

ANNEX 2 – INSTRUCTIONS FOR TECHNICAL PROPOSALS AND OFFERS

This section is intended to ensure that technical dossiers are submitted in a manner that they can be easily identified, stored, retrieved and assessed in an efficient manner. All technical documents MUST be UPLOADED to a UNICEF SharePoint¹ site as per instructions in Annex XX. For your SharePoint site to be established, send email to mpodobnikar@unicef.org with full name and address of bidder and INN descriptions of products of interest.

1. **UNICEF Technical Questionnaire for Pharmaceutical Manufacturers:**
All bidders shall fill in the UNICEF Technical Questionnaire for manufacturers (Annex 2a). Fill in One Technical Questionnaire per manufacture SITE from where FPPs offered are manufactured.
2. **UNICEF Technical Questionnaire for Pharmaceutical Wholesalers:**
Wholesalers and distributors shall to fill in the UNICEF Technical Questionnaire for wholesalers (Annex 2b). The bidder must provide evidence that they are authorized by the FPP manufacturer and/or marketing authorization holder to offer their product(s) in UNICEF tender
3. **Interagency Finished Pharmaceutical Product Questionnaire (IAFPPQ)**
Bidders are required to fill the electronic Inter Agency Finished Pharmaceutical Product Questionnaire (IAFPPQ) (Annex 2c) if
 - a. Product is manufactured and/or supplied from Non-ICH countries with no marketing authorization from an International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) regulatory member competent authority
 - b. Product is manufactured and/or supplied from Non-Pharmaceutical Inspectorate Cooperation Scheme (PIC/S) countries
 - c. Product is manufactured and/or sourced from an ICH or PIC/S country, but the product does not have marketing authorization in that country or is registered "FOR EXPORT ONLY"
 - d. UNICEF has limited or no prior procurement experience of the product(s) irrespective of country of manufacture or marketing authorization status.

Fill in ONE Interagency Questionnaire per Finished Pharmaceutical Product (FPP) offered.

- a. Documents submitted as Annexes to the Interagency Finished Pharmaceutical Product Questionnaire should be in editable PDF format and should be well indexed, labelled and organized as instructed in Annex XX instructions to upload technical documents in SharePoint
- b. Section 5 of the IAFPPQ Commitment and signature page (Annex 2d). This section contains the signed commitment and authorisation related to the product for which the Interagency Finished Pharmaceutical Product Questionnaire is submitted for. It must be submitted for each offered FPP/ Interagency Questionnaire.

IMPORTANT: The Interagency Questionnaire is a PDF form that must be filled in correctly in line with the documents/data submitted as Annexes (per Section 6 of the Interagency Questionnaire) and other relevant documentation. The filled in PDF form will be a key document used in UNICEF's technical evaluation for each product. The completed PDF form must be returned in the exact same PDF format. **(Do NOT print or scan, do not fill in with pen, do not include pictures).**

4. **An API declaration form (Annex 2e)** must be completed for each API used for manufacture of each FPP offered in this tender. Fill in ONE API declaration form for each API validated for use in the FPP.
5. **UNICEF Technical offer form (Annex 2f) or the UNICEF TECHNICAL COMMITMENT DECLARATION FORM (Annex 2g)**
Bidders shall fill the Technical offer form or UNICEF TECHNICAL COMMITMENT DECLARATION FORM if:
 - a. Product has been technically assessed by UNICEF in the preceding 5 years and accorded an unqualified "acceptable" status with no quality issues during that period;
 - b. Product has been assessed by UNICEF in the preceding 3 years and accorded a qualified or conditional "acceptable" status and the qualified or conditional acceptance status resolved;
 - c. Product has Marketing Authorization from a Stringent Regulatory Authority²

¹ Request an option for Cloud based file transfer ONLY if it is not feasible to upload documents in SharePoint

² 1)a member of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) prior to 23 October 2015, namely: the US Food and Drug Administration, the European Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or 2)an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or 3) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

- d. Product has Marketing Authorization from a regulatory authority that is PIC/S member for products manufactured in their own country. IAFPPQ (Annex XZ) is required if UNICEF has limited or no prior procurement experience from the manufacturing site in that PIC/S country.
- e. Product(s) and manufacture site(s) has been technically assessed and approved by the partners below
 - i. World Health Organization prequalification programme, <https://extranet.who.int/prequal/>
 - ii. WHO conducted Expert Review Panel (ERP)
 - iii. Médecins Sans Frontières (MSF) International
 - iv. Other agencies included in the IAFPPQ

Note: The bidder is required to sign a letter of authorization permitting UNICEF access to information from these agencies. Please contact rshonhiwa@unicef.org for a draft LETTER OF AUTHORIZATION.

6. Clarifications and additional information

- a. The bidder may be requested to clarify or provide additional information and/or documentation to facilitate technical evaluation.

7. About all technical documents

- Documents that are NOT originally in English language MUST be accompanied by an accurate professional English translation and certified as a true translation of the original
- No handwritten documents will be accepted
- All documents/filled forms shall have no interlineations, erasures, or overwriting. Any necessary corrections shall be initialled by the person or persons signing the bid

Annexes accompanying the IAPPQ should be uploaded individually and named appropriately in the manner shown below:

Annex-A - Batch Formula

Annex-AA - Graphic summary of BE results

Annex-AB - BE Study Report

Annex-B - Primary Packaging

Annex-C - Secondary Packaging

Annex-D- Manufacturing licence

Annex-E-CPP

Annex-G-WHO prequalification letter

Annex-I-Labeling

Annex-J- SmPC and PIL

Annex-K - API GMP certificate

Annex-L - API specification

Annex-M - Method validation

Annex-O - API COA

Annex-P1 - CEP certificate

Annex-P2 - Technical File

Annex-Q - FPP GMP certificate

Annex-R - FPP Specifications

Annex-S - FPP COA

Annex-T - Process Flow Sheet

Annex-V - Stability Data

Annex-W - Stability Declaration

Annex-X - Status of On-going Stability

Interagency Finished Pharmaceutical Product questionnaire

Other documents - API Declaration form

Other documents - Indicate name of document here

Signed pages

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