

**STANDARD BIDDING DOCUMENTS**

# **Procurement of Health Sector Goods**

**(Pharmaceuticals, Vaccines, and Condoms)**



**The World Bank  
Washington, D.C.**

**May 2000**

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and March 2003



## PREFACE

These Standard Bidding Documents (SBD) and its companion Technical Note (TN) have been prepared by the World Bank for use by borrowers and their implementing agencies in the procurement of pharmaceuticals, vaccines, and condoms through international competitive bidding (ICB). For the purpose of these documents, pharmaceuticals also include nutritional supplements and oral and injectable hormonal forms of contraception. The procedures and practices presented in these SBD have been developed through broad international experience and are mandatory for use in projects that are financed in whole or in part by the World Bank in accordance with the provisions of the latest edition of *Guidelines: Procurement under IBRD Loans and IDA Credits*. The purpose of the TN is to provide background information to the Bank's project staff and borrowers, about the complex issues in the procurement of health sector goods and to help them make well-informed decisions in each special situation.

As shown in the table below, these SBD contains two types of documents: those that must be used *unchanged*, and those that should be *customized* specifically for each procurement. An electronic version of these SBD is available on disk from the Bank's project staff or the Bank's Procurement Policy and Services Group Web site: <http://www.worldbank.org/html/opr/procure/contents.html>. This can be used to customize the Invitation for Bids and Sections II, V, VI, and VII to meet the requirements of the specific procurement. *Sections I, III, and IV, however, must be incorporated unchanged in the Bidding Documents.*

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

To be customized		To be used unchanged	
	Invitation for Bids	<b>Section I</b>	Instructions to Bidders
<b>Section II</b>	Bid Data Sheet	<b>Section III</b>	Eligibility for the Provision of Goods, Works, and Services in Bank-Financed Procurement
<b>Section V</b>	Special Conditions of Contract	<b>Section IV</b>	General Conditions of Contract
<b>Section VI</b>	Schedule of Requirements		
<b>Section VII</b>	Technical Specifications		
<b>Section VIII</b>	Sample Forms (including the Form of Contract Agreement)		

Additional Instructions to Bidders and the contract-specific details needed for the bidding and evaluation process to be properly carried out must be made through the Bid Data Sheet only. With the Bank's no objection, amendments to the General Conditions of Contract must be made through the Special Conditions of Contract. The Technical Requirements section of the Bidding Documents should not be used to modify any of the subjects covered by Sections I, III, or IV.

Clauses included in the Special Conditions of Contract of these SBD should be modified as appropriate to reflect the specific needs of each procurement. Because such modifications prevail over the General Conditions of Contract, major changes should be avoided unless absolutely necessary. If, in the opinion of the Purchaser, the specific nature of a procurement justifies a change, it should consult with the World Bank.

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

The following typographical conventions are used in these SBD.

- Standard SBD text is presented in a typeface such as used in this line (serif roman).
- Explanatory text and notes are presented in a typeface such as that used in this line and in the body of this Preface (sans serif).
- When parameters, options, instructions, and/or explanatory notes appear directly within the standard text, they are enclosed with square brackets, italicized, and the key parameter bolded.

For example:

“The authorized Procurement Agent is: [ *if applicable, specify: **identity of duly authorized Procurement Agent**, otherwise delete* ].”

- When options appear within the text, they are enclosed within square brackets and separated by the slash character “/”.

For example:

“The language of all correspondence and documents related to the bid is [ *select: **English / French / Spanish*** ].”

Specific details, such as the “name of the Purchaser” and “address for bid

submission,” should be furnished in the Invitation for Bids, in the Bid Data Sheet, and in the Special Conditions of Contract. The final documents should contain neither blank spaces nor options.

Accordingly, all explanatory text (i.e., all text in sans serif type face) must be removed from the final Bidding Documents. Also, all bracketed text must be either removed, if not relevant to the specific procurement, or selected for inclusion in the final Bidding Documents. Where options are presented, one must be selected and the final chosen text should be in standard roman typeface.

Footnotes that provide guidance and instruction to the Purchaser in preparing the Bidding Documents should also be removed from the final draft. However, some Sample Forms contain footnotes that provide instructions to bidders on how the form should be prepared. These should remain in the final Bidding Documents.

These SBD and TN for the procurement of health sector goods have been prepared through a close collaboration between the Procurement Policy and Services Group, Operational Core Services Network, and the Health Nutrition & Population, Human Development Network, with the support of various Bank staff. The significant contributions to these documents made by staff and consultants of the following institutions are gratefully acknowledged: WHO, UNICEF, UNFPA, MSH, and Crown Agents. Thanks are also due to a number of other stakeholders, such as representatives from the pharmaceutical industry and various NGOs for their comments on previous drafts of these documents.

The Bank welcomes any feedback or experiences from the use of these Bidding Documents from bidders and from others as well.

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# **INVITATION FOR BIDS**

## NOTES ON THE PREPARATION OF THE INVITATION FOR BIDS (IFB)

In accordance with the *Guidelines: Procurement under IBRD Loans and IDA Credits*, dated January 1995, revised January and August 1996, September 1997, and January 1999, the Invitation for Bids (IFB) / Specific Procurement Notice (SPN) shall be issued (in the language of the Bidding Documents) as:

- (a) an advertisement in at least one newspaper of general circulation in the Purchaser's country and in the official gazette, if any;
- (b) a letter addressed to interested Bidders who, following the publication of the General Procurement Notice, have expressed interest in bidding for the Health Sector Goods for which the Invitation for Bids (IFB) is issued; and
- (c) optionally, Purchasers are encouraged to advertise the bidding opportunity for smaller contracts in the United Nations publication *Development Business* and/or a circular to consular or diplomatic representatives of countries with potential bidders;
- (d) and, for contracts valued at above 10 million USD equivalent, or as otherwise stipulated in the loan/credit or trade agreement, advertisements in *Development Business* and *Scrip*.

The content of the Invitation for Bids should be consistent with the Bid Data Sheet (BDS). In particular, the dates, times, and place for bid submission and opening and the amount required for bid security in the IFB must be carefully checked to ensure consistency with the BDS. Also, the IFB could list key qualification criteria required for prospective Bidders to be responsive, as officially specified in the BDS (e.g., minimum financial capacity, the minimum number of years during which the prospective Bidder has manufactured and marketed similar goods).

Advertising inquiries about the UN Development Business publication can be directed to:

### Development Business

United Nations, Room DC1-560  
One United Nations Plaza  
New York, NY 10017 USA

Telephone: 1-212-963-1515  
Facsimile: 1-212-963-1318  
Telex: 422311 UNUI

Advertisements can also be arranged through the World Bank, where Development Business maintains a local office:

Development Business, Room MC10-436  
1818 H Street, N.W.  
Washington, D.C. 20433, USA

Telephone: 1-202-458-2397  
Facsimile: 1-202-522-3316

Advertising inquiries about the magazine *SCRIP* can be directed to:

SCRIP—World Pharmaceutical News

18-20 Hill Rise  
Richmond Surrey, TW10 6UA  
United Kingdom

Telephone: 44-208-332 8871  
Facsimile: 44-208-332 8999  
email: [rachel@scrip.demon.co.uk](mailto:rachel@scrip.demon.co.uk)

## Invitation for Bids (IFB)

[ insert: *name of country* ]

[ insert: *name of project* ]

[ insert: *brief description of the Goods* ]

[ insert: *loan / credit number* ]

[ insert: *IFB title* ]

[ insert: *IFB number* ]

1. This invitation for bids follows the general procurement notice for this project that appeared in *Development Business*, issue no. [insert number] of [insert date].<sup>1</sup>
2. The [insert name of borrower] [has received/has applied for/intends to apply for] a [loan/credit] from the [International Bank for Reconstruction and Development/International Development Association] toward the cost of [insert name of project], and it intends to apply part of the proceeds of this [loan/credit] to payments under the contract for [insert name/no. of contract].<sup>2</sup>
3. The [insert name of implementing agency] now invites sealed bids from eligible bidders for [insert brief description of goods or works to be procured].<sup>3, 4</sup>
4. Bidding will be conducted through the international competitive bidding procedures specified in the World Bank's *Guidelines: Procurement under IBRD Loans and IDA Credits*, and is open to all bidders from eligible source countries as defined in the Guidelines.<sup>5</sup>
5. Interested eligible bidders may obtain further information from [insert name of agency] and inspect the bidding documents at the address given below [state address at end of document] from [insert office hours].<sup>6</sup>
6. A complete set of bidding documents in [insert name of language] may be purchased by interested bidders on the submission of a written application to the address below [state address at the end of document] and upon payment of a nonrefundable fee<sup>7</sup> [insert amount in local currency] or in [insert amount in specified convertible currency]. The method of payment will be [insert method of payment].<sup>8</sup> The document will be sent by [insert delivery procedure].<sup>9</sup>

7. Bids must be delivered to the address below *[state address at the end of document]* at or before *[insert time and date]*. All bids must be accompanied by a bid security of *[insert amount in local currency or minimum percentage of bid price]* or an equivalent amount in a freely convertible currency.<sup>10</sup> Late bids will be rejected. Bids will be opened in the presence of the bidders' representatives who choose to attend at the address below *[state address at end of document]* at *[insert time and date]*.<sup>11</sup>

*[ insert: **name of office** ]*

*[ insert: **name of officer** ]*

*[ insert: **postal address** ] and/or*

*[ insert: **street address** ]*

*[ insert: **telephone number, indicate country and city code** ]*

*[ insert: **facsimile or cable number or e-mail address** ]*

## Footnotes to IFB

1. Day, month, year; for example, 31 January 1996.
2. *[Insert if applicable]*. This contract will be jointly financed by *[insert name of cofinancing agency]*. Bidding will be governed by the World Bank's eligibility rules and procedures.
3. A brief description of the type(s) of goods or works should be provided, including quantities, location of project, and other information necessary to enable potential bidders to decide whether or not to respond to the invitation. Bidding documents may require bidders to have specific experience or capabilities; such restrictions should also be included in this paragraph.
4. *[Insert if applicable.]* The delivery/construction period is *[insert no. of days/months/years or dates]*.
5. Occasionally, contracts may be financed out of special funds that would further restrict eligibility to a particular group of member countries. When this is the case, it should be mentioned in this paragraph. Also indicate any margin of preference that may be granted as specified in the Loan or Credit Agreement and set forth in the bidding documents.
6. For example, 0900 to 1200 hours.
7. The fee, to defray printing and mailing/shipping costs, should be nominal.
8. For example, cashier's check, direct deposit to specified account number, etc.
9. The delivery procedure is usually airmail for overseas delivery and surface mail or courier for local delivery. If urgency or security dictates, courier services may be required for overseas delivery.
10. The amount of bid security should be stated as a fixed amount or as a minimum percentage of the bid price. Alternatively, if a bid security is not required (often the case in supply contracts), the paragraph should so state.
11. The office for bid opening may not necessarily be the same as that for inspection or issuance of documents or for bid submission. If they differ, each address must appear at the end of paragraph 7 and be numbered; as, for example, (1), (2), (3). The text in the paragraph would then refer to address (1), (2), etc. Only one office and its address may be specified for submission of bids, and this location should be as close as possible to the place where bids will be opened to shorten the time between bid submission and bid opening.

## **SECTION I. INSTRUCTIONS TO BIDDERS**

## NOTES ON THE INSTRUCTIONS TO BIDDERS (ITB)

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This section of the Bidding Documents provides the information necessary for Bidders to prepare and submit responsive bids that meet the Purchaser's requirements. The ITB describe the critical steps of bid submission, opening and evaluation, and the award of contract.

***The ITB are to be used unchanged.*** Section II, which consists of the Bid Data Sheet (BDS), is designed to include provisions that supplement what is included in the ITB and provide the Contract-specific details needed for the bidding and evaluation process to be properly carried out. The Bid Data Sheet is specific to each procurement and must be filled in completely by the Purchaser.

Matters governing the performance of the Supplier, payments under the Contract, and affecting the risks, rights, and obligations of the parties under the Contract during actual performance are not included in the ITB, but rather in the General Conditions of Contract (Section IV) and/or the Special Conditions of Contract (Section V). Different sections of the Bidding Documents should not overlap or duplicate the coverage of a particular topic, to avoid creating ambiguity and/or contradictions.

The ITB and BDS do not form part of the final Contract.



