ANNEX 2 – TECHNICAL DOCUMENTS SUBMISSION GUIDELINES

This section is intended to ensure that technical documents (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 Instructions for uploading Technical Documents to SharePoint.** For your SharePoint site to be established, send email to Rennie Shonhiwa-Chikwanha at rshonhiwa@unicef.org include the following information:

- Full name and address of the Proposer
- INN description of products offered
- Manufacturing site information for each product offered (including street address, city & country).
- Email address(es) of the company contact person(s) who will access the SharePoint folder.

1. **UNICEF Technical Questionnaire for Pharmaceutical Manufacturers**:
   All proposers 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 fill in the UNICEF Technical Questionnaire for wholesalers (Annex 2b) The proposer 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):**
   Proposers are required to fill in the electronic Interagency Finished Pharmaceutical Product Questionnaire (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 Finished Pharmaceutical Product Questionnaire per Finished Pharmaceutical Product (FPP) offered.
   a. Documents submitted as Annexes to the Interagency Finished Pharmaceutical Product Questionnaire should be in PDF format and should be well indexed, labelled and organized as instructed in Annex 3 Instructions for uploading technical documents to 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 Finished Pharmaceutical Product Questionnaire.

   IMPORTANT: The Interagency Finished Pharmaceutical Product Questionnaire (Annex 2c) is a PDF form that must be filled in correctly in line with the documents/data submitted as Annexes (per Section 6-Checklist for Annexes and attachments 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. **UNICEF API declaration form** (Annex 2e) must be filled in by FPP manufacturer and 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 Abridged Finished Pharmaceutical Product Questionnaire** (Annex 2f) and the **UNICEF Technical commitment declaration form** (Annex 2g)

Proposers shall fill in the UNICEF Technical offer form and 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 Authority (SRA)/WHO Listed Authority (WLA)[1]
d. Product has Marketing Authorization from a regulatory authority that is PIC/S member for products manufactured in their own country. IAFPPQ (Annex 2c) 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 proposer is required to sign a Letter of Authorization permitting UNICEF access to information from WHO, ERP, MSF etc. (Annex 2i)

6. Clarifications and additional information

The proposer 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

[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

8. Naming of Annexes and Attachments of the Interagency Finished Pharmaceutical Product Questionnaire:

Annex 2a UNICEF Technical questionnaire for pharmaceutical manufacturers
Annex 2b UNICEF Technical Questionnaire for pharmaceutical wholesalers
Annex 2c Interagency Finished Pharmaceutical Product Questionnaire (IAFPPQ)
Annex 2d IAFPPQ Commitment and signature - Section 5
Annex 2e UNICEF API Declaration form
Annex 2f UNICEF Abridged Finished Pharmaceutical Product Questionnaire
Annex 2g UNICEF Technical commitment declaration form
Annex 2i Letter of Authorization permitting UNICEF access to information from WHO, ERP, MSF etc.

Annex A Batch Formula
Annex B Primary Packaging
Annex C Secondary Packaging
Annex D CPP
Annex E MA issued & approval history
Annex F Acceptance letter issued by WHO PQ/SRA/WLA
Annex G Product Photos
Annex H Label-Primary
Annex I Label-Secondary
Annex J SmPC and PIL
Annex K API GMP certificate and Manufacturing License
Annex L API specification (FPP Mfg. Internal spec)
Annex M Method Validation for API
Annex N CEP/WHO PQ certificate
Annex O Technical file (DMF)
Annex P Data on validation of sterile API
Annex Q API COA (API Mfg. & FPP Mfg.)
Annex R API source comparison
Annex S FPP GMP certificate and Manufacturing License
Annex T FPP Specifications (release & shelf life)
Annex U FPP CoA (3 Batches)
Annex V Process Flow Diagram (FPP mfg. process)
Annex W Process validation report
Annex X Data on validation of sterile aspects for sterile FPP
Annex Y Nitrosamines risk assessment
Annex Z Stability Data
Annex Z1 Status of On-going Stability
Annex AA Stability Declaration (API used)
Annex AB In-use Stability Data
Annex AC Summary of pharmacology, toxicology and efficacy of the product
Annex AD Graphic summary of BE results
Annex AE BE study report/CDP study report
Annex AF CRO inspection outcome evidence and certificate of Accreditation of Facility/Laboratory
Annex AG Schematic representation of BE study design
Annex AH Study protocol summary
Annex AI Latest Periodic Safety report
Annex AJ Power of Attorney