

STANDARD PROCUREMENT DOCUMENT

Prequalification Document Health Sector Goods

(Pharmaceuticals, Vaccines and Condoms)

(For use with a Request for Bids process)

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Revisions

October 2017

This revision dated October 2017 incorporates new provisions on beneficial ownership.

January 2017

In this revision dated January 2017 a few editorial enhancements have been made.

July 2016

This revision dated July 2016 incorporates a number of changes reflecting the *Procurement Regulations for IPF Borrowers*, July 2016.

Foreword

The Prequalification Document (PD) for procurement of Health Sector Goods (Pharmaceuticals, Vaccines and Condoms) shall be used by the Borrower with minimum changes as may be necessary, and acceptable to the Bank, when a Prequalification process takes place prior to the bidding process for procurement of Health Sector Goods through Request For Bids (RFB) procedure in projects that are financed, in whole or in part, by the World Bank.

This Standard Procurement Document (SPD) has been updated to reflect the World Bank's *Procurement Regulations for IPF Borrowers, July, 2016* as amended from time to time. This SPD is applicable to the Prequalification of suppliers for Health Sector Goods funded by IBRD or IDA-financed projects whose Legal Agreement makes reference to the *Procurement Regulations for IPF Borrowers*.

Those wishing to submit comments or questions on these documents or to obtain additional information on procurement under World Bank-financed projects are encouraged to contact:

Chief Procurement Officer
Standards, Procurement and Financial Management Department
The World Bank
1818 H Street, N.W.
Washington, D.C. 20433 U.S.A.
<http://www.worldbank.org>

Summary

Specific Procurement Notice - Invitation for Prequalification

The template attached is the Invitation for Prequalification. This is the template to be used by the Borrower.

Prequalification Document: Procurement of Health Sector Goods *[Insert type of health goods, e.g. Pharmaceuticals, Vaccines and Condoms]*

PART 1 – PREQUALIFICATION PROCEDURES

Section I - Instructions to Applicants (ITA)

This Section provides information to help the Applicants in preparing and submitting their Applications for Prequalification (“Applications”). Information is also provided on opening and evaluation of Applications. **Section I contains provisions that are to be used without modification.**

Section II - Prequalification Data Sheet (PDS)

This Section includes provisions that are specific to each Prequalification and supplement Section I, Instructions to Applicants.

Section III - Qualification Criteria and Requirements

This Section specifies the methods, criteria, and requirements to be used to determine how Applicants shall be prequalified and later invited to bid.

Section IV - Application Forms

This Section includes the Application Submission Form and other forms required to be submitted with the Application.

Section V - Eligible Countries

This Section contains information regarding eligible countries.

Section VI - Fraud and Corruption

This Section provides the Applicants with the reference to the Bank's policy in regard to Fraud and Corruption applicable to the Prequalification process.

PART 2 -- SUPPLY REQUIREMENTS**Section VII - Scope of Supply**

This Section includes a summary description, delivery and completion schedules, and Site and other Data of the Supply of the Health Sector Goods subject of this Prequalification.

Specific Procurement Notice Template

Invitation for Prequalification Health Goods

Country: _____

Name of Project: _____

Contract Title: _____

Loan No./Credit No./Grant No.: _____

Prequalification Reference No.:*[as per the Procurement Plan]*_____

1. The *[insert name of Borrower/Beneficiary/Recipient]* *[has received/has applied for/intends to apply for]* financing from the World Bank toward the cost of the *[insert name of project or grant]*, and intends to apply part of the proceeds toward payments under the contract ¹for *[insert title of contract]*².
2. The *[insert name of implementing agency]* intends to prequalify suppliers for *[insert contract number and/or name, a brief description of the type(s) of health goods to be provided, including quantities, location and other information necessary to enable potential Bidders to decide whether or not to respond to this Prequalification. This information may include the essential items listed in the Prequalification Document and also any important or specialized prequalification requirements]*. It is expected that the Request for Bids will be made in *[insert month and year]*.
3. Prequalification will be conducted through the procedures as specified in the World Bank's Procurement Regulations for IPF Borrowers - Procurement in Investment Projects Financing" *[insert date of applicable Procurement Regulations edition as per legal agreement]* ("Procurement Regulations"), and is open to all eligible Applicants as defined in the Procurement Regulations.

¹ If Prequalification is being invited for more than one contract, describe each contract and indicate whether Applications may be made for Prequalification for one or more of the contracts

² Insert if applicable: "This contract will be jointly financed by *[insert name of cofinancing agency]*. Procurement process will be governed by the World Bank's Procurement Regulations."

4. Interested eligible Applicants may obtain further information from the [insert name of agency] at the address below [insert address at end of document] during office hours [insert office hours if applicable, e.g. 0900 to 1700 hours]. A complete set of Prequalification Documents in [insert name of language] may be purchased by interested Applicants on the submission of a written Application to the address below and upon payment of a nonrefundable fee of [insert amount in local currency] or [insert amount in specified convertible currency, e.g. US\$]. The method of payment will be [insert method of payment]. The document will be sent by [insert delivery procedure].
5. Applications for Prequalification should be submitted in clearly marked envelopes and delivered to the address below by [insert time] on [insert date]. Electronic Applications will [will not] be permitted³. Late Applications may be rejected.

[Insert name of office]

[Insert name of officer and title]

[Insert postal address and/or street address, postal code, city and country]

[Insert telephone number, country and city codes]

[Insert facsimile number, country and city codes]

[Insert email address]

[Insert web site address]

³ 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. With the agreement of the World Bank, documents may be distributed by e-mail, downloaded from authorized web site(s) or electronic procurement system. PQ document (in Read Only form) should to be posted on the Purchaser's web page for inspection by prospective Applicants.

Prequalification Document

Health Goods

Procurement of:

[Insert type of Goods, e.g. Pharmaceuticals, Vaccines, Condoms]

Invitation for Prequalification No: *[insert reference from Procurement Plan]*

Project: *[insert name of project]*

Purchaser: *[insert the name of the Purchaser's agency]*

Country: *[insert country where Prequalification Document is issued]*

Issued on: *[insert date when Prequalification Document was issued to Applicants]*

(This Prequalification Document is for use with a Request for Bids process)

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PART 1 – Prequalification Procedures

Section I - Instructions to Applicants

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Section I - Instructions to Applicants

A. General

- 1. Scope of Application**
 - 1.1 In connection with the Invitation for Prequalification indicated in Section II, Prequalification Data Sheet (PDS), the Purchaser, as defined in the **PDS**, issues this Prequalification Document (“Prequalification Document”, “PD”) to prospective applicants (“Applicants”) interested in submitting applications (“Applications”) for Prequalification to bid for the of supply Health Sector Goods and Related Services incidental thereto as specified in Section VII, Scope of Supply. In case the Health Sector Goods are to be Bid as individual contracts (i.e. the slice and package procedure), these are listed **in the PDS**. The Request for Bids (RFB), number corresponding to this is also provided in the **PDS**.
- 2. Source of Funds**
 - 2.1 The Borrower or Recipient (hereinafter called “Borrower”) indicated in the **PDS** has applied for or received financing (hereinafter called “funds”) from the International Bank for Reconstruction and Development or the International Development Association (hereinafter called “the Bank”) towards the cost of the project named in the **PDS**. The Borrower intends to apply a portion of the funds to eligible payments under the contract(s) resulting from the Bidding for which this Prequalification is conducted.
 - 2.2 Payment by the Bank will be made only at the request of the Borrower and upon approval by the Bank, and will be subject, in all respects, to the terms and conditions of the Loan (or other financing) Agreement. The Loan (or other financing) Agreement prohibits a withdrawal from the loan (or credit) account for the purpose of any payment to persons or entities, or for any import of goods, equipment, plant or materials, or services 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 (or other financing) agreement or have any claim to the proceeds of the loan (or credit).
- 3. Fraud and Corruption**
 - 3.1 The Bank requires compliance with the Bank’s Anti-Corruption Guidelines and its prevailing sanctions policies and procedures as set forth in the WBG’s Sanctions Framework, as set forth in Section VI, Fraud and Corruption.
 - 3.2 In further pursuance of this policy, Applicants shall permit and shall cause their agents (where declared or not), subcontractors, subconsultants, service providers, suppliers, and their personnel, to permit the Bank to inspect all accounts, records and other

documents relating to any initial selection process, prequalification process, bid submission (in case prequalified), proposal submission, and contract performance (in the case of award), and to have them audited by auditors appointed by the Bank..