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## Instructions to Bidders

### A. INTRODUCTION

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- |                           |  |
|---------------------------|--|
| <b>1. Scope of Bid</b>    | <p>1.1 The Purchaser, as specified in the <b>Bid Data Sheet</b> and in the Special Conditions of Contract (SCC), invites bids for the supply of Goods (pharmaceuticals, vaccines, contraceptives, or nutritional supplements as specified in the <b>Bid Data Sheet</b>) described in the Schedule of Requirements. The name and identification number of the Contract is provided in the <b>Bid Data Sheet</b> and in the SCC.</p> <p>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.</p>  |
| <b>2. Source of Funds</b> | <p>2.1 The Borrower named in the <b>Bid Data Sheet</b> has applied for or received a loan or credit (as identified with the loan/credit number in the <b>Bid Data Sheet</b> and called a “loan” in these Bidding Documents) from the International Bank for Reconstruction and Development or from the International Development Association (interchangeably called “the Bank” in these Bidding Documents) equivalent to the amount in U.S. dollars indicated in the <b>Bid Data Sheet</b> toward the cost of the Project named in the <b>Bid Data Sheet</b>. The Borrower intends to apply a part of the proceeds of this loan to eligible payments under the Contract for which these bidding documents are issued.</p> <p>2.2 Payment by the Bank will be made only at the request of the Borrower and upon approval by the Bank in accordance with the terms and conditions of the Loan Agreement, and will be subject in all respects to the terms and conditions of that Agreement. The Loan Agreement prohibits a withdrawal from the loan account for the purpose of any payment to persons or entities, or for any import of Goods, if such payment or import, to the knowledge of the Bank, is prohibited by a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. No party other than the Borrower shall derive any rights from the Loan Agreement or have any claim to the loan proceeds.</p> |
| <b>3. Fraud and</b>       | <p>3.1 It is the Bank’s policy to require that Borrowers (including</p>  |

**Corruption**

beneficiaries of Bank loans), as well as Bidders/Suppliers/Contractors under Bank-financed contracts, observe the highest standard of ethics during the procurement and execution of such Contracts. In pursuance of this policy, the Bank:

- (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 any thing 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 Borrower; it includes collusive practices among bidders (prior to or after bid submission) designed to establish bid prices at artificial, noncompetitive levels and to deprive the Borrower of the benefits of free and open competition.
  - (b) will not accept a Borrower’s proposal 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 declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Bank-financed Contract if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Bank-financed contract.
- 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.
- 3.3 In pursuance of the policy defined in ITB Sub-Clause 3.1, the Bank will cancel the portion of the loan allocated to a Contract for Goods or works if it at any time determines that corrupt or fraudulent practices were engaged in by the representatives of the Borrower or of a beneficiary of the loan during the procurement or the execution of that Contract, without the Borrower having taken timely and

appropriate action satisfactory to the Bank to remedy the situation.

#### 4. Eligibility

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

- (a) those prequalified firms from eligible source countries, as defined in the edition specified by the **Bid Data Sheet** of the *Guidelines: Procurement under IBRD Loans and IDA Credits* herein referred to as the *Procurement Guidelines*, where a prequalification process has been undertaken for the Contract(s) for which these Bidding Documents have been issued, or
- (b) all firms from eligible source countries, as defined in the edition specified by the Bid Data Sheet of the *Procurement Guidelines*, where a prequalification process has not been undertaken for the contract(s) for which these Bidding Documents have been issued.

The Bank maintains a list of countries from which Bidders, Goods, and Services are not eligible to participate in procurement financed by the Bank. The list is regularly updated and can be obtained from the Public Information Center (PIC) of the World Bank. Joint ventures including members from ineligible source countries or including ineligible firms shall not be permitted to bid.

4.2 Firms of a member country may be excluded from bidding if:

- (a) either: (i) as a matter of law or official regulation, the Borrower's country prohibits commercial relations with that country, provided that the Bank is satisfied that such exclusion does not preclude effective competition for the supply of the Goods required; or (ii) by an act of compliance with a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations, the Borrower's country prohibits any import of Goods from that country or any payments to persons or entities in that country.
- (b) a firm has been engaged by (i) the Borrower or (ii) the Purchaser or (iii) a Purchasing Agent that has been duly authorized to act on behalf of the Borrower or Purchaser to provide consulting services for the preparation of the design, specifications, and other

documents to be used for the procurement of the Goods described in these Bidding Documents.

- (c) government-owned enterprises in the Borrower's country may participate only if they can establish that they (i) are legally and financially autonomous and (ii) operate under commercial law. No dependent agency of the Borrower or Sub-Borrower under a Bank-financed project shall be permitted to bid or submit a proposal for the procurement of Goods under the project.

4.3 A firm declared ineligible by the Bank in accordance with ITB Sub-Clause 3.1 (c) shall be ineligible to bid for a Bank-financed contract during the period of time determined by the Bank.

4.4 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.

4.5 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 Funds from Bank loans are disbursed only on account of expenditures for the Goods and Services, provided by nationals of, and produced in or supplied from, eligible source countries as defined in the edition of the *Procurement Guidelines* specified in the **Bid Data Sheet**. The Bank maintains a list of countries from which Bidders, Goods, and Services are not eligible to participate in procurement financed by the Bank. The list is regularly updated and can be obtained from the Public Information Center of the World Bank. Goods are produced in a Bank member country when they are mined, grown, or manufactured in the territory of that country. Goods produced or Services supplied from a Bank member country may be excluded if that member country is subject to the conditions specified in ITB Sub-Clause 4.2 (a) (i) or (ii).

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

- 5.2 For purposes of this clause, the nationality of the bidder is distinct from the country from where the Goods and Services are supplied.
- 5.3 For purposes of this clause, (a) the term “Goods” includes any Goods that are the subject of this Invitation for Bids and (b) the term “Services” includes related services such as transportation, insurance, commissioning, and training.
- 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 catalog 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 prequalification process has been undertaken for the Contract, the Bidder shall, as part of its bid, update any information submitted with its application for prequalification.
  - (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) in the case of a Bidder who is not doing business within the Purchaser's country (or for other reasons will not itself carry out service/maintenance obligations), the Bidder is or will be (if awarded the Contract) represented by a local service/maintenance provider in the Purchaser's country equipped and able to carry out the Bidder's warranty obligations prescribed in the Conditions of Contract and/or Technical Specifications; and
- (d) 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**

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**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 IV. General Conditions of Contract (GCC)
  - Section V. Special Conditions of Contract (SCC)
  - Section VI. Schedule of Requirements
  - Section VII. Technical Specifications
  - Section VIII. Sample Forms (including Contract Agreement)
- 10.2 The "Invitation for 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 fourteen (14) 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**

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**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 Form of Bid and Price Schedule, in accordance with the forms indicated in Section VIII;
- (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 prequalification, 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 prequalification 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 prequalification, or if there has been no change at all in said information, a statement to this effect;
- (h) any other documentation as requested in the **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) labor, 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 nonresponsive 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 may express the bid price of the Health Sector Goods to be supplied from outside the Purchaser's Country entirely in the currency or currencies of Bank member countries. If the Bidder wishes to be paid in a combination of different currencies, it must quote its price accordingly, but no more than three foreign currencies may be used.
  - (b) Unless otherwise specified in the **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 of the borrower.

**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 nonresponsive.
- 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.
- 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 cashier's or certified check;
  - (b) a letter of credit issued by a reputable bank located in any eligible country;
  - (c) a (bank) guarantee issued by a reputable bank selected by the Bidder located in any eligible country. The format of the (bank) guarantee shall be in accordance with the form of bid security included in Section VIII

or any other form acceptable to the Purchaser.

- 19.4 Any bid not accompanied by an acceptable bid security shall be rejected by the Purchaser as nonresponsive. 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 Contract 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 contract, or
    - (ii) furnish the required performance security.

## **20. Alternative Bids 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 interlineation, erasures, or overwriting to correct errors made by the Bidder should be initialed 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.

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**D. SUBMISSION OF BIDS**

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**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 Purchaser at 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 (IFB) 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 Purchaser at the address named in the **Bid Data Sheet**,
- (b) bear the specific identification of the bidding process (Contract name), the IFB title and IFB 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

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### 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 prequalification 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 prequalified 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, conditionalities, or reservations. A material deviation, exception, objection, conditionality, or reservation is one: (i) that limits in any substantial way the scope, quality, or performance of the Goods and related Services; (ii) that limits, in any substantial way that is inconsistent with the 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.

### **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) a currency widely used in international trade, such as 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.

31.3 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.
- 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) subject to ITB Sub-Clause 16.2 (a) (iii) or 16.2 (b) (iv) the 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 nonresponsive. 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 and of the Bank 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 nonexempt 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 nonexempt importer would have to pay and taxes exceed fifteen (15) percent of the CIF (or CIP border point or CIP place of destination) price of such Goods.

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

If the Group A 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**

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**34. Postqualification** 34.1 In the absence of prequalification, 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 postqualification criteria stated in the **Bid Data Sheet**. If a prequalification 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 prequalification 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 postqualification 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.

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| <b>36. Purchaser's<br/>Right to Accept<br/>Any Bid and to<br/>Reject Any or All<br/>Bids</b> | 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.  |
| <b>37. Purchaser's<br/>Right to Vary<br/>Quantities at<br/>Time of Award</b>                 | 37.1 The Purchaser reserves the right at the time of Contract award to increase or decrease, by the percentage indicated in the <b>Bid Data Sheet</b> , 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.   |
| <b>38. Notification of<br/>Award</b>   | 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.<br><br>38.2 The notification of award will constitute the formation of the Contract.<br><br>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.<br><br>38.4 If, after notification of award, a Bidder wishes to ascertain the grounds on which its bid was not selected, it should address its request to the Purchaser. The Purchaser will promptly respond in writing to the unsuccessful Bidder. |
| <b>39. Signing of<br/>Contract</b>   | 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.<br><br>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.   |
| <b>40. Performance<br/>Security</b>  | 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.
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## **SECTION II. BID DATA SHEET**

## **NOTES ON THE BID DATA SHEET**

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Section II is intended to assist the Purchaser in providing the specific information in relation to corresponding clauses in the Instructions to Bidders included in Section I and has to be prepared for each specific procurement.

The Purchaser should specify in the Bid Data Sheet information and requirements specific to the circumstances of the Purchaser, the processing of the procurement, the applicable rules regarding bid price and currency, and the bid evaluation criteria that will apply to the bids. In preparing Section II, the following aspects should be checked:

- (a) The correct version of the Bid Data Sheet must be used as a base, dependent upon the type of Goods being procured. For example, if changes or additions are made to the Bid Data Sheet it may require changes to the corresponding SCC.
- (b) Information that specifies and complements provisions of Section I, ITB, must be incorporated.
- (c) Amendments and/or supplements, if any, to provisions of Section I, ITB, as required by the circumstances of the specific procurement, must also be incorporated.



## 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	<p>Name of Purchaser: <i>[ insert: <b>name of Purchaser</b> ]</i>.</p> <p>Name of authorized Purchasing Agent: <i>[ if appropriate, insert: <b>name of the Purchasing Agent</b>, otherwise state: <b>"none"</b> ]</i>.</p> <p>Type of goods: <i>[ insert pharmaceuticals (including nutritional supplements and oral or injectable hormonal contraceptive), vaccines or condoms ]</i>.</p> <p>Name and identification number of the Contract: <i>[ insert: <b>name and identification number of the Contract</b> ]</i>.</p>
ITB 2.1	<p>Name of the Borrower: <i>[ insert: <b>name of Borrower</b> ]</i>.</p> <p>Loan or credit number: <i>[ insert: <b>loan / credit number</b> ]</i>.</p> <p>Loan or credit amount: <i>[ insert: <b>loan / credit amount as stated in the Loan Agreement governing the project</b> ]</i>.</p> <p>Name of Project: <i>[ insert: <b>name of project</b> ]</i>.</p>
ITB 4.1 & 5.1	<p>Applicable edition of the <i>Guidelines: Procurement under IBRD Loans and IDA Credits</i>: <i>[ insert either: <b>the date of latest edition</b>, for example "January 1995, Revised January and August 1996, September 1997, and January 1999" or insert: <b>the date of the edition specified in the Loan Agreement governing the project</b> ]</i>.</p>
ITB 6.3 (c)	<p>Documentation requirements for eligibility of Goods. In addition to the documents stated in Clause 6.2 and 6.3 (a) and (b), the following documents should be included with the Bid:</p> <p><i>[ Insert: <b>any other eligibility documentation required</b> ]</i></p>
ITB 6.4	<p><i>[Note: If the Purchaser's country does not require registration of</i></p>

	<p><i>the Goods, delete 6.4 (b) and 6.4.1 below and insert the following language:</i></p> <p><i>ITB Sub-Clause 6.4 is inapplicable. The Applicable Law does not require registration of the Goods to be supplied under the Contract.]</i></p> <p><b>Note:</b> The Purchaser shall not annul award of a Contract on the basis of a Bidder's failure to successfully register the Goods, without first seeking and obtaining the World Bank's no objection. There shall be no forfeiture of a bid or a performance security based on the failure to obtain registration.</p>
ITB 6.4 (b)	<p>By the time of Contract signing, the successful Bidder shall have complied with the following documentary requirements in order to register the Goods to be supplied under the Contract: <i>[ insert: specific documentary requirements or any other country specific requirement ]</i>.</p> <p>Note: Because of the potential for delay when various government agencies must intervene in the registration process, bidders are alerted to inquire about registration requirements and procedures as early as possible.</p>
ITB 6.4.1	<p>For the purpose of obtaining additional information about the requirements for registration, Bidders may contact <i>[ insert: name of agency, contact person, phone/fax/email address ]</i>.</p>
ITB 7.1 (a)	<p>Qualification requirements for Bidders are:</p> <p><i>[ insert, as appropriate: quantifiable qualification criteria for experience and / or financial viability ].</i></p> <p>The following documents must be included with the bid:</p> <p><i>Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:</i></p> <p>(i) <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:</i></p> <p>(a) <i>is incorporated in the country of manufacture of the Goods;</i></p>

- (b) *has been licensed by the regulatory authority in the country of manufacture to supply the Goods;*
- (c) *has manufactured and marketed the specific goods covered by this Bidding Document, for at least two (2) years, and for similar Goods for at least five (5) years;*
- (d) *has received a satisfactory GMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the goods or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the quality standards during the past two years prior to bid submission;*
- (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) *a statement of installed manufacturing capacity;*
- (b) *copies of its audited financial statements for the past three fiscal years;*
- (c) *details of on-site quality control laboratory facilities and services and range of tests conducted;*
- (d) *list of major supply contracts conducted within the last five years.*

**Note:** In addition, guidance on what qualification requirements are reasonable is given in the Bank's TN on the Procurement of Health Sector Goods. If bids for individual lots are permitted, the qualification criteria for each lot should be given separately. In the case where a prequalification process has been undertaken, the qualification criteria stated here should mirror the criteria established in the prequalification.

