including *[insert: **the date that is 30 days after the period of bid validity**]*, and any demand in respect thereof must reach the Bank not later than the above date.

For and on behalf of the Bank

Signed: _____

Date: _____

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

Common Seal of the Bank

5. Bid Security (Bid Bond)

BOND No._____

By this bond [insert name of Bidder] as Principal (hereinafter called "the Principal") and [insert name, legal title and address of surety], authorised to transact business in [insert name of the country of Purchaser], as Surety (hereinafter called "the Surety"), are held and firmly bound unto [insert name of Purchaser] as Obligee (hereinafter called "the Purchaser") in the sum of [insert amount of Bond][1] [insert amount in words], for the payment of which sum, well and truly to be made, we, the said Principal and Surety, bind ourselves, our successors and assigns, jointly and severally, firmly by these presents.

Whereas the Principal has submitted a written Bid to the Purchaser dated the___ day of _____, 20____, for the supply and delivery of [name of Contract] (hereinafter called the "Bid").

Now, therefore, the condition of this obligation is such that if the Principal:

(a) withdraws its Bid during the period of bid validity specified in the Form of Bid: or

(b) having been notified of the acceptance of its Bid by the Purchaser during the period of bid validity; (i) fails or refuses to execute the Contract Form, if required; or (ii) fails or refuses to furnish the Performance Security in accordance with the Instructions to Bidders;

then the Surety undertakes to immediately pay to the Purchaser up to the above amount upon receipt of the Purchaser's first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser shall state that the demand arises from the occurrence of any of the above events, specifying which event(s) has occurred.

The Surety hereby agrees that its obligation will remain in full force and effect up to and including the date 28 days after the date of expiration of the Bid validity as stated in the Invitation to Bid or extended by the Purchaser at any time prior to this date, notice of which extension(s) to the Surety being hereby waived.

In testimony whereof, the Principal and the Surety have caused theses presents to be executed in their respective names this _____ day of _____ 20_____.

Principal:_____ Surety:_____
Corporate Seal (where appropriate)

[1] **The amount of the Bond shall be denominated in the currency of the Purchaser's country or the equivalent amount in a freely convertible currency.**

_____ _____
(Signature) (Signature)
(Printed name and title) (Printed name and title)

6. Bid-Securing Declaration

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

Date: *[date (as day, month and year)]*
Bid No.: *[number of bidding process]*
Alternative No.: *[identification No if this is a Bid for an alternative]*

To: *[complete name of Purchaser]*

We, the undersigned, declare that:

We understand that, according to your conditions, bids must be supported by a Bid-Securing Declaration.

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

(a) have withdrawn our Bid during the period of bid validity specified in the Form of Bid; or

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

We understand this Bid Securing Declaration shall expire if we are not the successful Bidder, upon the earlier of (i) our receipt of your notification to us of the name of the successful Bidder; or (ii) twenty-eight days after the expiration of our Bid.

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

Name: *[complete name of person signing the Bid Securing Declaration]*

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

Dated on _____ day of _____, _____ *[date of signing]*
Corporate Seal (where appropriate)

[Note: In case of a Joint Venture, the Bid Securing Declaration must be in the name of all partners to the Joint Venture that submits the bid.]

7.Form of Contract Agreement

THIS CONTRACT AGREEMENT is made

the *[insert: **number**]* day of *[insert: **month**], [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 bids for certain goods and ancillary services, viz., *[insert: **brief description of goods and services**]* and has accepted a bid 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 Functional Requirements and Implementation Schedule)

   (e) The Supplier's bid 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.

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 _____

6. Performance Security Bank Guarantee

(unconditional)

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

Contract: *[insert:* ***name or number of Contract*** *]*

To: *[insert:* ***name and 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 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.

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. 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 Bidder**]* (hereinafter, the "Bidder") to submit a bid, and subsequently negotiate and sign the Contract with you against Tender *[insert: **title and Tender number**]* including the above Goods produced by us.

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

For and on behalf of the Manufacturer or Producer

Signed: _____

Date: _____

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

8. Certificate of a Pharmaceutical Product[1]

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

No. of certificate: _____

Exporting (certifying) country: _____

Importing (requesting) country: _____

1. Name and dosage form of product:

_____

1.1 Active ingredients[2] and amount(s) perunit 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 licence[7] and date of issue:

_____

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

_____

_____

_____

2A.3 Status of product-licence 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 licence?[11] yes/no/not provided *(key in as appropriate)*

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

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

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

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

_____

_____

_____

2B.3 Why is marketing authorization lacking?

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

2B.4 Remarks:[13]

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

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

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspections (years): _____

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

yes/no *(key in as appropriate)*

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

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

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

yes/no *(key in as appropriate)*

If no, explain: _____

_____

Address of certifying authority: _____

Telephone number: _____ Fax number: _____

Name of authorized person:

_____

Signature:

_____

Stamp and date:

_____

General instructions

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

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

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

Explanatory notes

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

[2] Use, whenever possible, international 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-licence 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 licence.

[6] Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the licence 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-licence holder or, in the case of non-registered products, the applicant. Non-completion 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 licence. If the production site is changed, the licence 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 licenced.

[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-licence 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-licence 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.