4. Eligible Applicants

- 4.1 Applicants shall meet the eligibility criteria as per ITA 5.1.
- 4.2 An Applicant may be a firm that is a private entity, a state-owned enterprise (subject to ITA 4.8), or any combination of such entities in the form of a joint venture (“JV”) under an existing agreement or with the intent to enter into such an agreement supported by a letter of intent. In the case of a joint venture, all members shall be jointly and severally liable for the execution of the entire Contract in accordance with the Contract terms. The JV shall nominate a Representative who shall have the authority to conduct all business for and on behalf of any and all the members of the JV during the Prequalification process, Bidding (in the event the JV submits a Bid) and during contract execution (in the event the JV is awarded the Contract). Unless specified **in the PDS**, there is no limit on the number of members in a JV.
- 4.3 A firm may apply for Prequalification both individually, and as part of a joint venture, or participate as a subcontractor. If prequalified, it will not be permitted to bid for the same contract both as an individual firm and as a part of the joint venture or as a subcontractor. However, a firm may participate as a subcontractor in more than one Bid, but only in that capacity. Bids submitted in violation of this procedure will be rejected.
- 4.4 A firm and any of its affiliates (that directly or indirectly control, are controlled by or are under common control with that firm) may submit its Application for Prequalification either individually, as joint venture or as a sub-contractor among them for the same contract. However, if prequalified only one prequalified Applicant will be allowed to bid for the same contract. All Bids submitted in violation of this procedure will be rejected.
- 4.5 An Applicant may have the nationality of any country, subject to the restrictions pursuant to ITA 5.1. An Applicant shall be deemed to have the nationality of a country if the Applicant is constituted, incorporated or registered in and operates in conformity with the provisions of the laws of that country, as evidenced by its articles of incorporation (or equivalent documents of constitution or association) and its registration documents, as the case may be. This criterion also shall apply to the determination of the nationality of proposed specialized sub-contractors or suppliers for any part of the Contract

including related Services.

- 4.6 Applicants shall not have a conflict of interest. Applicants shall be considered to have a conflict of interest, if they participated as a consultant in the preparation of the design or technical specifications or have been hired or proposed to be hired by the Purchaser or Borrower for contract implementation of the Health Sector Goods that are the subject of this Prequalification . In addition, Applicants may be considered to have a conflict of interest if they have a close business or family relationship with a professional staff of the Borrower (or of the project implementing agency, or of a recipient of a part of the loan) who:
- (a) are directly or indirectly involved in the preparation of the Prequalification Document or bidding document or specifications of the Contract, and/or the Bid evaluation process of such Contract; or
 - (b) would be involved in the implementation or supervision of such Contract, unless the conflict stemming from such relationship has been resolved in a manner acceptable to the Bank throughout the Bidding process and execution of the Contract.
- 4.7 An Applicant that has been sanctioned by the Bank, pursuant to the Bank’s Anti-Corruption Guidelines, and in accordance with its prevailing sanctions policies and procedures as set forth in the WBG’s Sanctions Framework, as described in Section VI, paragraph 2.2 d. shall be ineligible to be prequalified for, initially selected for, bid for, propose for, or be awarded a Bank-financed contract or benefit from a Bank-financed contract, financially or otherwise, during such period of time as the Bank shall have determined. The list of debarred firms and individuals is available at the electronic address specified in the PDS.
- 4.8 Applicants that are state-owned enterprises or institutions in the Purchaser’s Country may be eligible to participate only if they can establish, in a manner acceptable to the Bank, that they:
- (a) are legally and financially autonomous;
 - (b) operate under commercial law, and
 - (c) are not under supervision of the Purchaser.
- 4.9 An Applicant shall not be under suspension from Bidding by the Purchaser as the result of the execution of a Bid/Proposal–Securing Declaration.

4.10 An Applicant shall provide such documentary evidence of eligibility satisfactory to the Purchaser, as the Purchaser shall reasonably request.

4.11 A firm that is under a sanction of debarment by the Borrower from being awarded a contract is eligible to participate in this procurement, unless the Bank, at the Borrower's request, is satisfied that the debarment:

(a) relates to fraud or corruption; and

(b) followed a judicial or administrative proceeding that afforded the firm adequate due process.

5. Eligibility

5.1 Firms and individuals may be ineligible if they are nationals of ineligible countries as indicated in Section V. The countries, persons or entities are ineligible if:

(a) as a matter of law or official regulations, 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 goods or the contracting of works or services required; or

(b) 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 or contracting of works or services from that country, or any payments to any country, person, or entity in that country.

B. Contents of the Prequalification Document

6. Sections of Prequalification Document

6.1 This Prequalification Document consists of Parts 1 and 2 which comprise all the sections indicated below, and which should be read in conjunction with any Addendum issued in accordance with ITA 8.

PART 1 Prequalification Procedures

- Section I - Instructions to Applicants (ITA)
- Section II - Prequalification Data Sheet (PDS)
- Section III - Qualification Criteria and Requirements
- Section IV - Application Forms
- Section V - Eligible Countries
- Section VI - Fraud and Corruption

PART 2 Supply Requirements

- Section VII - Scope of Supply
- 6.2 Unless obtained directly from the Purchaser, the Purchaser accepts no responsibility for the completeness of the document, responses to requests for clarification, the minutes of the pre-Application meeting (if any), or Addenda to the Prequalification Document in accordance with ITA 8. In case of any discrepancies, documents issued directly by the Purchaser shall prevail.
- 6.3 The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Document and to furnish with its Application all information or documentation as is required by the Prequalification Document.
- 7. Clarification of Prequalification Document and Pre-Application Meeting**
- 7.1 An Applicant requiring any clarification of the Prequalification Document shall contact the Purchaser in writing at the Purchaser's address indicated **in the PDS**. The Purchaser will respond in writing to any request for clarification provided that such request is received no later than fourteen (14) days prior to the deadline for submission of the Applications. The Purchaser shall forward a copy of its response to all prospective Applicants who have obtained the Prequalification Document directly from the Purchaser, including a description of the inquiry but without identifying its source. If so indicated **in the PDS**, the Purchaser shall also promptly publish its response at the web page identified **in the PDS**. Should the Purchaser deem it necessary to amend the Prequalification Document as a result of a clarification, it shall do so following the procedure under ITA 8 and in accordance with the provisions of ITA 17.2.
- 7.2 If indicated **in the PDS**, the Applicant's designated representative is invited at the Applicant's cost to attend a pre-Application meeting at the place, date and time mentioned **in the PDS**. During this pre-Application meeting, prospective Applicants may request clarification of the project requirement, the criteria for qualifications or any other aspects of the Prequalification Document.
- 7.3 Minutes of the pre-Application meeting, if applicable, including the text of the questions asked by Applicants, including those during the meeting (without identifying the source) and the responses given, together with any responses prepared after the meeting will be transmitted promptly to all prospective Applicants who have obtained the Prequalification Document. Any modification to the Prequalification Document that may become necessary as a result of the pre-Application meeting shall be made by the Purchaser exclusively through the use of an Addendum pursuant to ITA 8. Non-attendance at the pre-Application meeting will not be a cause

for disqualification of an Applicant.