## B. THE BIDDING DOCUMENTS

ITB 11.1	Purchaser's / duly authorized Purchasing Agent's address: <i>[ insert: Purchaser's address, telephone, telex, and facsimile numbers; also specify a responsible contact person or officer to whom Bidder communications should be addressed ]</i> .
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## C. PREPARATION OF BIDS

ITB 13.1	The language of all correspondence and documents related to the bid is: <i>[ select: <b>English</b> / <b>French</b> / <b>Spanish</b> ]</i> . Moreover, the key passages of all accompanying printed literature in any other language must be translated into the above language.
ITB 14.1 (i)	<p>In addition to the documents stated in Paragraphs 14.1 (a) through (h), the following documents must be included with the Bid <i>[ insert: <b>list of documents</b> ]</i>:</p> <p><i>[Sample clause]</i></p> <p>Bidders who are not primary manufacturers should provide evidence that their product conforms to the quality standards of the primary manufacturer and they have the capacity to supply the specified quantities. A "primary manufacturer" is defined as a company that performs all the manufacturing and formulating operations needed to produce pharmaceuticals or nutritional supplements in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling, and quality testing. The Bidder shall furnish a certificate from the competent Regulatory Authority (RA) that the manufacturer is licensed to manufacture the Goods offered.</p>
ITB 16.2 (a) (iii), (iv) (optional)	Prices for inland transportation, insurance, and other local costs incidental to delivery of the Goods offered from within the Purchaser's country shall be quoted as:

	<p>Price of other incidental services shall be quoted as:</p> <p><i>[ specify EXW and whether prices for inland transportation and price of incidental services, must be quoted in addition to EXW ].</i></p> <p><b>Note:</b> If the price for inland transportation is not to be quoted separately, then estimated dimensions and shipping weight of each package should be requested in accordance with 32.5 (a). The related provisions shall be reflected accordingly in SCC and Price Schedules.</p>
ITB 16.2 (b) (i) (ii), (iii) (optional) (iv), (v) (optional)	<p>Prices for Goods offered from abroad shall be quoted as:</p> <p><i>[ select, in accordance with the Schedule of Requirements, "CIP named place of destination or CIP border point or CIF named port of destination" ].</i></p> <p><i>[ specify whether FOB or FCA prices (or other terms, CFR or CPT) are required pursuant to ITB Sub-Paragraph 16.2 (b) (ii) or (iii) ].</i></p> <p><i>[ specify whether prices for inland transportation and prices of incidental services, pursuant to ITB Sub-Paragraph 16.2 (b) (iv) and (v), must be quoted in addition to the above CIF or CIP prices ].</i></p> <p><b>Note:</b> If the price for inland transportation is not to be quoted separately, then estimated dimensions and shipping weight of each package should be requested in accordance with 32.5 (a). The related provisions shall be reflected accordingly in SCC and Price Schedules.</p>
ITB 16.5	<p>Prices quoted by the Bidder shall be <i>[ state: "<b>fixed</b>"; or, if a price adjustment mechanism is required, then specify the exact formula that will apply, including the nature of the indices that will be used ]</i>.</p>

ITB 16.6	Bids are being invited for [ indicate “one or more items,” or “individual contracts ( <i>lots</i> )” ]
ITB 17.1 (b)	<p>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: [ select: <b>currency of Purchaser’s country</b> / <b>other currency, as specified by the Purchaser</b> ].</p> <p><b>Note:</b> Bid prices are usually lower if Bidders are allowed to quote and be paid in either the currency of expenditure or another internationally traded currency of their choice.</p> <p>Normally the currency of bid and payment for locally supplied Health Sector Goods and Services is the currency of the Purchaser’s country. However, Borrowers may allow domestic Bidders to bid in a stable foreign currency for their local costs. Alternatively, they may allow those prices to be adjusted. If payments must be made in the local currency to conform to local law or regulation, any such payments due to a domestic Supplier are converted from the currency of bid to local currency at the exchange rate prevailing at the time of payment.</p> <p>The presence of such restriction on the currency of payment for locally supplied Health Sector Goods and Services, as well as the precise method of selecting the exchange rate to use in such a case (i.e., the date/time and source of the exchange rate), must be specified in the SCC regarding payment, along with the presence of such restrictions on the currency of payment for locally supplied Health Sector Goods and Services.</p>
ITB 18.1	<p>The bid validity period shall be [ insert: <b>number (X)</b> ] days after the deadline for bid submission, as specified below in reference to ITB Clause 23. Accordingly, each bid shall be valid through [ insert: <b>the actual date of the expiration of the bid validity period</b> (i.e., <i>X days after the date of bid opening</i>) ].</p> <p><b>Note:</b> The bid validity period should be sufficient to permit</p>

	<p>completion of the evaluation, review of the recommended award by the management of the implementing agency and the Bank, the receipt of all necessary approvals, including the Bank's no objection, and issuance of the notification of award. In most cases ninety (90) days should be adequate, but whatever period is selected, it should be realistic so that requests for extensions are kept to the minimum.</p> <p>Bid security must be valid twenty-eight (28) days after the end of the bid validity period. Accordingly, a bid with a bid security that expires before <i>[ insert: the actual <b>date of the expiration of the bid security</b>, i.e., twenty-eight (28) days after the end of the bid validity period ]</i> shall be rejected as nonresponsive.</p> <p><b>Note:</b> Bank experience also shows that many bids are rejected on the basis of simple errors in calculating the bid security validity period. Accordingly, the Purchaser should explicitly state above the date through which bid security must be valid.</p>
ITB 19.1	<p>The amount of bid security required is: <i>[ insert: <b>fixed amount and currency</b> ]</i>.</p> <p><b>Note:</b> The amount may be expressed as either a fixed amount or an amount "not less than" a specified percentage of the Bidder's bid price. To avoid premature disclosure of bid prices by commercial bank personnel or others, a fixed amount of not less than 2 percent to no more than 3 percent of the budget estimate for the contract (estimated) bid amount is strongly recommended. (Requiring higher bid security risks driving away potentially qualified Bidders.) Asking for smaller, or even no bid security at all, however, is acceptable for simple contracts where the market is relatively stable and mature.</p> <p>Also, in the case of Bidding Documents covering multiple lots, a bid security should be specified as representing not less than "x" percent of the total Bid Price for all lots covered by the bid.</p>
ITB 20.1	<p>Alternative bids <i>[ indicate: will or will not ]</i> be accepted.</p> <p><b>Note:</b> When Bidders are permitted to submit alternative bids,</p>

	<p>only the alternative submitted by the Bidder whose basic bid is the lowest evaluated bid will be considered. Such alternatives will be evaluated in accordance with the evaluation criteria and methods specified in this BDS. An alternative bid can be selected for award only if it was submitted by the Bidder whose basic bid is the lowest evaluated bid. The alternative bid must be fully responsive to the requirements specified in the Bid Data Sheet, the SCC, and the Specifications of the Bidding Documents and the lowest evaluated bid when compared with the basic bid submitted by the bidder.</p> <p>The evaluation criteria are [ <i>insert: criteria</i> ].</p> <p>Requirements for responsive bids are [ <i>insert: requirements</i> ].</p>
ITB 21.1	Required number of copies of the bid: [ <i>insert: number (X) of copies</i> ].

## D. SUBMISSION OF BIDS

ITB 22.2 (b)	<p>The address for bid submission is: [ <i>insert: address adequate for mail, courier, or physical delivery, including responsible officer or person</i> ].</p> <p><b>Note:</b> Do not use a postal box or similar address.</p>
ITB 22.2 (c) & (d)	<p>See the above data for ITB 1.1 for the name of the Contract.</p> <p>The Invitation for Bids title and number are: [ <i>if applicable, insert: Invitation for Bids Title and Invitation for Bids Number (if any); otherwise, state "none"</i> ].</p> <p>See the below data for ITB 23.1 for the deadline for bid submission.</p> <p><b>Note:</b> The Purchaser should establish a clear and recognizable numbering system for its Contracts. Failure to do so typically results in misunderstandings in routine communications, review delays, and inadequate monitoring of overall project progress.</p>
ITB 23.1	See the above data for ITB Sub-Clause 22.2 (b) for the address and



	<p>deadline for bid submission.</p> <p>Deadline for bid submission is: [ <i>insert: date and time</i> ].</p> <p><b>Note:</b> The bid submission date is generally six to twelve weeks from the date of issuance of the Bidding Documents, depending on the value, scope, and/or complexity of the Health Sector Goods being purchased.</p>
ITB 24.1	See the above data for ITB Sub-Clause 23.1 for the deadline for bid submission.
ITB 25.2 (a)	The required number of copies of bid modifications is the same as the number of copies of the original bid specified above in the data for ITB Sub-Clause 21.1.
ITB 25.3 (a)	See the above data for ITB Paragraph 22.2 (b) for the address to use for submission of a bid withdrawal notice.

## E. BID OPENING AND EVALUATION

ITB 26.1	<p>Time, date, and place for bid opening are: [ <i>insert: time, date, and place</i> ].</p> <p><b>Note:</b> The date for the bid opening should be the same as specified for the bid submission deadline, and the time should be shortly thereafter, to minimize possible complaints regarding insecure storage arrangements. If the address for bid submission and the place of bid opening are not the same, adequate time between bid submission deadline and bid opening times should be allowed, to accommodate physically moving the bids from one site to the other. However, this delay must be kept to a minimum and reflect only the requirements of logistics, say, no more than two hours.</p>

ITB 31.3	<p>The currency chosen for the purpose of converting to a common currency is: <i>[ specify either: <b>the local currency, or a convertible currency commonly used for procurement of Health Sector Goods, for example, U.S. dollars ]</b>.</i></p> <p>The source of exchange rate is: <i>[insert: <b>publication, name of bank, etc. ]</b>.</i></p> <p><b>Note:</b> If the common currency is other than the local currency, for example, U.S. dollars, indicate the name of an internationally circulated newspaper that lists daily currency selling exchange rates, which will be used for converting prices in foreign currencies. For prices in local currency and if the common currency selected above is the local currency, specify either the Central Bank or a commercial bank in the Purchaser's country, and identify the publication where the specified rates are published.</p> <p>The date of exchange rate determination is: <i>[ select: <b>a date that shall not be earlier than four (4) weeks prior to the original deadline for the receipt of bids as specified for ITB Sub-Clause 23.1, and no later than the expiration of the original bid validity period ]</b>.</i></p>
ITB 32.4 (d)	<p><i>The evaluation will take into account [ insert: <b>factors and other specific criteria ]</b>.</i></p>
ITB 32.5	<p>The factors retained pursuant to ITB Sub-Clause 32.4 and the quantification methods are: <i>[ insert: <b>factors ]</b>.</i></p>
ITB 32.5 (a)	<p>Inland transportation from EXW/port of entry/border point to <i>[insert: <b>name of project site(s) ]</b></i>, insurance and incidentals.</p> <p>Bidder shall furnish:</p> <p><i>[ state: <b>estimated dimensions and shipping weight of each package and approximate EXW/CIF/CIP value of each package ]</b>.</i></p> <p><b>Note:</b> This information is not required when the Bidders are invited to submit a bid in accordance with ITB Sub-Paragraph 16.2 (a) (iii) or ITB Sub-Paragraph 16.2 (b) (iv).</p>
ITB 32.5 (b) (i) (ii)	<p>Delivery schedule <i>[ specify: <b>relevant parameters in accordance</b></i></p>

