

ANNEX 2 – INSTRUCTIONS FOR TECHNICAL PROPOSALS AND OFFERS

This annex 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 SharePoint site as per instructions in Annex 3. For your SharePoint site to be established, send email to rshonhiwa@unicef.org with full name and address of bidder and INN descriptions of products of interest.

1. UNICEF Technical Questionnaire for Pharmaceutical Manufacturers:

All Proposers that are manufacturers shall fill in the UNICEF Technical Questionnaire for manufacturers (Annex 2a). Fill in One Technical Questionnaire per manufacturing SITE where FPPs offered are manufactured.

2. UNICEF Technical Questionnaire for Pharmaceutical Wholesalers:

All Proposers, who are not manufacturers, are required 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) to UNICEF tender.

3. Interagency Finished Pharmaceutical Product Questionnaire (IAFPPQ)

Proposers offering products that are not WHO prequalified, or SRA approved are required to fill the electronic Interagency Finished Pharmaceutical Product Questionnaire (IAFPPQ) (Annex 2c).

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 3 - Instructions to upload technical documents to SharePoint.

b. Section 5 of the IAFPPQ Commitment and authorization page (Annex 2d). This section contains the signed commitment and authorization related to the product for which the Interagency Finished Pharmaceutical Product Questionnaire is submitted for. It must be submitted for each Interagency Questionnaire filled.

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) and the UNICEF Technical commitment declaration form (Annex 2g)

All proposers that are offering WHO PQ medicines or medicines with Marketing Authorization from SRA shall fill the UNICEF Technical offer form and UNICEF Technical commitment declaration form for each FPP offered in this tender. All supportive documents requested in the Technical offer form should be submitted.

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. Interagency Finished Pharmaceutical Product Questionnaire for BTPs and SBPs (Annex 2h)

All bidders offering biological products or biosimilar products are required to complete the Interagency Finished Pharmaceutical Product Questionnaire for BTPs and SBPs for each biological product offered.

7. Letter of authorization permitting UNICEF and PAHO to access information submitted to the tender (Annex 2i)

Proposers, by participating in this RFP, are deemed to permit access to a limited number of designated UNICEF, WHO and PAHO staff to relevant information related to all current and future product dossiers to facilitate technical evaluation of products submitted to this RFP.

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8. Clarifications and additional information

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

9. 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 initialed by the person or persons signing the bid

10. All the annexes accompanying the IAPPQ should be named appropriately for easy identification and retrieval (see examples 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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1 Request an option for Cloud based file transfer ONLY if it is not feasible to upload documents in SharePoint