- 8. Amendment of Prequalification Document**
- 8.1 At any time prior to the deadline for submission of Applications, the Purchaser may amend the Prequalification Document by issuing an Addendum.
- 8.2 Any Addendum issued shall be part of the Prequalification Document and shall be communicated in writing to all Applicants who have obtained the Prequalification Document from the Purchaser. The Purchaser shall promptly publish the Addendum at the Purchaser’s web page identified **in the PDS**.
- 8.3 To give Applicants reasonable time to take an Addendum into account in preparing their Applications, the Purchaser may, at its discretion, extend the deadline for the submission of Applications in accordance with ITA 17.2.

C. Preparation of Applications

- 9. Cost of Applications**
- 9.1 The Applicant shall bear all costs associated with the preparation and submission of its Application. The Purchaser will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the Prequalification process.
- 10. Language of Application**
- 10.1 The Application as well as all correspondence and documents relating to the Prequalification exchanged by the Applicant and the Purchaser, shall be written in the language specified **in the PDS**. Supporting documents and printed literature that are part of the Application may be in another language, provided they are accompanied by an accurate translation of the relevant passages in the language specified **in the PDS**, in which case, for purposes of interpretation of the Application, the translation shall govern.
- 11. Documents Comprising the Application**
- 11.1 The Application shall comprise the following:
- (a) **Application Submission Letter**, in accordance with ITA 12.1;
 - (b) **Eligibility**: documentary evidence establishing the Applicant’s eligibility, in accordance with ITA 13.1;
 - (c) **Qualifications**: documentary evidence establishing the Applicant’s qualifications, in accordance with ITA 14; and
 - (d) any other document required as specified **in the PDS**.
- 11.2 The Applicant shall furnish information on commissions and gratuities, if any, paid or to be paid to agents or any other party relating to this Application
- 12. Application**
- 12.1 The Applicant shall complete an Application Submission Letter as

- Submission Letter** provided in Section IV, Application Forms. This Form must be completed without any alteration to its format.
- 13. Documents Establishing the Eligibility of the Applicant** 13.1 To establish its eligibility in accordance with ITA 4, the Applicant shall complete the eligibility declarations in the Application Submission Letter and Form ELI-1.1 (eligibility), included in Section IV, Application Forms.
- 14. Documents Establishing the Qualifications of the Applicant** 14.1 To establish its qualifications to perform the contract(s) in accordance with Section III, Qualification Criteria and Requirements, the Applicant shall provide the information requested in the corresponding Information Sheets included in Section IV, Application Forms.
- 14.2 Wherever an Application Form requires an Applicant to state a monetary amount, Applicants should indicate the USD equivalent using the rate of exchange determined as follows:
- (a) for turnover or financial data required for each year - Exchange rate prevailing on the last day of the respective calendar year (in which the amounts for that year is to be converted).
 - (b) value of single contract - Exchange rate prevailing on the date of the contract.
- 14.3 Exchange rates shall be taken from the publicly available source identified **in the PDS**. Any error in determining the exchange rates in the Application may be corrected by the Purchaser.
- 15. Signing of the Application and Number of Copies** 15.1 The Applicant shall prepare one original of the documents comprising the Application as described in ITA 11 and clearly mark it “ORIGINAL”. The original of the Application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant. In case the Applicant is a JV, the Application shall be signed by an authorized representative of the JV on behalf of the JV and so as to be legally binding on all the members as evidenced by a power of attorney signed by their legally authorized signatories.
- 15.2 The Applicant shall submit copies of the signed original Application, in the number specified **in the PDS**, and clearly mark them “COPY”. In the event of any discrepancy between the original and the copies, the original shall prevail.

D. Submission of Applications

- 16. Sealing and** 16.1 The Applicant shall enclose the original and the copies of the

- Identification of Applications**
- Application in a sealed envelope that shall:
- (a) bear the name and address of the Applicant;
 - (b) be addressed to the Purchaser, in accordance with ITA 17.1; and
 - (c) bear the specific identification of this Prequalification process indicated **in the PDS** reference ITA 1.1.
- 16.2 The Purchaser will accept no responsibility for not processing any envelope that was not identified as required in ITA 16.1 above.
- 17. Deadline for Submission of Applications**
- 17.1 Applicants may either submit their Applications by mail or by hand. Applications shall be received by the Purchaser at the address and no later than the deadline indicated **in the PDS**. When so specified **in the PDS**, Applicants have the option of submitting their Applications electronically, in accordance with electronic Application submission procedures specified **in the PDS**.
- 17.2 The Purchaser may, at its discretion, extend the deadline for the submission of Applications by amending the Prequalification Document in accordance with ITA 8, in which case all rights and obligations of the Purchaser and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.
- 18. Late Applications**
- 18.1 The Purchaser reserves the right to accept Applications received after the deadline for submission of Applications, unless otherwise specified **in the PDS**.
- 19. Opening of Applications**
- 19.1 The Purchaser shall open all Applications at the date, time and place specified **in the PDS**. Late Applications shall be treated in accordance with ITA 18.1.
- 19.2 Applications submitted electronically, if permitted pursuant to ITA 17.1, shall be opened in accordance with the procedures specified **in the PDS**.
- 19.3 The Purchaser shall prepare a record of the opening of Applications to include, as a minimum, the name of the Applicants. A copy of the record shall be distributed to all Applicants.
- E. Procedures for Evaluation of Applications**
- 20. Confidentiality**
- 20.1 Information relating to the Applications, their evaluation and results of the Prequalification shall not be disclosed to Applicants or any other persons not officially concerned with the Prequalification process until the notification of Prequalification

results is made to all Applicants in accordance with ITA 28.

- 20.2 From the deadline for submission of Applications to the time of notification of the results of the Prequalification in accordance with ITA 28, any Applicant that wishes to contact the Purchaser on any matter related to the Prequalification process may do so only in writing.
- 21. Clarification of Applications**
- 21.1 To assist in the evaluation of Applications, the Purchaser may, at its discretion, ask an Applicant for a clarification (including missing documents) of its Application, to be submitted within a stated reasonable period of time. Any request for clarification from the Purchaser and all clarifications from the Applicant shall be in writing.
- 21.2 If an Applicant does not provide clarifications and/or documents requested by the date and time set in the Purchaser’s request for clarification, its Application shall be evaluated based on the information and documents available at the time of evaluation of the Application.
- 22. Responsiveness of Applications**
- 22.1 The Purchaser may reject any Application which is not responsive to the requirements of the Prequalification Document. In case the information furnished by the Applicant is incomplete or otherwise requires clarification as per ITA 21.1, and the Applicant fails to provide satisfactory clarification and/or missing information, it may result in disqualification of the Applicant.
- 23. Margin of Preference**
- 23.1 Unless otherwise specified **in the PDS**, a margin of preference shall not apply in the Bidding process resulting from this Prequalification.
- 24. Sub-contractors**
- 24.1 Subcontractors’ qualification and experience will not be considered for evaluation of the Applicant. The Applicant on its own (without taking into account the qualification and experience of the Subcontractor) should meet the qualification criteria.