& (iii)	<p><i>with option selected ].</i></p> <p>The adjustment per week for delivery delays beyond the time specified in the Schedule of Requirements is [ <i>specify: adjustment in percentage</i> ].</p> <p>Or</p> <p>The adjustment per week for delivery delays beyond the range of weeks specified in the Schedule of Requirements is [ <i>specify: adjustment in percentage</i> ].</p> <p>Or</p> <p>The adjustment for partial shipments is [ <i>specify: adjustments for early and late deliveries</i> ].</p> <p><b>Note:</b> For evaluation purposes, a rate of one-half (0.5) percent per week is a reasonable figure.</p>
ITB 32.5 (c) (ii)	<p>The Purchaser [ <i>select: will / will not</i> ] accept deviations in the payment schedule in the SCC.</p> <p><b>Note:</b> If deviations are accepted, add the following text.</p> <p>The percentage adjustment for payment schedule deviations is: [ <i>insert: percentage</i> ] % per week.</p> <p><b>Note:</b> If inflation expectations widely diverge between local and foreign currencies, and Bidders are expected to quote significant amounts in local currencies, different adjustment rates for local and foreign currency prices should be provided.</p>
ITB 32.5 (d)	<p>[ <i>insert: other factors to be used in the evaluation and their evaluation method or reference to the Technical Specifications</i> ]</p> <p><i>Evaluation criteria for items/lots</i></p> <p>[<i>Select one of the two sample clauses below</i>]</p> <p><i>If bids have been invited for <u>items only</u>, the BDS should state the following:</i></p> <p><i>Bidders may bid for any one or more items. Bids will be evaluated for each item and the Contract will comprise the item(s) awarded to the successful Bidder.</i></p>

	<p><i>If <u>lots</u> will be accepted, the BDS should state the following:</i></p> <p><i>Bidders can bid for one or more lots. Bids will be evaluated lot by lot. Bidders must quote for the entire quantity of each item and at least eighty percent (80%) of the number of items in the lot to be treated as substantially responsive.</i></p> <p><i>Bid evaluation of such bids will be carried out as per the following procedures. The average price of an item quoted by substantially responsive bidders will be added to the bid price of those who did not quote for that item and the equivalent total cost of the bid so determined will be used for bid comparison, evaluation, and award.</i></p>
ITB 33.1	A margin of domestic preference [specify: <b>will or will not</b> ] apply.

## F. POSTQUALIFICATION AND AWARD OF CONTRACT

ITB 34.1	<p>Postqualification</p> <p><i>[ insert: Any specific <b>postqualification requirements</b>, such as the required number of years of manufacturing experience. ]</i></p>
ITB 37.1	<p>Percentage for increase or decrease of quantity of Goods and Services originally specified: <i>[ insert: <b>percentage</b> not more than 20% ].</i></p>

## Bid Data Sheet

# PHARMACEUTICALS

(Additional Clauses)

[Note: The below data should be included in the Bid Data Sheet used in Bidding Documents for the procurement of pharmaceuticals.]

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



## Bid Data Sheet

### VACCINES

(Additional Clauses)

[Note: The below data should be included in the Bid Data Sheet used in Bidding Documents for the procurement of vaccines.]

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 6.3 (c)	<p><i>[ Sample clauses ]</i></p> <ol style="list-style-type: none"> <li>1. <i>The Goods to be supplied under the Contract must be licensed both in the country of manufacture and in the Purchaser's country by the time of Contract signing by a recognized NCA. An NCA is an organization that performs all six critical functions for control of biological products as defined by the World Health Organization, namely: licensing based on published set of requirements; surveillance of vaccine field performance; system of lot release for vaccines; use of laboratory when needed; regular inspections for good manufacturing practice and evaluation of clinical performance. The license from country of manufacture must state that the Bidder is licensed to manufacture the Goods by the NCA in the manufacturing country. Documentary evidence in the form of a certified copy of the license and a copy of the vaccine license/registration that the offered vaccine has been licensed by the NCAs of the manufacturer's country shall accompany the bid and a copy of the license issued by an NCA in the Purchaser's country must be submitted by Contract signing. If there is no NCA with specific biologics expertise in the Purchaser's country, the Bidder shall furnish evidence that the Goods meet the qualification criteria in the Technical Specifications.</i></li> <li>2. <i>If the Goods offered do not meet the specified pharmacopoeial standards as stated in the Technical Specification, the Bidder will provide testing protocols and alternative reference standards.</i></li> </ol>
ITB 7.1 (a) & (d)	<i>Documentary evidence of the Bidder's qualifications to perform the</i>

*Contract if its bid is accepted:*

- (e) *is certified by a competent authority in the country of manufacture according to resolution WHA 28 65 (2) of the World Health Organization's Certificate Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.*

The Bidder will submit the following additional information:

- (f) *list of vaccines being manufactured by the Bidder with product registration/license number and date.*



**SECTION III. ELIGIBILITY FOR THE PROVISION  
OF GOODS, WORKS, AND SERVICES IN BANK-  
FINANCED PROCUREMENT**

## **NOTES ON THE ELIGIBILITY SECTION**

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Purchasers and suppliers may obtain the latest Eligibility sheet from either the Bank's project staff or from the World Bank's Web site: <http://www.worldbank.org/html/pic/PROCURE.html>. Replace the following page with the most current text. The Eligibility section must remain unaltered.

**Public Information Center<sup>1</sup>**

As of February 2001

For the information of borrowers and bidders, and with reference to paragraph 1.6, footnote 9, of the *Guidelines: Procurement under IBRD Loans and IDA Credits*, dated January 1995, set forth below is a list of countries from which bidders, goods, and services are not eligible to participate in procurement financed by the bank or IDA.<sup>2</sup>

- Andorra
- Cuba
- Democratic People's Republic of Korea (North Korea)
- Liechtenstein
- Monaco
- Nauru
- Tuvalu

In addition, bidders, goods, and services from other countries or territories may be declared ineligible by a provision in bidding documents if the borrower's country has excluded them by a law, official regulation, or act of compliance meeting the requirements of paragraph 1.8 (a) of the *Guidelines: Procurement under IBRD Loans and IDA Credits*.

The Loan/Credit Agreement also prohibits a withdrawal from the Loan/Credit Account for the purpose of any payment to persons or entities, or for any import of goods, if such payment or import, to the knowledge of the Bank, is prohibited by a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. At the present time, this prohibition applies to:

- Iraq

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<sup>1</sup> The most current listing of eligible countries can be viewed on the Public Information Center's Web page at: <http://www.worldbank.org/html/pic/PROCURE.html>. A list of firms debarred from participating in World Bank projects is available at: <http://www.worldbank.org/html/opr/procure/debarr.html>.

<sup>2</sup> Any questions regarding this list should be addressed to the Manager, Procurement Policy and Services Group, Operations Policy and Country Services VPU.



## **SECTION IV. GENERAL CONDITIONS OF CONTRACT**

## **NOTES ON THE GENERAL CONDITIONS OF CONTRACT**

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The General Conditions of Contract (GCC) in Section IV, read in conjunction with the Special Conditions of Contract (SCC) in Section V and other documents listed in the Contract Agreement, should be a complete document expressing all the rights and obligations of the parties.

GCC must remain unaltered. Contract-specific information, deletions, extensions, and modifications to the GCC shall be introduced only through the SCC.

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## General Conditions of Contract

### 1. Definitions

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

- (a) “The Contract” means the agreement entered into between the Purchaser and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
- (b) “The Contract Price” means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.
- (c) “Day” means calendar day.
- (d) “Effective Date” means the date on which this Contract becomes effective pursuant to GCC Clause 6.2.
- (e) “Eligible Country” means the countries and territories eligible for participation in procurements financed by the World Bank as defined in the *Guidelines: Procurement under IBRD Loans and IDA Credits*.
- (f) “End User” means the organization(s) where the goods will be used, as **named in the SCC**.
- (g) “GCC” means the General Conditions of Contract contained in this section.
- (h) “The Goods” means all of the pharmaceuticals including nutritional supplement and oral and injectable forms of contraception, vaccines, and condoms that the Supplier is required to supply to the Purchaser under the Contract.
- (i) “The Purchaser” means the organization purchasing the Goods, as **named in the SCC**.
- (j) “The Purchaser’s country” is the country **named in the SCC**.
- (k) “Registration Certificate” means the certificate of registration or other documents in lieu thereof establishing that the Goods supplied under the Contract are registered for use in the Purchaser’s country in



accordance with the Applicable Law.

- (l) “SCC” means the Special Conditions of Contract.
- (m) “The Services” means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.
- (n) “The Site,” where applicable, means the place or places **named in the SCC**.
- (o) “The Supplier” means the individual or firm supplying the Goods and Services under this Contract, as **named in the SCC**.
- (p) “The World Bank” means the International Bank for Reconstruction and Development (IBRD) or the International Development Association (IDA).

## 2. Application

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

## 3. Country of Origin

- 3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules of the World Bank, as further **elaborated in the SCC**.
- 3.2 For purposes of this Clause, “origin” means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.
- 3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.

## 4. Standards

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

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|---|---|
| <b>5. Use of Contract Documents and Information; Inspection and Audit by the Bank</b> | <p>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.</p> <p>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.</p> <p>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.</p> <p>5.4 The Supplier shall permit the Bank 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 Bank, if so required by the Bank.</p> |
| <b>6. Certification of Goods in Accordance with Laws of the Purchaser's Country</b>   | <p>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.</p> <p>6.2 Unless otherwise <b>specified in the SCC</b>, 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.</p> <p>6.3 If thirty (30) days, or such longer period <b>specified in the SCC</b>, 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.</p>  |
| <b>7. Patent Rights</b>   | <p>7.1 The Supplier shall indemnify the Purchaser against all</p>   |

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, or in a freely convertible currency acceptable to the Purchaser, and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Purchaser's country or abroad, acceptable to the Purchaser, in the format provided in the Bidding Documents or another format acceptable to the Purchaser; or

(b) a cashier's or certified check.

8.4 The performance security will be discharged by the Purchaser and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless **specified otherwise in the SCC**.

**9. Inspections and  
Tests**

9.1 The Purchaser or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications. The **SCC** and the Technical Specifications shall specify what inspections and tests the Purchaser requires and where they are to be conducted. The Purchaser shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

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

Goods.

- (b) The Supplier may have an independent quality test conducted on a batch ready for shipment. The cost of such tests will be borne by the Supplier.
- (c) Upon receipt of the Goods at place of final destination, the Purchaser's representative shall inspect the Goods or part of the Goods to ensure that they conform to the condition of the Contract and advise the Purchaser that the Goods were received in apparent good order. The Purchaser will issue an Acceptance Certificate to the Supplier in respect of such Goods (or part of Goods). The Acceptance Certificate shall be issued within ten (10) days of receipt of the Goods or part of Goods at place of final destination.

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

**10. Packing**

- 10.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt, and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.
- 10.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, **specified in the SCC** or Technical Specifications, and in any subsequent instructions ordered by the Purchaser.

**11. Delivery and Documents**

- 11.1 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are **specified in the SCC**.
- 11.2 For purposes of the Contract, “EXW,” “FOB,” “FCA,” “CIF,” “CIP,” and other trade terms used to describe the obligations of the parties shall have the meanings assigned to them by the current edition of *Incoterms* published by the International Chamber of Commerce, Paris.
- 11.3 Documents to be submitted by the Supplier are **specified in the SCC**. *Incoterms* provides a set of international rules for the interpretation of the more commonly used trade terms.

