

1. The **Product (Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPPQ)- Automated pdf version)** and the **Manufacturer (Annex 2a UNICEF Technical Questionnaire for manufacturers)** questionnaires are the basis of the UNICEF evaluation.
2. Please ensure that when you upload the **Product and Manufactures questionnaires they are in their original format**. i.e. please DO NOT print and scan them before uploading. They are automated forms and cannot be processed if a scanned version is uploaded. Save any changes using only the “Save” function, once you have filled them in. Do not use “Save as”.
3. In the UNICEF Supplier Document library, each supplier has its own product folder. Each product folder contains “Site Documents”, “API Documents” and “Product Documents”. The table below lists the documents that must be loaded into each of the folders.
4. Please upload only PDF, Word Doc, or Jpeg (for pictures/ Images) files. Do not upload any “zip folders” or “folders” in Products documents and Site documents folder. (e.g. COA’s for 3 batches should be scanned as one file). Scanned files can be uploaded.

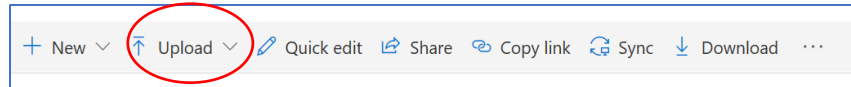
Site Documents (for a specific manufacturing site where the product is produced)- manual metadata entry	Product Documents (refers to product specific documents)- manual metadata entry
Annex 2a UNICEF Technical Questionnaire for manufacturers	Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPPQ)- Automated pdf version
Site Master File (pdf or word document)	Annex 2d IAFPPQ Commitment and signature - Section 5
Manufacturing License from your National Regulatory Authority.	Annex A Batch Formula
Copy of the latest inspection report.	Annex AA Graphic summary of BE results
Most recent GMP Certificate(s).	Annex AB BE study Report
List of all the recent GMP inspections performed at the site.	Annex AC Schematic representation of BE study design
Copy of relevant closing letters from the GMP inspections.	Annex AD Therapeutic Equivalence Protocol
List of products currently supplied to UNICEF.	Annex AE Power of Attorney
List of products submitted for tender.	Annex B Primary Packaging
Annex 2b UNICEF Technical Questionnaire for wholesalers	Annex C Secondary Packaging
Evidence from wholesaler that they are authorized by manufacturer to distribute the product.	Annex D Manufacturing License
	Annex D1 Copy of product registration & market status - License No.

API Documents	Annex E CPP
Annex K API GMP certificate	Annex F Acceptance / Deficiency letter issued by PQP /SRA
Annex L API specification	Annex G WHO Prequalification letter
Annex M Method Validation	Annex H WHO acceptance letter for Product Dossier
Annex N Data on validation for sterile API	Annex I Labelling
Annex O API COA (API mfr and FPP mfr)	Annex J SmPC and PIL
Annex P1 CEP certificate	Annex Q FPP GMP certificate
Annex P2 Technical file	Annex R FPP Specifications
	Annex S FPP COA (3 batches)
	Annex T Process Flow Sheet
	Annex U Data on validation of sterile aspects for sterile FPP products
	Annex V Stability Data
	Annex W Stability Declaration
	Annex X Status of On-going Stability
	Annex Y In-use Stability Data
	Annex Z Summary of pharmacology, toxicology and efficacy of the product.
	Annex 2e UNICEF API Declaration form to be filled by FPP manufacturer
	Annex 2f UNICEF Technical Offer form
	Annex 2g UNICEF Technical commitment declaration form
	Letter of Authorization permitting UNICEF access to information from WHO, ERP, MSF etc.

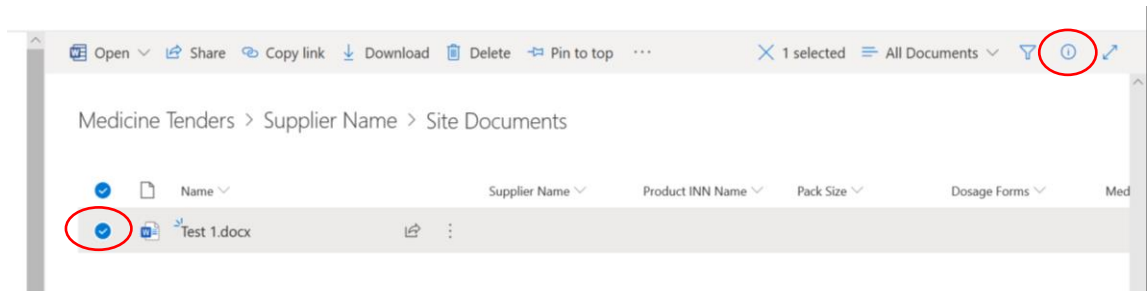
5. To upload files on our SharePoint:

- i. Click on the link provided. It will take you to your supplier folder.
- ii. Click on the appropriate type of folder for the document to be uploaded (Site Documents or Product Documents)
- iii. Click on "Upload".

INSTRUCTIONS FOR UPLOADING TECHNICAL DOCUMENTS TO SHAREPOINT




- iv. Select “Files” and choose the file you want to upload.
- v. Once the file is uploaded, select the file by ticking the circle that appears on left when you mouse over the files and click on the “i” icon (*open details pane*) on the top right corner.




- vi. Using the vertical sidebar at the far right, scroll down to “Properties” and click on “Edit All”.




- vii. Complete the relevant fields. *NB ensure to complete only the Medicine Product Documents field for medicines, the API Documents field for API related Documents, or Medicine Site documents for manufacturing site but do not complete any of the other fields for one document.*

 Content Type


UNICEF Document

 Name *


Test 1 .docx

 Medicine Product Documents


Select options

 Medicine Site Documents

Select options

 Dosage Forms


Select options

 Pack Size

Enter value here

Save Cancel

- viii.
- ix. When entering the pack size value, the following format must be used; for blister packs e.g 10 x10, 5 x 10 etc. & loose or bulk packs eg 100, 1000 etc. Also indicate whether it's a vial, ampoule, bag etc.

 Pack Size

Enter value here

- x. Click on "Save".
- xi. Repeat for all the documents. These will be secured for future tenders, so the documents uploaded will remain in this file for each tender unless amended. Updates can be made if needed.
- xii. When uploading documents for more than one product, please ensure that you upload the files in the correct product folder.
- xiii. It is advisable to upload all the documents into the supplier folder, tag the documents and then drag and drop them into the correct folders, according to whether they are Site, API or Product Documents.