F. Evaluation of Applications and Prequalification of Applicants

- 25. Evaluation of Applications**
- 25.1 The Purchaser shall use the factors, methods, criteria, and requirements defined in Section III, Qualification Criteria and Requirements, to evaluate the qualifications of the Applicants, and no other methods, criteria, or requirements shall be used. The Purchaser reserves the right to waive minor deviations from the qualification criteria if they do not materially affect the technical capability and financial resources of an Applicant to perform the contract.

- 25.2 Subcontractors proposed by the Applicant shall be fully qualified for their parts of the Scope of Supply and Related Services of the Health Sector Goods.
- 25.3 In case of multiple contracts, Applicants should indicate in their Applications the individual contract or combination of contracts in which they are interested. The Purchaser shall prequalify each Applicant for the maximum combination of contracts for which the Applicant has thereby indicated its interest and for which the Applicant meets the appropriate aggregate requirements. The Qualification Criteria and Requirements are mentioned in Section III.
- 25.4 Only the qualifications of the Applicant shall be considered. The qualifications of other firms such as the Applicant’s subsidiaries, parent entities, affiliates, subcontractors or any other firm(s) different from the Applicant shall not be taken into consideration in determining the qualifications of the Applicant.
- 26. Purchaser’s Right to Accept or Reject Applications** 26.1 The Purchaser reserves the right to accept or reject any Application, and to annul the Prequalification process and reject all Applications at any time, without thereby incurring any liability to the Applicants.
- 27. Prequalification of Applicants** 27.1 All Applicants whose Applications substantially meet or exceed the specified qualification requirements will be prequalified by the Purchaser.
- 27.2 An Applicant may be “conditionally prequalified,” that is, qualified subject to the Applicant submitting or correcting certain specified nonmaterial documents or deficiencies to the satisfaction of the Purchaser.
- 27.3 Applicants that are conditionally prequalified will be so informed along with the statement of the condition(s) which must be met to the satisfaction of the Purchaser before or at the time of submitting their Bids.
- 28. Notification of Prequalification** 28.1 The Purchaser shall notify all Applicants in writing of the names of those Applicants who have been prequalified or conditionally prequalified. In addition, those Applicants who have been disqualified will be informed separately.
- 28.2 Applicants that have not been prequalified may write to the Purchaser to request, in writing, the grounds on which they were disqualified.
- 29. Request for** 29.1 Promptly after the notification of the results of the Prequalification,

- Bids** the Purchaser shall request Bids from all the Applicants that have been prequalified or conditionally prequalified.
- 29.2 Bidders may be required to provide a Bid Security or a Bid-Securing Declaration acceptable to the Purchaser in the form and an amount to be specified in the bidding document, and the successful Bidder shall be required to provide a Performance Security as specified in the bidding document.
- 29.3 If required in the Bidding documents, the successful Bidder shall provide additional information about its beneficial ownership using the Beneficial Ownership Disclosure Form included in the bidding document.
- 30. Changes in Qualifications of Applicants**
- 30.1 Any change in the structure or formation of an Applicant after being prequalified in accordance with ITA 27 and invited to bid (including, in the case of a JV, any change in the structure or formation of any member thereto) shall be subject to the written approval of the Purchaser prior to the deadline for submission of Bids. Such approval shall be denied if:
- (a) a prequalified Applicant proposes to associate with a disqualified Applicant or in case of a disqualified joint venture, any of its members;
 - (b) as a consequence of the change, the Applicant no longer substantially meets the qualification criteria set forth in Section III, Qualification Criteria and Requirements; or
 - (c) in the opinion of the Purchaser, the change may result in a substantial reduction in competition.
- 30.2 Any such change should be submitted to the Purchaser not later than fourteen (14) days after the date of the RFBs.
- 31. Procurement Related Complaint**
- 31.1 The procedures for making a Procurement-related Complaint are as specified in the PDS.

Section II - Prequalification Data Sheet (PDS)	
A. General	
ITA 1.1	<p>The identification number of the Invitation for Prequalification is: <i>[insert number]</i></p> <p>The Purchaser is: <i>[insert full name, including name of Project Officer, and address]</i></p> <p>The list of contracts is: <i>[insert number, names and identification numbers. If the Health Sector Goods have not been divided into contracts, add the name of the Health Sector Goods]</i></p>
ITA 2.1	<p>The name of the Borrower is: <i>[insert name of Borrower]</i></p> <p>The name of the Project is: <i>[insert name of Project]</i></p>
ITA 4.2	Maximum number of members in the JV shall be: <i>[insert a number or insert “not limited”]</i>
ITA 4.7	A list of debarred firms and individuals is available on the Bank’s external website: http://www.worldbank.org/debarr .
B. Contents of the Prequalification Document	
ITA 7.1	<p>For clarification purposes, the Purchaser’s address is: <i>[insert information or state “same as in ITA1.1 above”]</i></p> <p>Attention: <i>[insert name and room number of Project Officer]</i></p> <p>Address: <i>[insert street name and number]</i> <i>[insert floor and room number, if applicable]</i></p> <p>City: <i>[insert name of city or town]</i></p> <p>ZIP Code: <i>[insert postal (ZIP) code, if applicable]</i></p> <p>Country: <i>[insert name of country]</i></p> <p>Telephone: <i>[insert telephone number including country and city codes]</i></p> <p>Facsimile number: <i>[insert fax number including country and city codes]</i></p> <p>Electronic mail address: <i>[insert e-mail address of Project Officer]</i></p>
ITA 7.1 & 8.2	Web page: <i>[In case used, identify the widely used website or electronic portal of free access where Prequalification information is published]</i>

ITA 7.2	Pre-Application Meeting will be held: <i>[Yes/No]</i> <i>[If Yes, please add the address, date and time of the meeting]</i>
C. Preparation of Applications	
ITA 10.1	<p>This Prequalification document has been issued in the <i>[Insert “English” or “French” or “Spanish”]</i> language.</p> <p><i>[Note: In addition to one of the above languages, and if agreed with the Bank, the Borrower has the option to issue translated versions of the Prequalification document in another language which should either be: (a) the national language of the Borrower; or (b) the language used nation-wide in the Borrower’s country for commercial transactions. In such case, the following text shall be added:]</i></p> <p><i>“In addition, the Prequalification document is translated into the [insert national or nation-wide used] language [if there are more than one national or nation-wide used language, add “and in the _____” [insert the second national or nation-wide language].</i></p> <p><i>Applicants shall have the option to submit their Prequalification Application in any one of the languages stated above. Applicants shall not submit Applications in more than one language.]”</i></p> <p>All correspondence exchange shall be in _____ language.</p> <p>The Application as well as all correspondence shall be submitted in _____. <i>[Insert the language of the Prequalification document in case of one language]</i></p> <p><i>[Note: If the Prequalification document is issued in more than one language, the following text shall be inserted above: “in one of the above languages”]</i></p> <p>Language for translation of supporting documents and printed literature is _____. <i>[Specify one language]</i></p>
ITA 11.1 (d)	The Applicant shall submit with its Application, the following additional documents: <i>[insert list of additional documents]</i>
ITA 14.2	The source for determining exchange rates is <i>[insert a publicly available source]</i>
ITA 15.2	In addition to the original, the number of copies to be submitted with the Application is: <i>[insert number of copies]</i>
D. Submission of Applications	
ITA 17.1	<p>The deadline for Application submission is:</p> <p>Date: <i>[insert date]</i></p> <p>Time: <i>[insert time]</i></p>