**12. Insurance**

- 12.1 The Goods supplied under the Contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage, and delivery in the manner **specified in the SCC**.
- 12.2 Where delivery of the Goods is required by the Purchaser on a CIF or CIP basis, the Supplier shall arrange and pay for cargo insurance, naming the Purchaser as beneficiary. Where delivery is on an FOB or 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 Contract to transport the Goods to a specified place of destination within the Purchaser’s country, defined as the Site, transport to such

place of destination in the Purchaser's country, including 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 counteranalysis 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 counteranalysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective goods. In the event of the independent analysis confirming the quality of the product, the Purchaser will meet all costs for such analysis.
- 15.4 If, after being notified that the defect has been confirmed pursuant to GCC Sub-Clause 15.2 above, the Supplier fails to replace the defective Goods within the period **specified in the SCC**, the Purchaser may proceed to take such remedial action as may be necessary, including removal and disposal, at the Supplier's risk and expense and without prejudice to any other rights that the Purchaser may have against the Supplier under the Contract. The Purchaser will also be entitled to claim for storage in respect of the defective Goods for the period following notification and deduct the sum from payments due to the Supplier under this Contract.
- 15.5 *Recalls.* In the event any of the Goods are recalled, the Supplier shall notify the Purchaser within fourteen (14) days, providing full details of the reason for the recall and promptly replace, at its own cost, the items covered by the recall with Goods that fully meet the requirements of the Technical Specification and arrange for collection or destruction of any defective Goods. If the Supplier fails to fulfill its recall obligation promptly, the Purchaser will, at the Supplier's expense, carry out the recall.

## 16. Payment

- 16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be **specified in the SCC**.
- 16.2 The Supplier's request(s) for payment shall be made to the Purchaser in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 11, and upon fulfillment of other obligations stipulated in the Contract.

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

16.4 The currency or currencies in which payment is made to the Supplier under this Contract shall be **specified in the SCC** subject to the following general principle: Payment will be made in the currency or currencies in which the payment has been requested in the Supplier's 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 any thing 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 Borrower, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial noncompetitive levels

and to deprive the Borrower of the benefits of free and open competition.

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

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

#### **24. Force Majeure**

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

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

24.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

#### **25. Termination for Insolvency**

25.1 The Purchaser may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy that has accrued or will accrue thereafter to the Purchaser.

#### **26. Termination for Convenience**

26.1 The Purchaser, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that

termination is for the Purchaser's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

26.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Purchaser at the Contract terms and prices. For the remaining Goods, the Purchaser may elect:

- (a) to have any portion completed and delivered at the Contract terms and prices; and/or
- (b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

## **27. Settlement of Disputes**

27.1 If any dispute or difference of any kind whatsoever shall arise between the Purchaser and the Supplier in connection with or arising out of the Contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given.

27.2.1 Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract.

27.2.2 Arbitration proceedings shall be conducted in accordance with the rules of procedure **specified in the SCC**.

27.3 Notwithstanding any reference to arbitration herein,

- (a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise

agree; and

- (b) the Purchaser shall pay the Supplier any monies due the Supplier.

**28. Limitation of Liability**

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

**29. Governing Language**

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

**30. Applicable Law**

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

**31. Notices**

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

- 32. Taxes and Duties**
- 32.1 A Supplier supplying Goods from abroad shall be entirely responsible for all taxes, stamp, duties, license fees, and other such levies imposed outside the Purchaser's country.
- 32.2 A Supplier supplying Goods offered locally shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted Goods to the Purchaser.
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## **SECTION V. SPECIAL CONDITIONS OF CONTRACT**

## **NOTES ON THE SPECIAL CONDITIONS OF CONTRACT**

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Similar to the Bid Data Sheet in Section II, the clauses in this Section V are intended to assist the Purchaser in providing Contract-specific information in relation to corresponding clauses in the General Conditions of Contract (GCC).

The provisions of Section V complement the GCC included in Section IV, specifying contractual requirements linked to the special circumstances of the Purchaser, the Purchaser's country, the sector, and the Goods purchased. In preparing this section, the following aspects should be checked:

- (a) The correct version of the Special Conditions of Contract must be used as a base, dependent upon the type of Goods being procured.
- (b) Information that complements provisions of Section IV, GCC, must be incorporated
- (c) Amendments and/or supplements to provisions of Section IV, GCC, as necessitated by the circumstances of the specific purchase, must also be incorporated.



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## Special Conditions of Contract

<p>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.</p> <p><i>[Instructions for completing the Special Conditions of Contract are provided as needed in the notes in italics mentioned for the relevant SCC. Where sample provisions are furnished, they are only illustrative of the provisions that the Purchaser should draft specifically for each procurement.]</i></p>	
<b>1. Definitions (GCC Clause 1)</b>	
GCC 1.1 (g)	The Purchaser is: <i>[ insert: <b>name of Purchaser</b> ].</i>
GCC 1.1 (h)	The Purchaser's country is: <i>[ insert: <b>name of Purchaser's country</b> ].</i>
GCC 1.1 (i)	The Supplier is: <i>[ insert: <b>name of Supplier</b> ].</i>
GCC 1.1 (k)	The Site is/are: <i>[ insert, if applicable: <b>identity of Site, street address and city</b>, or insert: <b>"as specified in the Schedule of Requirements"</b> ].</i>
GCC 1.1 (m)	The end user is: <i>[ insert, if applicable: <b>the organization(s) stated in the Schedule of Requirements</b>, where the Goods will be used ].</i>
<b>2. Application (GCC Clause 2)</b>	
GCC 2	<i>[ insert: <b>necessary and appropriate clauses</b>, or state: <b>"There are no Special Conditions of Contract applicable to GCC Clause 2."</b> ]</i>

<b>3. Country of Origin (GCC Clause 3)</b>	
GCC 3.1	The Bank maintains a list of countries whose Bidders, Goods, and Services are not eligible to participate in procurement financed by the Bank. This list is updated regularly, and it is available from the Public Information Center of the World Bank. A copy of this list is contained in the section of the Bidding Documents entitled "Eligibility for the Provisions of Goods, Works, and Services in Bank-Financed Procurement."
<b>4. Standards (GCC Clause 4)</b>	
GCC 4	<i>[ insert: necessary and appropriate clauses, or state: "There are no Special Conditions of Contract applicable to GCC Clause 4." ]</i>
<b>5. Use of Contract Documents and Information (GCC Clause 5)</b>	
GCC 5	<i>[ insert: necessary and appropriate clauses, or state: "There are no Special Conditions of Contract applicable to GCC Clause 5." ]</i>
<b>6. Certification of Goods in Accordance with Laws of the Purchaser's Country (GCC Clause 6)</b>	
GCC 6.1	<i>[ insert: details of <b>registration</b> and other <b>certification</b> necessary to prove registration in Purchaser's country. ]</i>
GCC 6.2	The Effective Date of the Contract is <i>[ insert: <b>date of Contract signing</b> if EITHER: (i) the Goods have already been registered at the time of Contracting signing OR (ii) registration of the Goods is not a requirement under the Applicable Law. Otherwise, delete and insert "<b>NOT USED.</b>" ]</i>
GCC 6.3	The time period shall be <i>[ insert: <b>a number greater than 30</b> ]</i> days. <i>[ If not used, delete and insert "<b>NOT USED.</b>" ]</i>

<b>7. Patent Rights (GCC Clause 7)</b>	
GCC 7	<i>[ insert: necessary and appropriate clauses, or state: “There are no Special Conditions of Contract applicable to GCC Clause 7.” ]</i>
<b>8. Performance Security (GCC Clause 8)</b>	
GCC 8.1	Performance security shall be for an amount equal to <i>[ insert: number ]</i> . Note: Five (5) to ten (10) percent of the Contract Price is a reasonable amount.
GCC 8.4	<i>[ insert: any additional requirement related to the discharge of the performance security, or state: “There are no Special Conditions of Contract applicable to GCC Sub-Clause 8.4.” ]</i>
<b>9. Inspections and Tests (GCC Clause 9)</b>	
GCC 9.1	<i>[ insert: any additional requirement related to the inspections and tests, or state: “There are no Special Conditions of Contract applicable to GCC Sub-Clause 9.” ]</i>
<b>10. Packing (GCC Clause 10)</b>	
GCC 10.2	<i>[ insert: any necessary additional requirements with respect to packing and marking or state that additional requirements are indicated in the Technical Specifications. ]</i>

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

GCC 11.1 & 11.3

### ***Sample provision (CIF/CIP terms)***

#### ***For Goods supplied from abroad:***

Upon shipment, the Supplier shall notify the Purchaser and the insurance company in writing the full details of the shipment including Contract number, description of the Goods, quantity, date and place of shipment, mode of transportation, and estimated date of arrival at place of destination. In the event of Goods sent by airfreight, the Supplier shall notify the Purchaser a minimum of forty-eight (48) hours ahead of dispatch, the name of the carrier, the flight number, the expected time of arrival, and the waybill number. The Supplier shall fax and then send by courier the following documents to the Purchaser, with a copy to the insurance company:

- (i) three originals and two copies of the Supplier's invoice, showing Purchaser as *[ enter correct description of Purchaser for customs purposes ]*; the Contract number, loan 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 *[ enter correct name of Purchaser for customs purposes ]* and Notify Party as stated in the Contract, with delivery through to final destination as per the Schedule of Requirements and two copies of non-negotiable bill of lading, or three copies of railway consignment note, road consignment note, truck or air waybill, or multimodal transport document, marked "freight prepaid" and showing delivery through to final destination as per the Schedule of Requirements;
- (iii) four copies of the packing list identifying contents of each package;
- (iv) copy of the Insurance Certificate, showing the Purchaser as the beneficiary;
- (v) one original of the manufacturer's or Supplier's Warranty Certificate covering all items supplied;
- (vi) one original of the Supplier's Certificate of Origin covering

all items supplied;

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

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

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

(ii) two copies of delivery note, railway consignment note, road consignment note, truck or air waybill, or multimodal transport document showing Purchaser as *[ enter correct name of Purchaser for customs purposes ]* and delivery through to final destination as stated in the Contract;

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

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

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

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

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

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

**Note:** In the event that the documents presented by the Supplier are not in accordance with the Contract, then payment will

	be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 9 (GCC 9) above.
<b>12. Insurance (GCC Clause 12)</b>	
GCC 12.1	The insurance shall be in an amount equal to 110 percent of the CIF or CIP value of the Goods from “warehouse” to “warehouse” on “All Risks” basis, including war risks and strikes (only if contract placed on CIF or CIP basis).
<b>13. Transportation (GCC Clause 13)</b>	
GCC 13	<i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 13.” ]</i>
<b>14. Incidental Services (GCC Clause 14)</b>	
GCC 14.1	<p>Incidental services to be provided are:</p> <p><i>[Sample clauses]</i></p> <p>(a) The Supplier shall provide all necessary licenses and permissions for use of the Goods in the Purchaser’s country that may be required for the Goods. The cost shall be deemed included in the Contract Price.</p> <p>(b) The Supplier shall provide such other services as are stated in the Technical Specifications. <i>[ insert: sections of the Technical Specifications where the services are listed. ]</i></p>
<b>15. Warranty (GCC Clause 15)</b>	
GCC 15.1	<i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 15.” ]</i>



GCC 15.4	The period for the replacement of defective goods is: <i>[ insert <b>period for replacement of defective goods</b> ]</i> .
<b>16. Payment (GCC Clause 16)</b>	
GCC 16.1 & 16.4	<p><i>[Sample provision]</i></p> <p>The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:</p> <p><b>Payment for Goods supplied from abroad:</b></p> <p>Payment of foreign currency portion shall be made in <i>[ insert: <b>currency of the Contract Price</b> ]</i> in the following manner:</p> <ul style="list-style-type: none"> <li>(i) <b>Advance Payment:</b> Ten (10) percent of the Contract Price shall be paid within thirty (30) days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Section VIII, Advance Payment Bank Guarantee.</li> <li>(ii) <b>On Shipment:</b> Eighty (80) percent of the Contract Price of the Goods shipped shall be paid through irrevocable confirmed letter of credit opened in favor of the Supplier in a bank in its country, upon submission of documents specified in GCC Clause 11 or, alternatively, at the Supplier's option, within thirty (30) days of submission of documents specified in GCC Clause 11 above by direct bank transfer to the Supplier's nominated bank account. Opening charges and charges for amendment of the letter of credit at the request of or due to a fault or default of the Purchaser are for the account of the Purchaser. Confirmation charges and charges for amendment to letters of credit at the request of or due to a fault or default on behalf of the Supplier are for the account of the Supplier.</li> <li>(iii) <b>On Acceptance:</b> Ten (10) percent of the Contract Price of Goods received shall be paid within thirty (30) days of receipt of the Goods upon submission of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed</li> </ul>

in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

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

**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 [ *insert: **currency*** ], as follows:

- (i) **Advance Payment:** Ten (10) percent of the Contract Price shall be paid within thirty (30) days of signature of Contract and receipt of the Performance Guarantee, upon submission of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) and a bank guarantee in the form provided in Section VIII, Advance Payment Bank Guarantee.
- (ii) **On Shipment:** Eighty (80) percent of the Contract Price of the Goods shipped shall be paid within 30 days of submission of documents specified in GCC Clause 11 above by direct bank transfer to the Supplier's nominated bank account.
- (iii) **On Acceptance:** Ten (10) percent of the Contract Price of Goods received shall be paid within thirty (30) days of receipt of the Goods upon submission of an invoice (showing Purchaser's name; the Contract number, loan number; description of payment and total amount, signed in original, stamped or sealed with the company stamp/seal) supported by the Acceptance Certificate issued by the Purchaser.

*[Please note that percentages may be changed to meet procurement specific requirements or trade norms.]*

<b>17. Prices (GCC Clause 17)</b>	
GCC 17.1	<p><i>[Sample provision]</i></p> <p>Prices shall be fixed and firm for the duration of the Contract.</p>
<b>18. Change Orders (GCC Clause 18)</b>	
GCC 18	<p><i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 18.” ]</i></p>
<b>19. Contract Amendments (GCC Clause 19)</b>	
GCC 19	<p><i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 19.” ]</i></p>
<b>20. Assignment (GCC Clause 20)</b>	
GCC 20	<p><i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 20.” ]</i></p>
<b>21. Delays in the Supplier’s Performance (GCC Clause 21)</b>	
GCC 21	<p><i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 21.” ]</i></p>
<b>22. Liquidated Damages (GCC Clause 22)</b>	
GCC 22.1	<p><i>[ insert: applicable rate ]</i></p> <p><i>[ insert: maximum deduction ]</i></p> <p><b>Note:</b> Applicable rate shall not exceed one-half (0.5) percent per</p>

	week, and the maximum shall not exceed ten (10) percent of the Contract Price.
<b>23. Termination for Default (GCC Clause 23)</b>	
GCC 23	<i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 23.” ]</i>
<b>24. Force Majeure (GCC Clause 24)</b>	
GCC 24	<i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 24.” ]</i>
<b>25. Termination for Insolvency (GCC Clause 25)</b>	
GCC 25	<i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 25.” ]</i>
<b>26. Termination for Convenience (GCC Clause 26)</b>	
GCC 26	<i>[ insert: necessary and appropriate clauses, or state “There are no Special Conditions of Contract applicable to GCC 26.” ]</i>
<b>27. Settlement of Disputes (GCC Clause 27)</b>	
GCC 27.2.2	<p>The dispute resolution mechanism to be applied pursuant to GCC Sub-Clause 27.2.2 shall be as follows:</p> <p><b>(a) Contracts with foreign Supplier:</b></p> <p><i>[For Contracts entered into with foreign Supplier, International commercial arbitration may have practical advantages over other dispute settlement methods. The World Bank should not be named as arbitrator, nor should</i></p>

*it be asked to name an arbitrator. Among the rules to govern the arbitration proceedings, the Employer may wish to consider the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules of 1976, the Rules of Conciliation and Arbitration of the International Chamber of Commerce (ICC), the Rules of the London Court of International Arbitration or the Rules of Arbitration Institute of the Stockholm Chamber of Commerce.]*

***If the Purchaser chooses the UNCITRAL Arbitration Rules, the following sample clause should be inserted:***

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.

***If the Purchaser chooses the Rules of ICC, the following sample clause should be inserted:***

GCC 27.2.2 (a)–All disputes arising in connection with the present Contract shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with said Rules.

***If the Purchaser chooses the Rules of Arbitration Institute of Stockholm Chamber of Commerce, the following sample clause should be inserted:***

GCC 27.2.2 (a)–Any dispute, controversy, or claim arising out of or in connection with this Contract, or the breach, termination, or invalidity thereof, shall be settled by arbitration in accordance with the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce.

***If the Purchaser chooses the Rules of the London Court of International Arbitration, the following clause should be inserted:***

GCC 27.2.2 (a)–Any dispute arising out of or in connection with this Contract, including any question regarding its existence, validity, or termination shall be referred to and finally resolved by arbitration under the Rules of the London Court of International Arbitration, which rules are

	<p>deemed to be incorporated by reference to this clause.</p> <p><b>(b) <i>Contracts with Supplier national of the Purchaser's country:</i></b></p> <p>In the case of a dispute between the Purchaser and a Supplier who is a national of the Purchaser's country, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Purchaser's country.</p> <p><i>[ The bidding documents should contain one clause to be retained in the event of a Contract with a foreign Supplier and one clause to be retained in the event of a Contract with a Supplier who is a national of the Purchaser's country. At the time of finalizing the Contract, the respective applicable clause should be retained in the Contract. The following explanatory note should therefore be inserted as a header to SCC 27.2.2 in the bidding document.</i></p> <p><i>"Clause 27.2.2 (a) shall be retained in the case of a Contract with a foreign Supplier and Clause 27.2.2 (b) shall be retained in the case of a Contract with a national of the Purchaser's country." ]</i></p>
<b>28. Limitation of Liability (GCC Clause 28)</b>	
GCC 28	<i>[ insert: necessary and appropriate clauses, or state "There are no Special Conditions of Contract applicable to GCC 28." ]</i>
<b>29. Governing Language (GCC Clause 29)</b>	
GCC 29.1	<i>[ insert: the governing language ]</i>

<b>30. Applicable Law (GCC Clause 30)</b>	
GCC 30.1	The Contract shall be interpreted in accordance with the laws of the: <i>[ insert: <b>name of country</b> ].</i>
<b>31. Notices (GCC Clause 31)</b>	
GCC 31.1	<i>[ insert: the <b>Purchaser's</b> address for notice purposes ]</i> <i>[ insert: the <b>Supplier's</b> address for notice purposes ]</i>
<b>32. Taxes and Duties (GCC Clause 32)</b>	
GCC 32	<i>[ insert: <b>necessary and appropriate clauses</b>, or state "<b>There are no Special Conditions of Contract applicable to GCC 32.</b>" ]</i>





## Special Conditions of Contract

### PHARMACEUTICALS

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in Bidding Documents for the procurement of pharmaceuticals.

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

GCC 11.1 & 11.3

***For Goods supplied from abroad:***

- (ix) One original of the Certificate of Pharmaceutical Product as recommended by the WHO for each of the items supplied.
- (x) Certificate of quality control test results in conformity with the World Health Organization "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade" stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods.
- (xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.



## Special Conditions of Contract

### VACCINES

(Additional Clauses)

The below data should be included in the Special Conditions of Contract used in Bidding Documents for the procurement of vaccines.

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

GCC 11.1 & 11.3

##### *For Goods supplied from abroad:*

- (ix) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.
- (x) Certificate of quality control test results in conformity with the World Health Organization “Certification Scheme on the Quality of Pharmaceutical Products Moving in International Trade” stating quantitative assays, chemical analysis, sterility, pyrogen content, uniformity, microbial limit, and other tests as appropriate to the Goods.
- (xi) Original copy of the certificate of weight issued by the port authority/licensed authority and six copies.

##### *For Goods from within the Purchaser’s country:*

- (x) one copy of the Lot Release Certificate issued by the NCA of the country of manufacture for each lot shipped.

#### 15. Warranty (GCC Clause 15)

GCC 15.1

##### *[Sample clauses]*

The Purchaser reserves the right to request evidence of bio-availability and/or bio-equivalence data and/or evidence of the basis for expiration dating and other stability data concerning the Goods to verify shelf life claimed for the Goods.

If an adverse event following immunization (AEFI) occurs in the Purchaser’s country and the cause of such event cannot be immediately established, the Purchaser will, with all urgency and

	<p>in accordance with the procedures laid down by the NCA of the Purchaser's country, take steps to advise the Supplier in order that an investigation may be launched immediately. If the vaccine has been supplied through an agency of the United Nations, the most current procedures laid down by the WHO for such situations will be used.</p>
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## Special Conditions of Contract

### CONDOMS

The following Special Conditions of Contract shall supplement the General Conditions of Contract in the procurement of condoms. 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.

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

GCC 9	(d) <i>The Supplier shall test batches of Goods ready for shipment in accordance with the WHO specification. The size of the sample for testing will be calculated by reference to ISO2859-1. With each consignment, the Supplier must provide a certificate of quality control test results in conformity with the standards laid down in ISO 2859-1 and in accordance with the general sampling levels appropriate to each feature as necessary. The Supplier will bear the cost of such tests.</i>
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#### 11. Delivery and Documents (GCC Clause 11)

GCC 11.1 & 11.3	<p><b><i>For Goods supplied from abroad:</i></b></p> <ul style="list-style-type: none"> <li>(ix) original copy of quality control tests for each consignment as stated in SCC 9 above.</li> <li>(x) original copy of the certificate of inspection furnished to Supplier by nominated inspection agency and six copies [ <i>where separate inspection is required</i> ].</li> </ul> <p><b>For Goods from within the Purchaser's country:</b></p> <ul style="list-style-type: none"> <li>(ix) certificate of in-house analysis.</li> </ul>
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## **SECTION VI. SCHEDULE OF REQUIREMENTS**

## NOTES FOR PREPARING THE SCHEDULE OF REQUIREMENTS

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The Schedule of Requirements provides a concise description of each product and the quantity required, along with any technical specifications unique to that item. If it can be printed with sufficient space for Suppliers to enter offers, having Suppliers use this space for bids greatly simplifies the collation of offers. Sufficient space should be provided so that the Supplier can enter all relevant information, including the name of the original manufacturer.

The Schedule of Requirements should include the international nonproprietary name (INN) or generic name (for combination product, the name of each generic component), the strength in metric units for each component, the basic unit (tablet, capsule, vial, bottle), the package size, and the number of packages needed. Some Schedules of Requirements list both the total number of packages and the total number of basic units needed, to avoid misunderstanding and to allow for the possibility that a Supplier may offer a different (but acceptable) package size representing the same number of basic units. The schedule of requirements should specify whether the listed package sizes are the only ones acceptable.

The delivery schedule expressed as weeks stipulates hereafter a delivery date that is the date of delivery (i) at EXW premises or (ii) to the carrier at the port of shipment when the Contract is placed on FOB or CIF terms or (iii) to the first carrier when the Contract is placed on FCA or 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.<sup>3</sup>

Number	Description	Strength	Quantity <sup>4</sup>	Delivery schedule (shipment) In weeks from _____ <sup>5</sup>	Mode of Shipment <sup>6</sup>
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<sup>3</sup> The delivery may be specified for a single shipment, for several partial shipments, for a specific date, or range of acceptable delivery periods.

<sup>4</sup> If the quantity required is very large, and competition is likely to be very restricted because of lack of manufacturing capacity, the Purchaser may decide at the time of preparing Bidding Documents to divide the required quantities into more than one lot. However, as far as practical, the size of lots should be for comparable quantity and the number of lots should normally not be more than three. The BDS should indicate whether or not discounts for combined lots will be taken into account for bid evaluation and award of Contract.

<sup>5</sup> The Purchaser must specify here the date from which the delivery schedule will start. That date should be a date not later than the Contract Effective Date and may be the Contract Effective Date itself, the date the letter of credit is opened, or the date of confirmation of the letter of credit, as appropriate. The Bid Form should include only a cross reference to this Schedule.

<sup>6</sup> Delete if both air and sea shipments are acceptable. If some items must be sent only by air shipment, this should be specified clearly.



## **SECTION VII. TECHNICAL SPECIFICATIONS**

## NOTES FOR PREPARING THE TECHNICAL SPECIFICATIONS [Procurement Specific]

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A set of precise and clear specifications is a prerequisite for Bidders to respond realistically and competitively to the requirements of the Purchaser without qualifying their bids. The sample text provided in this section should serve as guidance only. This text is not intended to be used verbatim since technical specifications specific to each procurement should be drafted by the Purchaser for inclusion in the bidding documents. In the context of international competitive bidding (ICB) among qualified firms, the specifications must be drafted to permit the widest possible competition. The technical specifications establish the requirements for good manufacturing practices (GMPs), pharmacopoeial standards, nomenclature, and description required for each product, shelf life and package expiration date parameters, labeling instructions, packaging instructions, GMP and quality assurance certificates required, and other evidence of product quality to be submitted with the bid and with each shipment. Only if this is done will the objectives of economy, efficiency, and fairness in procurement be realized, responsiveness of bids be ensured, and the subsequent task of bid evaluation facilitated.

Specific pharmacopoeial standards should be listed for each product; if any of a range of standards is adequate (*British Pharmacopoeia*, *United States Pharmacopoeia*, *European Pharmacopoeia*, or *International Pharmacopoeia*), this should be noted. If special packaging or labeling is required for a subset of products, this should be indicated on the schedule of requirements (see above), but a generic statement of packaging and labeling applied to all products should be included in the general technical specifications. Instructions about labeling (contents and language) and package inserts can be included in the technical specifications, unless there are specific requirements for each batch or schedule of requirements.