	<p><i>[The time allowed for preparation and submission of the Prequalification Document should be sufficient for Applicants to gather all the information required—preferably eight weeks, but in any case not less than six weeks after the date when the documents are available for distribution or the date of the advertisement, whichever is later. This period may be longer for very large projects, where time should be allowed for the formation of joint ventures and assembly of the necessary resources.]</i></p> <p>For Application submission purposes only, the Purchaser’s address is:</p> <p><i>[insert information requested below or insert “Purchaser’s address is the same as that indicated in 1.1]</i></p> <p>Attention: <i>[insert name and room number of Project Officer]</i></p> <p>Address: <i>[insert street name and number]</i></p> <p><i>[insert floor and room number, if applicable]</i></p> <p>City: <i>[insert name of city or town]</i></p> <p>ZIP Code: <i>[insert postal (ZIP) code, if applicable]</i></p> <p>Country: <i>[insert name of country]</i></p> <p>Telephone: <i>[insert telephone number including country and city codes]</i></p> <p>Facsimile number: <i>[insert fax number including country and city codes]</i></p> <p>Email address: <i>[insert e-mail address of Project Officer]</i></p> <p>Applicants <i>[insert “shall” or “shall not”]</i> have the option of submitting their Applications electronically.</p> <p><i>[The following provision should be included and the required corresponding information inserted <u>only</u> if Applicants have the option of submitting their Applications electronically. Otherwise omit.]</i></p> <p>The electronic Application submission procedures shall be: <i>[insert a description of the electronic Application submission procedures.]</i></p>
ITA 18.1	<p><i>[Choose one of the two options below:]</i></p> <p>Late Applications will be returned unopened to the Applicants.</p> <p><i>[or]</i></p> <p>The Purchaser reserves the right to accept or reject late Applications.</p>
ITA 19.1	<p>The opening of the Applications shall be at <i>[Insert date, time and address]</i></p>
ITA 19.2	<p><i>[The following provision should be included and the required corresponding information inserted <u>only</u> if Applicants have the option of submitting their Applications electronically. Otherwise omit.]</i></p> <p>The electronic Application opening procedures shall be: <i>[insert a description</i></p>

	<i>of the electronic Application opening procedures.]</i>
E. Procedures for Evaluation of Applications	
ITA 23.1	<p><i>[The following provision should be included and the required corresponding information inserted <u>only</u> if the Procurement Plan authorizes the Application of a margin of preference and the Purchaser intends to apply it to the subject contract. Otherwise omit]</i></p> <p>A margin of domestic preference <i>[insert either “shall” or “shall not”]</i> _____ apply</p>
ITA 31.1	<p>The procedures for making a Procurement-related Complaint are detailed in the “Procurement Regulations for IPF Borrowers (Annex III).” If an Applicant wishes to make a Procurement-related Complaint, the Applicant should submit its complaint following these procedures, in writing (by the quickest means available, that is either by email or fax), to:</p> <p>For the attention: <i>[insert full name of person receiving complaints]</i></p> <p>Title/position: <i>[insert title/position]</i></p> <p>Purchaser : <i>[insert name of Purchaser]</i></p> <p>Email address: <i>[insert email address]</i></p> <p>Fax number: <i>[insert fax number] delete if not used</i></p> <p>In summary, at this stage, a Procurement-related Complaint may challenge any of the following:</p> <ol style="list-style-type: none"> 1. the terms of the Prequalification Documents; and 2. the Purchaser’s decision not to prequalify an Applicant.

Section III - Qualification Criteria and Requirements

This Section contains the methods, criteria, and requirements that the Purchaser shall use to evaluate Applications. The information to be provided in relation to each requirement and the definitions of the corresponding terms are included in the respective Application Forms.

Contents

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2. Historical Contract Non-Performance.....	24
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4. Experience	26

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
No.	Subject	Requirement	Single Entity	Joint Venture (existing or intended)			Submission Requirements
				All Members Combined	Each Member	One Member	
1. Eligibility							
1.1	Nationality	Nationality in accordance with ITA 4.5	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
1.2	Conflict of Interest	No conflicts of interest in accordance with ITA 4.6	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Application Submission Letter
1.3	Bank Eligibility	Not having been declared ineligible by the Bank, as described in ITA 4.7 and 5.1	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Application Submission Letter
1.4	State-owned enterprise of the Borrower country	Meet conditions of ITA 4.8	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
1.5	United Nations resolution or Borrower’s country law	Not having been excluded as a result of prohibition in the Borrower’s country laws or official regulations against commercial relations with the Applicant’s country, or by an act of compliance with UN Security Council resolution, both in accordance with ITA 5.1 and Section V.	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
2. Historical Contract Non-Performance							
2.1	History of Non-	Non-performance of a contract ¹ did not occur as a	Must meet	Must meet requirements	Must meet requirement ²	N/A	Form PER-1

¹ Non performance, as decided by the Purchaser, shall include all contracts where (a) non performance was not challenged by the Supplier, including through referral to the dispute resolution mechanism under the respective contract, and (b) contracts that were so challenged but fully settled against the Supplier. Non performance shall not include contracts where Purchaser’s decision was overruled by the dispute resolution mechanism. Non performance must be based on all information on fully settled disputes or litigation, i.e. dispute or litigation that has been resolved in accordance with the dispute resolution mechanism under the

Eligibility and Qualification Criteria				Compliance Requirements			Documentation
No.	Subject	Requirement	Single Entity	Joint Venture (existing or intended)			Submission Requirements
				All Members Combined	Each Member	One Member	
	Performing Contracts	result of Supplier's default since 1 st January [<i>insert year</i>].	requirement ²				
2.2	Suspension Based on Execution of Bid/Proposal Securing Declaration by the Purchaser	Not under suspension based on execution of a Bid/Proposal Securing Declaration pursuant to ITA 4.9.	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Application Submission Letter
2.3	Pending Litigation	Applicant's financial position and prospective long term profitability still sound according to criteria established in 3.1 below and assuming that all pending litigation will be resolved against the Applicant	Must meet requirement	N/A	Must meet requirement	N/A	Form PER-1
2.4	Litigation History	No consistent history of court/arbitral award decisions against the Applicant since 1 st January [<i>insert year</i>] ³	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Form PER-1
3. Financial Situation and Performance							
3.1	Financial Capabilities	The audited balance sheets or, if not required by the laws of the Applicant's country, other	Must meet requirement	N/A	Must meet requirement	N/A	

respective contract and where all appeal instances available to the Applicant have been exhausted.

² This requirement also applies to contracts executed by the Applicant as JV member.

³ The Applicant shall provide accurate information on the Application Submission Form about any litigation or arbitration resulting from contracts completed or ongoing under its execution over the last five years. A consistent history of court/arbitral awards against the Applicant or any member of a joint venture may result in disqualifying the Applicant.