**Technical Specifications**

*[Text of Technical Specifications to be inserted in the Bidding Documents by the Purchaser, as applicable.]*

**TECHNICAL SPECIFICATIONS:      PHARMACEUTICALS**

**TECHNICAL SPECIFICATIONS:      CONDOMS**

**TECHNICAL SPECIFICATIONS:      VACCINES**



## Sample Technical Specifications

### PHARMACEUTICALS

**1. Product and  
Package  
Specifications**

- 1.1 The Goods to be purchased by the Purchaser under this Invitation for Bids are included in the Purchaser's *current* national essential drugs list or national formulary. The required packing standards and labeling must meet the latest requirements of the World Health Organization (WHO) good manufacturing practices (GMP) standards in all respects. (These standards are contained in "Good Practices in the Manufacture and Quality Control of Drugs.")
- 1.2 Product specifications indicate dosage form (e.g., tablet, capsules, dry syrup, liquid, ointment, injectable, emulsion, suspension, etc.) and the drug content (exact number of mg *or international units* [IU] or % v/v, w/w *or* v/w acceptable range). The Goods should conform to standards specified in the following compendia: [The Borrower should specify an acceptable pharmacopoeia standard from one of the following: the *British Pharmacopoeia*, the *United States Pharmacopoeia*, the *French Pharmacopoeia*, the *International Pharmacopoeia*, or the *European Pharmacopoeia*, the latter particularly for raw materials.] *The standards will be the latest edition unless otherwise stated by the Purchaser or other if applicable.* In case the pharmaceutical product is not included in the specified compendium, *but included in the Purchaser's national essential drug list, the Purchaser should clearly indicate acceptable limits and* the Supplier, upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing.
- 1.3 Not only the pharmaceutical item, but also the packaging and labeling components (e.g., bottles, closures, and *labeling*) should also meet specifications suitable for distribution, storage, and use in a climate similar to that prevailing in the country of the Purchaser. All packaging must be properly sealed and tamper-proof, *and packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer's national regulatory authority (RA).* The Purchaser should specify any additional special requirements.

- 1.4 All labeling and packaging inserts shall be in the language requested by the Purchaser or English if not otherwise stated.
- 1.5 Goods requiring refrigeration or freezing *or those that should not fall below a certain minimum temperature* for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.
- 1.6 Upon award, the successful Supplier shall, on demand, provide a translated version in the language of the bid of the prescriber's information for any specific goods the Purchaser may request.

## **2. Labeling Instructions**

- 2.1 The label of the primary container for each pharmaceutical and vaccine products shall meet the W210 GMP standard and include:
  - (a) The international nonproprietary name (INN) or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name;
  - (b) dosage form, e.g., tablet, ampoule, syrup, etc.;
  - (c) the active ingredient "per unit, dose, tablet or capsule, etc.";
  - (d) the applicable pharmacopoeial standard;
  - (e) the Purchaser's logo and code number and any specific color coding if required;
  - (f) content per pack;
  - (g) instructions for use;
  - (h) special storage requirements;
  - (i) batch number;
  - (j) date of manufacture and date of expiry (in clear language, not code);
  - (k) name and address of manufacture;
  - (l) any additional cautionary statement.

- 2.2 The outer case or carton should also display the above information.
- 3. Case Identification**
- 3.1 All cases should prominently indicate the following:
- (a) Purchaser's line and code numbers;
  - (b) the generic name of the product;
  - (c) the dosage form (tablet, ampoule, syrup);
  - (d) date of manufacture and expiry (in clear language not code);
  - (e) batch number;
  - (f) quantity per case;
  - (g) special instructions for storage;
  - (h) name and address of manufacture;
  - (i) any additional cautionary statements.
- 3.2 No case should contain pharmaceutical products from more than one batch.
- 4. Unique Identifiers**
- 4.1 The Purchaser shall have the right to request the Supplier to imprint a logo, if the quantity so justifies it, on the *labels of the containers* used for packaging and in certain dosage forms, such as tablets, *and ampoules* and this will be in the Technical Specifications. The design *and detail will be clearly indicated at the time of bidding, and confirmation of the design of such logo shall be provided to the Supplier at the time of contract award.*
- 5. Standards of Quality Control for Supply**
- 5.1 The successful Supplier will be required to furnish to the Purchaser:
- (a) With each consignment, and for each item a WHO certificate of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the Goods being supplied and the manufacturer's certificate of analysis.
  - (b) Assay methodology of any or all tests if requested.
  - (c) Evidence of bio-availability and/or bio-equivalence for

certain critical Goods upon request. *This information would be supplied on a strictly confidential basis only.*

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

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



## Sample Technical Specification

### VACCINES

#### 1. Product Qualification Requirements

##### Option A

- 1.1 The Goods to be purchased by the Purchaser under this Invitation for Bids must be produced under the control of a recognized, well-functioning National Control Authority (NCA) for biologicals, which performs all six critical functions as defined by the World Health Organization (WHO):
- (a) licensing based on published set of requirements
  - (b) surveillance of vaccine field performance
  - (c) system of lot release for vaccines
  - (d) use of laboratory when needed
  - (e) regular inspections for good manufacturing practices (GMP)
  - (f) evaluation of clinical performance

Or state the following:

##### Option B

- 1.1 The Goods under this Invitation for Bids should be purchased from WHO-approved sources only.
- 1.2 The Goods to be purchased by the Purchaser under this Invitation for Bids must be produced in accordance with the GMP recommendations of WHO for biological products.
- 1.3 The Goods to be purchased by the Purchaser under this Invitation for Bids must be registered by the National Control Authority (NCA) of the Purchaser's country.

#### 2. Product Specifications

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

- 2.2 Type (e.g.: “live attenuated,” “manufactured from purified inactivated (...) obtained from human plasma or manufactured using recombinant DNA technology,” etc.).
- 2.3 Administration (e.g.: “intended for intramuscular injection,” etc.).
- 2.4 Description of intended use (e.g.: “immunization of newborn infants,” etc.).
- 2.5 Dosage size (if not restrictive), or expected immunogenic reaction (e.g.: each dose shall contain that amount of Hbsag protein with micrograms/ml specified by the manufacturer for newborn dosage, that when given as part of a primary immunization series [3 doses] is capable of producing specific humoral antibody [anti HBs] at a level of at least 10 milli international units in >-90 percent of recipients,” etc.).
- 2.6 Dose package (e.g.: “5 infant dose sterile glass vials,” etc.).
- 2.7 Filling volume (e.g.: “final product should contain 15% overfill,” etc.).
- 2.8 Closures (e.g.: “vaccine vials shall be fitted with closures that conform to ISO standard 8362-2”).
- 2.9 Storage temperature (e.g.: “2–8 degrees C. Do not freeze,” or as appropriate, etc.).
- 2.10 The product should remain stable up to the indicated test expiry date if kept according to the required storage temperature.
- 2.11 Standards (e.g.: “The vaccine should conform to standards established by the Purchaser’s country or, where no standard has been adopted, meet current requirements published by the WHO Expert Committee on Biological Standardization, or requirements of an established body of equivalent stature such as the *U.S. Pharmacopoeia*, the *British Pharmacopoeia*, the *French Pharmacopoeia*, or the *International Pharmacopoeia*”).

### **3. Labeling Requirements**

- 3.1 Each vial or ampoule shall carry the manufacturer’s standard label in the language of Purchaser’s country, if available at no extra charge; otherwise, the label shall be in English.
- 3.2 Each vial or ampoule label shall state the following:
  - (a) name of the vaccine;

- (b) name of the manufacturer;
- (c) place of manufacture;
- (d) lot number;
- (e) composition;
- (f) concentration;
- (g) dose mode for administration;
- (h) expiration date;
- (i) storage temperature;
- (j) any other information that is appropriate.

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

#### **4. Packing Requirements**

- 4.1 Inner boxes: Inner Boxes shall contain not more than (*number*) individual vials/ampoules and shall be constructed of sturdy white cardboard outfitted with individual segments for protecting and separating each vial/ampoules.
- 4.2 Printed materials: Each inner box shall contain at least (*number*) manufacturer's standard package inserts in the language of Purchaser's country if available at no extra charge; otherwise, package insert shall be in English.
- 4.3 Overpacking: Inner boxes shall be overpacked so that the vaccine remains refrigerated as designated in Clause 2.9. The overpacking must be suitable for export handling and be in accordance with WHO Expanded Program of Immunization (EPI) Guidelines on International Packaging and Shipping of Vaccines including all measures needed to maintain required temperatures for seventy-two (72) hours. It must have adequate insulation and sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above that designated in Sub-Clause 2.9 when exposed to continuous outside temperature of +43 degrees C, nor fall below that specified of -20 degrees C during transit and for a period of at least twenty-four (24) hours after arrival at the airport destination. Additional cushioning shall be provided sufficient to protect the vials/ampoules from breakage during transit and handling.
- 4.4 Exterior shipping cartons: Product and printed materials, packaged as described above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a

bursting test strength of not less than 1,900 kPa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

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

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

- (a) At least two suitable cold chain monitor cards, as approved by the Purchaser, shall be packed in each transport case of vaccine.
- (b) Freeze watch indicators shall be included in each transport case at the direction of Purchaser.

**5. Marking Requirements**

- 5.1 All containers and invoices must bear the following information:

- (a) the name of the vaccine;
- (b) expiration date of the vaccine;
- (c) appropriate storage temperature.

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

- (a) Generic name and trade name of the vaccine;
- (b) Manufacturer's name and trade registered address;
- (c) Manufacturer's national registration number;
- (d) Lot or batch number;
- (e) Composition and concentration;
- (f) Number of vials contained in box;
- (g) Expiration date (month and year in clear language, not code);
- (h) Instructions for storage and handling;
- (i) Place of manufacture (Made in \_\_\_\_\_).

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

- (a) Generic name and trade name of the vaccine;
- (b) Lot or batch number;
- (c) Expiration date (month and year in clear language, not code);
- (d) Manufacturer's name and registered address;
- (e) Manufacturer's national registration number;
- (f) Destination airport and routing;
- (g) Consignee's name and address in full;
- (h) Consignee contact name and telephone number;
- (i) Number of vials or ampoules contained in the carton;
- (j) Gross weight of each carton (in kg);
- (k) Carton # \_\_\_\_ of \_\_\_\_;
- (l) Instructions for storage and handling;
- (m) Contract number;
- (n) Place of manufacture (Made in \_\_\_\_).

**6. Quality  
Control for  
Supply**

6.1 All goods must:

- (a) meet the requirements of manufacturing legislation and regulation of vaccines in the country of origin;
- (b) meet internationally recognized standards for safety, efficacy, and quality;
- (c) conform to all the specifications and related documents contain herein;
- (d) be fit for the purposes expressly made known to the Supplier by the Purchaser;
- (e) be free from defects in workmanship and materials;

and

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

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

- (a) A certificate of quality control and test results in conformity with the WHO release certificate.
- (b) Assay methodology of any or all tests if required.
- (c) Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

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

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

## Sample Technical Specifications

### CONDOMS

- |  |   |
|--|---|
| <b>1. Product and Package Specifications</b> | <p>1.1 The Goods must conform to the manufacturer's current standards for condoms and specified in line with the ISO 4074 Standard for Latex Rubber Condoms.</p> <p>1.2 The specifications for the Goods shall indicate critical factors, i.e., bursting volume and pressure, freedom from holes, width and length, thickness, lubricant quality, and viscosity.</p> <p>1.3 The Goods and packaging and labeling components shall meet the standards specified in the latest WHO specification, including batch-by-batch independent quality control laboratory tests.</p> <p>1.4 Condoms should be shipped in special containers to ensure stability in transit from point of shipment to port/air port of entry and point of destination for CIP deliveries. Any special temperature requirements must be designed to meet the climatic conditions prevailing in the country of the Purchaser, and the Purchaser should advise the Supplier of any particular requirements.</p> |
| <b>2. Labeling</b>                           | <p>2.1 The primary pack should be labeled in accordance with the latest WHO specifications and include:</p> <ul style="list-style-type: none"> <li>(a) Manufacturer's name;</li> <li>(b) Batch number (printed at the time of packaging);</li> <li>(c) Month and year of expiry; and</li> <li>(d) Any other information as requested by the Purchaser.</li> </ul> <p>2.2 The secondary packing, i.e., the inner box, should be labeled in accordance with the latest WHO specifications and include:</p> <ul style="list-style-type: none"> <li>(a) Batch number;</li> <li>(b) Month and year of manufacture (including the words: Date of Manufacture/month/year);</li> </ul>  |

- (c) Manufacturer's name and registered address;
  - (d) Nominal width expressed in millimeters;
  - (e) Number of condoms in box;
  - (f) Instructions for storage; and
  - (g) Month and year of expiry.
- 3. Packaging Specification**
  - 3.1 All exterior shipping cartons and packaging must comply with the latest WHO specification for packaging of condoms.
- 4. Case Identification**
  - 4.1 All cases should predominantly indicate the following:
    - (a) Batch number;
    - (b) Month and year of manufacture (including the words: Date of Manufacture/month/year);
    - (c) Name and address of supplier;
    - (d) Nominal width expressed in millimeters;
    - (e) Number contained in the carton;
    - (f) Instructions for storage and handling; and
    - (g) Month and year of expiry.
- 5. Lot Traceability**
  - 5.1 All exterior shipping cartons for each batch should be assembled and shipped together to facilitate the monitoring of batch quality during shipping and storage.
  - 5.2 Both codes should be used on exterior shipping cartons, color coded for ease of identification if requested by the Purchaser.
- 6. Unique Identifiers**
  - 6.1 The Purchaser will have the right to request the Supplier to imprint, provided the quantity justifies it, a logo on the packaging of the condoms. The design and details will be clearly indicated at the time of bidding and shall be provided to the Supplier at the time of contract award.
- 7. Standards of Quality Control for Supply**
  - 7.1 The Supplier will be required to provide the Purchaser with access to its manufacturing facilities to inspect compliance with the GMP requirements and quality control mechanisms.