Eligibility and Qualification Criteria			Compliance Requirements				Documentation
No.	Subject	Requirement	Single Entity	Joint Venture (existing or intended)			Submission Requirements
				All Members Combined	Each Member	One Member	
		financial statements acceptable to the Purchaser, for the last <i>[insert number]</i> years shall be submitted and must demonstrate the current soundness of the Applicant’s financial position and indicate its prospective long-term profitability.					
3.2	Average Annual Turnover	Average annual turnover (Average Annual Sales Revenue) from supply of Health Sector Goods of US\$ <i>[insert amount in US\$ equivalent in words and figures]</i> , calculated as total certified payments received for contracts in progress and/or completed during the last three years. <i>[Insert a figure which is at least five times the estimated contract amount]</i>	Must meet requirement	Must meet requirement	N/A	N/A	Form FIN – 3.2
3.3	Current Commitments	The Applicant shall also demonstrate, to the satisfaction of the Purchaser, that it has adequate sources of finance to meet the cash flow requirements on contracts currently in progress and for future contract commitments.					Form CON -1
4. Experience							
4.1	General	Experience in supply of	Must meet	N/A	Must meet	N/A	Form EXP –1

Eligibility and Qualification Criteria			Compliance Requirements			Documentation	
No.	Subject	Requirement	Single Entity	Joint Venture (existing or intended)			Submission Requirements
				All Members Combined	Each Member	One Member	
	Experience	Health Sector Goods for at least the last three years	requirement		requirement		
4.2 (a)	Specific Experience	(i) Documentary evidence of the Applicant’s qualifications to perform the Contract in accordance with 4.2 (b)(i) below (ii) Technical and Production Capability in accordance with 4.2(b)(ii) as below. (iii) Experience on Packaging, Distribution in accordance with 4.2(b)(iii) below. (iv) Registration Requirement in accordance with 4.2(b)(iv) below.	Must meet requirement Must meet requirement Must meet requirement Must meet requirement	Must meet requirement Must meet requirement Must meet requirement Must meet requirement	N/A N/A N/A Must meet requirement	Must meet requirement Must meet requirement Must meet requirement Must meet requirement	
4.2 (b)	See below for details						

Specific Experience Requirements

The Specific Experience Requirements under 4.2 (b) are as follows:

4.2 (b)(i) Documentary evidence

The following documents must be included with the Application:

Documentary evidence of the Applicant's qualifications to perform the Contract if its Bid is accepted:

- (i) that, in the case of an Applicant offering to supply Goods under the Contract that the – Applicant manufactures or otherwise produces (using ingredients supplied by primary manufacturers) that the Applicant:
 - (a) is incorporated in the country of manufacture of the Goods;
 - (b) has been licensed by the regulatory authority in the country of manufacture to supply the Goods;
 - (c) has manufactured and marketed the specific goods covered by this Prequalification 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 Application submission;
- (ii) that, in the case of an Applicant offering to supply Goods under the Contract that the Applicant does not manufacture or otherwise produce,
 - (a) that the Applicant 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 using the Manufacturer Authorization Form; and
- (iii) the Applicant shall also submit the following additional information:
 - (a) a statement of installed manufacturing capacity;
 - (b) details of on-site quality control laboratory facilities and services and range of tests conducted;
 - (c) list of major supply contracts conducted within the last three years.

4.2(b)(ii) Technical and Production Capability

The Applicant shall provide evidence that it has the technical, and production capability necessary to perform the Contract:

- (i) that it has successfully completed or substantially completed at least [*insert number*] similar contracts for supply of the goods and within the last five years. [*The number of similar contracts required should be not less than three and not more than five (normally four), depending on the size and complexity of the subject contract.*] Similar contracts are those of approximately the same size and that includes comparable products, e.g., capsules, tablets, vaccines.

The goods may have been supplied by the Applicant as a manufacturer or by its agent, with references being submitted to confirm satisfactory performance,

- (ii) that it has achieved an annual average production rate of _____ [*The annual production rate required should be at least three times the quantities specified under the contract*] during the last three years

4.2 (b)(iii) Experience on Packaging, Distribution and Transportation

The Applicant should provide proof of experience with and knowledge of modes of packing, distribution, and transportation of pharmaceuticals similar to those subject to bidding under logistical and climatic conditions similar to the ones in the purchaser's country. It should provide names of countries to which the Applicant has supplied (including packaged, distributed, and transported) products worth at least the amount [*insert the amount*] within the past three years.

4.2(b)(iv) Registration Requirements

The Goods to be supplied under the Contract shall be registered with the relevant authority in the Purchaser's country. An Applicant who has already registered its Goods by the time of Prequalification should submit a copy of the Registration Certificate with its Application (subject to subsequent confirmation at Bid submission). An Applicant who has not registered its goods subject of Bidding and wishes to commence the process of registration, should refer to the agency and contact person identified below. [*insert name, address, telephone, e-mail address, and contact persons for registration offices, i.e., Pharmaceutical registration, Pharmacological committee of Ministry of Health, Pharmacopoeia committee of Ministry of Health, Department of governmental control for quality, efficiency and safety of pharmaceuticals and medical equipment*]

If Registration is a requirement in the country of the Purchaser, the bidding document for the Procurement of Health Sector Goods stipulates that:

A Bidder who has already registered the 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 been obtained;
- (b) evidence establishing to the Purchaser's satisfaction that the Bidder has complied with the following documentary requirements in order to register the Goods to be supplied under the Contract: *[insert documentary requirements]*

Section IV - Application Forms

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Application Submission Letter

Date: *[insert day, month, and year]*
 RFB No. and title: *[insert RFB number and title]*

To: *[insert full name of Purchaser]*

We, the undersigned, apply to be prequalified for the referenced RFB and declare that:

- (a) **No reservations:** We have examined and have no reservations to the Prequalification Document, including Addendum(s) No(s), issued in accordance with Instructions to Applicants (ITA) 8: *[insert the number and issuing date of each addendum]*.
- (b) **No conflict of interest:** We have no conflict of interest in accordance with ITA 4.6;
- (c) **Eligibility:** We (and our subcontractors) meet the eligibility requirements as stated ITA 4.1, we have not been suspended by the Purchaser based on execution of a Bid/Proposal Securing Declaration in accordance with ITA 4.9;
- (d) **Suspension and Debarment:** We, along with any of our subcontractors, suppliers, consultants, manufacturers, or service providers for any part of the contract, are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the World Bank Group or a debarment imposed by the World Bank Group in accordance with the Agreement for Mutual Enforcement of Debarment Decisions between the World Bank and other development banks. Further, we are not ineligible under the Purchaser’s country laws or official regulations or pursuant to a decision of the United Nations Security Council;
- (e) **State-owned enterprise or institution:** *[select the appropriate option and delete the other] [We are not a state-owned enterprise or institution] / [We are a state-owned enterprise or institution but meet the requirements of ITA 4.8];*
- (f) **Commissions, gratuities, fees:** We declare that the following commissions, gratuities, or fees have been paid or are to be paid with respect to the Prequalification process, the corresponding Bidding process or execution of the Contract:

<u>Name of Recipient</u>	<u>Address</u>	<u>Reason</u>	<u>Amount</u>
<i>[insert full name for each occurrence]</i>	<i>[insert street/number/city/country]</i>	<i>[indicate reason]</i>	<i>[specify amount currency, value, exchange rate and US\$ equivalent]</i>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

[If no payments are made or promised, add the following statement: “No commissions or gratuities have been or are to be paid by us to agents or any third party relating to this Application.]

- (g) **Not bound to accept:** We understand that you may cancel the Prequalification process at any time and that you are neither bound to accept any Application that you may receive nor to invite the prequalified Applicants to bid for the contract subject of this Prequalification process, without incurring any liability to the Applicants, in accordance with ITA 26.1.
- (h) **True and correct:** All information, statements and description contained in the Application are in all respect true, correct and complete to the best of our knowledge and belief.