**8. Quality  
Control  
Testing**

- 8.1 (a) The Supplier shall be required to carry out testing of a proposed shipment in line with the WHO specification, and the size of sample will be calculated by reference to ISO 2859-1.
- (b) With each consignment the Supplier must provide a certificate of quality control test results in conformity with the WHO specifications and in accordance with the general sampling levels appropriate to each feature as necessary.



## **SECTION VIII. SAMPLE FORMS**

## NOTES TO THE PURCHASER ON THE PREPARATION OF THE SAMPLE FORMS

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The Sample Forms provided in these SBD provide standard formats for a number of the key documents that the Purchaser and Bidders will exchange in the process of bidding, awarding, and implementing the Contract. Most of the Sample Forms are to be completed by the Purchaser. Except for the Bid Form and Form of Contract Agreement, the Purchaser or the Bidder may modify the forms to suit the particular procurement. The forms are included in the Bidding Documents **before** they are released to potential Bidders. In turn, the Bidders or winning Bidder must complete other forms, as indicated on the form, and submit them to the Purchaser. Notes providing instructions for the Purchaser, the Bidders, and the winning Bidder have been provided. To avoid confusion, the Purchaser should remove all the instructions to the Purchaser from the final version of the Bidding Documents that is released to potential Bidders.

The typographical aides used in the previous sections of the SBD continue in this section. General explanatory text that appears in this text (sans serif typeface) remains intended for the Purchaser. General instructions or explanatory text aimed at Bidders and/or the winning Bidder appear in standard roman typeface. Instructions that appear directly in the forms continue to be in italicized roman typeface, set off with square brackets and intended for the Bidders or the winning Bidder. If an instruction is meant for the Purchaser, it is identified as such. Purchasers are encouraged to provide as many of these Sample Forms as possible in revisable, electronic format in the Bidding Documents. This will expedite bid preparation, reduce the number of inadvertent mistakes made by Bidders, and, as a result, simplify the evaluation.

*Bid Form and Form of Contract Agreement:* Except as indicated by blanks and/or instructions to fill in information, the text of the Bid Form and the Contract Agreement should be left unaltered in the Bidding Documents from how it appears in these SBD. It would be at the time of Contract award when the Purchaser has an opportunity to add the final details needed in the Contract Agreement form, by making any necessary insertions or changes to paragraph 2.

Since the Price Schedules will form part of the final Contract, if there have been any corrections or modifications to the winning bid resulting from price corrections, pursuant to the Instructions to Bidders, these too should be reflected in the Price Schedules at the time of Contract award.

*Price Schedules:* The price breakdown given in the sample Price Schedules generally follows the usual breakdown requested for procurement of Goods in order for the domestic preference procedure to be applied. It is essential that Bidders submit their prices in the manner prescribed by the Price Schedules. Failure to do so, may result in loss of the preference, if applicable.

*Manufacturer's Authorization Form:* In accordance with ITB Sub-Clause 7.1 (b), Bidders must submit, as part of their bids, Manufacturer's Authorization Form(s) in the format provided in the SBD for all items specified in the Bid Data Sheet.

*Bid Security Form:* Regarding ITB Clause 19, the Purchaser should include the Bid Security form provided in the SBD in the Bidding Documents. The Purchaser must ensure that the new form substantially complies with the features of the form included here in respect to its degree of protection and clarity of conditions under which it can be made effective.

*Performance Security Form:* Pursuant to GCC Sub-Clause 8.1, the successful Bidder is required to provide the performance security within twenty-eight (28) days of notification of Contract award.

*Advance Payment Bank Guarantee:* Pursuant to GCC Sub-Clause 16.1, the successful Bidder is required to provide a bank guarantee securing the advance payment, if SCC related to GCC Sub-Clause 16.1 provides for one.

## NOTES TO BIDDERS ON THE PREPARATION OF SAMPLE FORMS

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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 italicized text within square brackets.

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

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## SAMPLE FORMS

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## 1. Bid Form

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

Loan/Credit No.: [ Purchaser insert: **number** ]

[ Purchaser specify: “IFB No.: [ number ]” ]

[ insert: **name of Contract** ]

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:

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

(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 \_\_\_\_\_ IFB 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 manufacturer	Ctry. of origin	Pharmaceutical standard
						[a] Unit price FOB or FCA port or place of 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:

Signed: \_\_\_\_\_

Dated: \_\_\_\_\_

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

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

(Group A and Group B bids)

Name of Bidder \_\_\_\_\_ IFB 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	Pharmaceutical 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 incidental 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 labor, 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:

Signed: \_\_\_\_\_

Dated: \_\_\_\_\_

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

## 4. Bid Security Form (Bank Guarantee)

*[insert: **Bank's Name, and Address of Issuing Branch or Office**]*

**Beneficiary:** *[insert: **Name and Address of Employer**]*

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

**BID GUARANTEE No.:** *[insert: **Bid Guarantee No.**]*

We have been informed that *[insert: **name of the Bidder**]* (hereinafter called "the Bidder") has submitted to you its bid dated *[insert: **date**]* (hereinafter called "the Bid") for the execution of *[insert: **name of contract**]* under Invitation for Bids No. *[insert: **IFB number**]* ("the IFB").

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the Bidder, we *[insert: **name of Bank**]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert: **amount in figures**]* (*[insert: **amount in words**]*) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Bidder is in breach of its obligation(s) under the bid conditions, because the Bidder:

- (a) has withdrawn its Bid during the period of bid validity specified by the Bidder in the Form of Bid; or
- (b) does not accept the correction of its Bid price in accordance with the Instructions to Bidders (hereinafter "the ITB") of the IFB; or
- (c) having been notified of the acceptance of its Bid by the Employer 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 ITB.

This guarantee will expire: (a) if the Bidder is the successful bidder, upon our receipt of copies of the contract signed by the Bidder and the performance security issued to you upon the instruction of the Bidder; or (b) if the Bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the Bidder of the name of the successful bidder; or (ii) twenty-eight days after the expiration of the Bidder's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

---

*[signature(s)]*

## 5. 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 Technical Specifications)
  - (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 \_\_\_\_\_

#### CONTRACT AGREEMENT

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

BETWEEN

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

and

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

## 6. Performance Security Bank Guarantee

\_\_\_\_\_ *[insert: Bank's Name, and Address of Issuing Branch or Office]*

**Beneficiary:** \_\_\_\_\_ *[insert: Name and Address of Purchaser]*

**Date:** \_\_\_\_\_

**PERFORMANCE GUARANTEE No.:** \_\_\_\_\_

We have been informed that *[insert: name of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert: reference number of the contract]* dated \_\_\_\_\_ with you, for the supply of *[insert: description of goods]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, a performance guarantee is required.

At the request of the Supplier, we *[insert: name of Bank]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert: amount in figures]* (\_\_\_\_) *[insert: amount in words]*<sup>7</sup> upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Contract, without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the \_\_\_\_ day of \_\_\_\_\_, 2\_\_\_\_,<sup>8</sup> and any demand for payment under it must be received by us at this office on or before that date.

<sup>7</sup> The Guarantor shall insert an amount representing the percentage of the Contract Price specified in the Contract and denominated either in the currency(ies) of the Contract or a freely convertible currency acceptable to the Purchaser.

<sup>8</sup> Established in accordance with Clause 8.4 of the General Conditions of Contract ("GCC"), taking into account any warranty obligations of the Supplier under Clause 15.2 of the GCC intended to be secured by a partial performance guarantee. The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."



This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

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*[signature(s)]*

## 7. Bank Guarantee Form for Advance Payment

\_\_\_\_\_ *[insert: Bank's Name, and Address of Issuing Branch or Office]*

**Beneficiary:** \_\_\_\_\_ *[insert: Name and Address of Purchaser]*

**Date:** \_\_\_\_\_

**ADVANCE PAYMENT GUARANTEE No.:** \_\_\_\_\_

We have been informed that *[insert: name of Supplier]* (hereinafter called "the Supplier") has entered into Contract No. *[insert: reference number of the contract]* dated \_\_\_\_\_ with you, for the supply of *[insert: description of goods]* (hereinafter called "the Contract").

Furthermore, we understand that, according to the conditions of the Contract, an advance payment in the sum *[insert: amount in figures]* (\_\_\_\_) *[insert: amount in words]* is to be made against an advance payment guarantee.

At the request of the Supplier, we *[insert: name of Bank]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert: amount in figures]* (\_\_\_\_) *[insert: amount in words]* upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation under the Contract because the Supplier used the advance payment for purposes other than toward delivery of the goods.

It is a condition for any claim and payment under this guarantee to be made that the advance payment referred to above must have been received by the Supplier on its account number \_\_\_\_\_ at \_\_\_\_\_ *[insert: name and address of Bank]*.

This guarantee shall expire, at the latest, upon our receipt of copy(ies) of \_\_\_\_\_<sup>9</sup>, or on the \_\_\_\_ day of \_\_\_\_\_, 2\_\_\_\_,<sup>10</sup> whichever is earlier. Consequently, any demand for payment under this guarantee must be received by us at this office on or before that date.

<sup>9</sup> Insert documents establishing "delivery" of the goods in accordance with the particular Incoterm selected. (See SCC 11.)

<sup>10</sup> Insert the delivery date stipulated in the original delivery schedule. The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months][one year], in response to the

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

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*[signature(s)]*

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Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

## 8. Manufacturer's Authorization Form

(Manufacturer's or Producer's letterhead)

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

WHEREAS *[ insert: name of the manufacturer or producer ]* (hereinafter, "we" or "us") who are established and reputable manufacturers or producers of *[ insert: name and/or description of the Goods requiring this authorization ]* (hereinafter, "Goods") having production facilities at *[ insert: address of factory ]* do hereby authorize *[ insert: name and address of Bidder ]* (hereinafter, the "Bidder") to submit a bid, and subsequently negotiate and sign the Contract with you against IFB *[ insert: title and reference number of the Invitation for Bids ]* 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 ]*

## 9. Specimen Certificate of a Pharmaceutical Product

### Certificate of a Pharmaceutical Product<sup>1</sup>

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<sup>2</sup> and amount(s) per unit dose.<sup>3</sup>

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

For complete qualitative composition including excipients, see attached.<sup>4</sup>

1.2 Is this product licensed to be placed on the market for use in the exporting country?<sup>5</sup> 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.<sup>6</sup>

2A. 1 Number of product license<sup>7</sup> and date of issue:

\_\_\_\_\_

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

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

2A.3 Status of product-license holder:<sup>8</sup> 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:<sup>9</sup>

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

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

2A.6 Applicant for certificate, if different from license holder (name and address):<sup>12</sup>

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:<sup>9</sup>

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2B.3 Why is marketing authorization lacking?

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

2B.4 Remarks:<sup>13</sup>

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

yes/no/not applicable<sup>14</sup> (*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?<sup>15</sup>

yes/no/not applicable<sup>16</sup> (*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?<sup>11</sup>

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**

<sup>1</sup> 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.

<sup>2</sup> Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.

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

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

- <sup>5</sup> When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.
- <sup>6</sup> Sections 2A and 2B are mutually exclusive.
- <sup>7</sup> Indicate, when applicable, if the license is provisional or if the product has not yet been approved.
- <sup>8</sup> 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.
- <sup>9</sup> This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Noncompletion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license must be updated or it will cease to be valid.
- <sup>10</sup> This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- <sup>11</sup> This refers to product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SPC).
- <sup>12</sup> In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission must be provided to the authority by the applicant.
- <sup>13</sup> 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.
- <sup>14</sup> 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.
- <sup>15</sup> 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).
- <sup>16</sup> This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 7 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

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