Signed: *[insert signature(s) of an authorized representative(s) of the Applicant]*

Name: *[insert full name of person signing the Application]*

In the capacity of: *[insert capacity of person signing the Application]*

Duly authorized to sign the Application for and on behalf of: *[insert full name of the Applicant or the name of the JV]*

Address: *[insert street number/town or city/country address]*

Dated: *[insert date the document is signed i.e. day number] day of [insert month], [insert year]*

[For a joint venture, either all members shall sign or only the authorized representative, in which case the power of attorney to sign on behalf of all members shall be attached]

Form ELI -1.1

Applicant Information Form

Date: *[insert day, month, year]*

RFB No. and title: *[insert RFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

Applicant's name <i>[insert full name]</i>
In case of Joint Venture (JV), name of each member: <i>[insert full name of each member in JV]</i>
Applicant's actual or intended country of registration: <i>[indicate country of Constitution]</i>
Applicant's actual or intended year of incorporation: <i>[indicate year of Constitution]</i>
Applicant's legal address [in country of registration]: <i>[insert street/ number/ town or city/ country]</i>
Applicant's authorized representative information Name: <i>[insert full name]</i> Address: <i>[insert street/ number/ town or city/ country]</i> Telephone/Fax numbers: <i>[insert telephone/fax numbers, including country and city codes]</i> E-mail address: <i>[indicate e-mail address]</i>
1. Attached are copies of original documents of <input type="checkbox"/> Articles of Incorporation (or equivalent documents of constitution or association), and/or documents of registration of the legal entity named above, in accordance with ITA 4.5. <input type="checkbox"/> In case of JV, letter of intent to form JV or JV agreement, in accordance with ITA 4.2. <input type="checkbox"/> In case of state-owned enterprise or institution, in accordance with ITA 4.8 documents establishing: <ul style="list-style-type: none"> • Legal and financial autonomy • Operation under commercial law • Establishing that the Applicant is not under supervision of the Purchaser
2. Included are the organizational chart, a list of Board of Directors, and the beneficial ownership.

In case of JV, the Applicant's information shall include information on each JV member and letter of intent to form JV or JV agreement, in accordance with ITA 4.2

Form ELI -1.1 (continued) Applicant Information Form

Date: *[insert day, month, year]*

RFB No. and title: *[insert RFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

1. Applicant's name			
2. 2. Street Address:	Postal Code:	City:	Country:
3. P.O. Box and Mailing Address:			
4. Telephone Number:			
5. Fax Number:			
6. E-mail Address:			
7. Web Site:			
8. Contact Name:			
9. Contact Title:			
10. Type of Business:			
11. If Other, specify:			
12. Nature of Business:			
13. Year Established:			
14. Dates, Numbers, and Expiration Dates of Current Licenses and Permits:			
15. Current health authority registration information:			
16. Proof of product and facility registrations with purchaser's country regulatory authority and international agencies (e.g., WHO Certification Scheme, GMP)			
17. Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods:			
Date of last inspection:			

18. Quality Assurance Certification (Please include a copy of your latest certificate with the PQ Application):	
19. Production capacity: <i>[insert peak and average production capacity over the last three years in units/day or units/month, etc.]</i>	
20. List of names and addresses of sources of raw material and what products they will be used in:	
21. Proof of raw material product and facility registrations with purchaser's country regulatory authority and international agencies (e.g., WHO Certification Scheme, GMP):	
22. Raw materials tested prior to use:	
23. Presence and characteristics of in-house quality control laboratory	
24. Names and addresses of external quality control laboratories used:	
25. Are all finished products tested and released by quality control prior to release for sale? Yes ___ No ___, If not, why?	
26. List control tests done during production? If so list.	
27. Procedures for dealing with rejected batches:	
28. List tests conducted after production and prior to release of product on market:	
29. List product recalls linked to defects during the last 36 months. Include reason and date of recall.	
30. Are technical documents available in: <i>[Purchaser should insert language]</i> Yes No	

Form FIN – 3.1 Financial Situation and Performance

[The following table shall be filled in for the Applicant and for each member of a Joint Venture]

Applicant's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]*

RFB No. and title: *[insert RFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

1. Financial data

Type of Financial information in (currency)	Historic information for previous <i>[insert number]</i> years, <i>[insert in words]</i> (amount in currency, currency, exchange rate*, USD equivalent)				
	Year 1	Year 2	Year 3		
Statement of Financial Position (Information from Balance Sheet)					
Total Assets (TA)					
Total Liabilities (TL)					
Total Equity/Net Worth (NW)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital (WC)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					
Cash Flow Information					

Cash Flow from Operating Activities					
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* Refer ITA 14 for the exchange rate

3. Financial documents

The Applicant and its parties shall provide copies of financial statements for *[number]* years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

- (a) reflect the financial situation of the Applicant or in case of JV member, and not an affiliated entity (such as parent company or group member).
 - (b) be independently audited or certified in accordance with local legislation.
 - (c) be complete, including all notes to the financial statements.
 - (d) correspond to accounting periods already completed and audited.
- Attached are copies of financial statements¹ for the *[number]* years required above; and complying with the requirements

¹ If the most recent set of financial statements is for a period earlier than 12 months from the date of Application, the reason for this should be justified.

Form FIN - 3.2

Average Annual Turnover (Annual Sales Value)

[The following table shall be filled in for the Applicant and for each member of a Joint Venture]

Applicant's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]*

RFB No. and title: *[insert RFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

Annual turnover data			
Year	Amount Currency	Exchange rate*	USD equivalent
<i>[indicate calendar year]</i>	<i>[insert amount and indicate currency]</i>		
		Average Annual Turnover **	

* Refer ITA 14 for date and source of exchange rate.

** Total USD equivalent for all years divided by the total number of years. See Section III, Qualification Criteria and Requirements, ITA 3.2.

Current Contract Commitments / Contracts in Progress Form CON-1

1. Name of Contract(s)
2. Purchaser Contact Information [insert address, telephone, fax, e-mail address]
3. Value of outstanding contracts [current US\$ equivalent]
4. Estimated delivery date
5. Average monthly invoices over the last six months (US\$/mon.)

Form- EXP-1

44. Contracts over <i>[insert amount]</i> during the last three years:				
Purchaser	Value	Year	Goods/Services Supplied	Country of Destination

Form- PER 1

Historical Contract Non-Performance, and Pending Litigation and Litigation History

[The following table shall be filled in for the Applicant and for each member of a Joint Venture]

Applicant's Name: *[insert full name]*

Date: *[insert day, month, year]*

Joint Venture Member Name: *[insert full name]*

RFB No. and title: *[insert RFB number and title]*

Page *[insert page number]* of *[insert total number]* pages

Non-Performed Contracts in accordance with Section III, Qualification Criteria and Requirements			
<input type="checkbox"/> Contract non-performance did not occur since 1 st January <i>[insert year]</i> specified in Section III, Qualification Criteria and Requirements, Sub-Factor 2.1.			
<input type="checkbox"/> Contract(s) not performed since 1 st January <i>[insert year]</i> specified in Section III, Qualification Criteria and Requirements, requirement 2.1			
Year	Non-performed portion of contract	Contract Identification	Total Contract Amount (current value, currency, exchange rate and US\$ equivalent)
<i>[insert year]</i>	<i>[insert amount and percentage]</i>	Contract Identification: <i>[indicate complete contract name/ number, and any other identification]</i> Name of Purchaser: <i>[insert full name]</i> Address of Purchaser: <i>[insert street/city/country]</i> Reason(s) for nonperformance: <i>[indicate main reason(s)]</i>	<i>[insert amount]</i>
Pending Litigation, in accordance with Section III, Qualification Criteria and Requirements			
<input type="checkbox"/> No pending litigation in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.3			
<input type="checkbox"/> Pending litigation in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.3 as indicated below.			
Year of dispute	Amount in dispute (currency)	Contract Identification	Total Contract Amount (currency), USD Equivalent

			(exchange rate)
<i>[insert year]</i>	<i>[insert amount]</i>	<p>Contract Identification: [indicate complete contract name, number, and any other identification] Name of Purchaser: <i>[insert full name]</i> Address of Purchaser: <i>[insert street/city/country]</i> Matter in dispute: <i>[indicate main issues in dispute]</i> Party who initiated the dispute: <i>[indicate "Purchaser" or "Supplier"]</i></p> <p>Status of dispute: <i>[Indicate if it is being treated by the Adjudicator, under Arbitration or being dealt with by the Judiciary]</i></p>	<i>[insert amount]</i>
<p><input type="checkbox"/> No consistent history of court/arbitral award decisions in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.4.</p> <p><input type="checkbox"/> Consistent history of court/arbitral award decisions in accordance with Section III, Qualification Criteria and Requirements, Sub-Factor 2.4 as indicated below.</p>			
Year of award	Outcome as percentage of Net Worth	Contract Identification	Total Contract Amount (currency), USD Equivalent (exchange rate)
<i>[insert year]</i>	<i>[insert percentage]</i>	<p>Contract Identification: [indicate complete contract name, number, and any other identification] Name of Purchaser: <i>[insert full name]</i> Address of Purchaser: <i>[insert street/city/country]</i> Matter in dispute: <i>[indicate main issues in dispute]</i> Party who initiated the dispute: <i>[indicate "Purchaser" or "Supplier"]</i> Court/ arbitral award decision: <i>[Indicate if the award decision was against the Applicant or any member of a joint venture.]y]</i></p>	<i>[insert amount]</i>

Manufacturer's Authorization

[The Applicant shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. This letter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer.]

Date: *[insert date (as day, month and year) of Application Submission]*
RFB No.: *[insert number]*

To: *[insert complete name of Purchaser]*

WHEREAS

We *[insert complete name of Manufacturer]*, who are official manufacturers of *[insert type of goods manufactured]*, having factories at *[insert full address of Manufacturer's factories]*, do hereby authorize *[insert complete name of Applicant]* to **submit a Prequalification Application and submit a Bid** the purpose of which is to provide the following Goods, manufactured by us *[insert name and or brief description of the Goods]*, and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with the **General Conditions of Contract**, with respect to the Goods offered by the above firm.

Signed: *[insert signature(s) of authorized representative(s) of the Manufacturer]*

Name: *[insert complete name(s) of authorized representative(s) of the Manufacturer]*

Title: *[insert title]*

Dated on _____ day of _____, _____ *[insert date of signing]*

Section V - Eligible Countries

Eligibility for the Provision of Goods, Works and Services in Bank-Financed Procurement

In reference to ITA 5.1, for the information of the Applicants, at the present time firms and individuals, supply of goods, or contracting of works or services, from the following countries are excluded from this Prequalification process:

Under ITA 5.1 (a): *[insert a list of the countries following approval by the Bank to apply the restriction or state "none"]*

Under ITA 5.1 (b): *[list the countries or state "none"]*

Section VI - Fraud and Corruption

(This Section VI shall not be modified)

1. Purpose

1.1 The Bank's Anti-Corruption Guidelines and this annex apply with respect to procurement under Bank Investment Project Financing operations.

2. Requirements

2.1 The Bank requires that Borrowers (including beneficiaries of Bank financing); bidders (applicants/proposers), consultants, contractors and suppliers; any sub-contractors, sub-consultants, service providers or suppliers; any agents (whether declared or not); and any of their personnel, observe the highest standard of ethics during the procurement process, selection and contract execution of Bank-financed contracts, and refrain from Fraud and Corruption.

2.2 To this end, the Bank:

a. Defines, for the purposes of this provision, the terms set forth below as follows:

- i. "corrupt practice" is the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;
- ii. "fraudulent practice" is any act or omission, including misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain financial or other benefit or to avoid an obligation;
- iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;
- iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;
- v. "obstructive practice" is:
 - (a) deliberately destroying, falsifying, altering, or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive, or collusive practice; and/or threatening, harassing, or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

- (b) acts intended to materially impede the exercise of the Bank’s inspection and audit rights provided for under paragraph 2.2 e. below.
- b. Rejects a proposal for award if the Bank determines that the firm or individual recommended for award, any of its personnel, or its agents, or its sub-consultants, sub-contractors, service providers, suppliers and/ or their employees, has, directly or indirectly, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question;
- c. In addition to the legal remedies set out in the relevant Legal Agreement, may take other appropriate actions, including declaring misprocurement, if the Bank determines at any time that representatives of the Borrower or of a recipient of any part of the proceeds of the loan engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices during the procurement process, selection and/or execution of the contract in question, without the Borrower having taken timely and appropriate action satisfactory to the Bank to address such practices when they occur, including by failing to inform the Bank in a timely manner at the time they knew of the practices;
- d. Pursuant to the Bank’s Anti-Corruption Guidelines, and in accordance with the Bank’s prevailing sanctions policies and procedures, may sanction a firm or individual, either indefinitely or for a stated period of time, including by publicly declaring such a firm or individual ineligible (i) to be awarded or otherwise benefit from a Bank-financed contract, financially or in any other manner;¹ (ii) to be a nominated² sub-contractor, consultant, manufacturer or supplier, or service provider of an otherwise eligible firm being awarded a Bank-financed contract; and (iii) to receive the proceeds of any loan made by the Bank or otherwise to participate further in the preparation or implementation of any Bank-financed project;
- e. Requires that a clause be included in request for bid/request for proposals documents and in contracts financed by a Bank loan, requiring (i) bidders (applicants/proposers), consultants, contractors, and suppliers, and their sub-contractors, sub-consultants, service providers, suppliers, agents personnel, permit the Bank to inspect³ all accounts, records and other documents relating to the

¹ For the avoidance of doubt, a sanctioned party’s ineligibility to be awarded a contract shall include, without limitation, (i) applying for pre-qualification, expressing interest in a consultancy, and bidding, either directly or as a nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider, in respect of such contract, and (ii) entering into an addendum or amendment introducing a material modification to any existing contract.

² A nominated sub-contractor, nominated consultant, nominated manufacturer or supplier, or nominated service provider (different names are used depending on the particular bidding document) is one which has been: (i) included by the bidder in its pre-qualification Application or bid because it brings specific and critical experience and know-how that allow the bidder to meet the qualification requirements for the particular bid; or (ii) appointed by the Borrower.

³ Inspections in this context usually are investigative (i.e., forensic) in nature. They involve fact-finding activities undertaken by the Bank or persons appointed by the Bank to address specific matters related to investigations/audits, such as evaluating the veracity of an allegation of possible Fraud and Corruption, through the appropriate mechanisms. Such activity includes but is not

procurement process, selection and/or contract execution, and to have them audited by auditors appointed by the Bank.

limited to: accessing and examining a firm's or individual's financial records and information, and making copies thereof as relevant; accessing and examining any other documents, data and information (whether in hard copy or electronic format) deemed relevant for the investigation/audit, and making copies thereof as relevant; interviewing staff and other relevant individuals; performing physical inspections and site visits; and obtaining third party verification of information.

PART 2 – Scope of Supply

Section VII - Scope of Supply

[Insert name of goods]

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1. Scope of Supply

2. Delivery Schedule