1. For a link to the UNICEF Supplier Document Library on SharePoint send a request to Rennie Shonhiwa-Chikwanha (email: rshonhiwa@unicef.org); including full name and address of bidder, INN descriptions of products of interest and their respective manufacturing sites.

2. 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 technical evaluation.

3. Please ensure you upload the Product and Manufacturers questionnaires in their original format. i.e. please DO NOT upload printed/scanned versions. The forms are automated hence cannot be processed if a scanned version is uploaded.

4. In the UNICEF Supplier Document library, each supplier has its own folder, which contains Named Product folders (for each INN and strength) and Site documents folder. Only one Site Documents folder is allocated to each supplier and it contains a Product Mfg. Site Locator (excel file) and Manufacturing site folders 1,2...etc.) as depicted in figure 1 below.
   Figure 1: Supplier folder structure
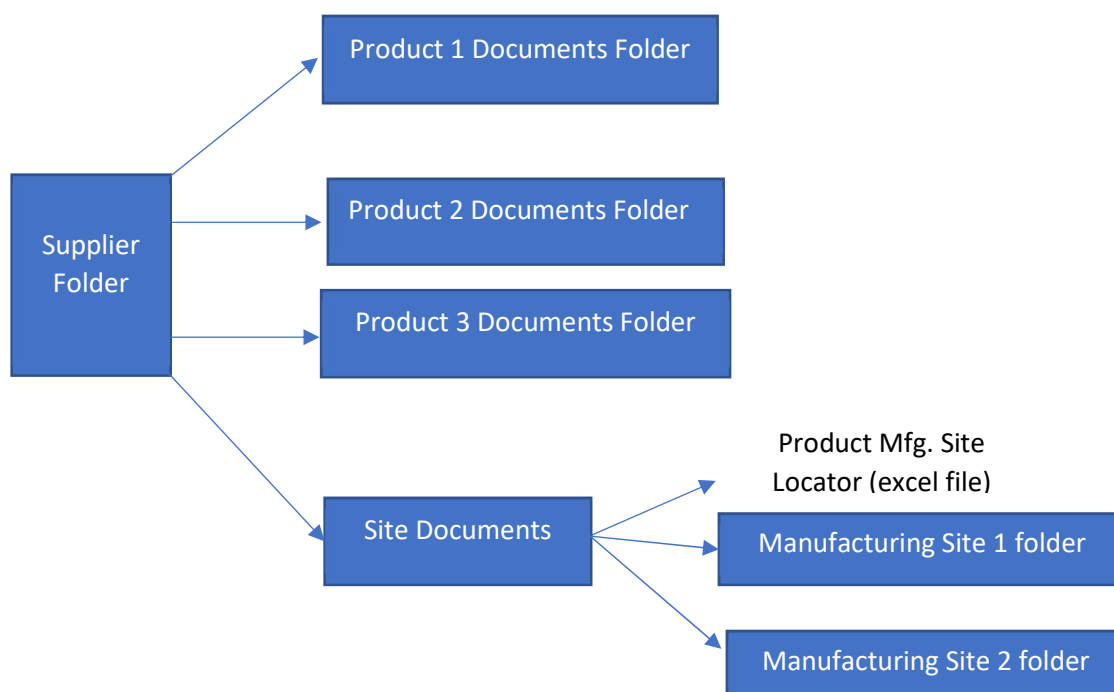
Please note that product folders are created for each product strength (for e.g., Amoxycillin 250mg and Amoxycillin 500mg) and you need to upload documents into respective Product documents and Site documents folders even if they are similar or have been already uploaded in the other product folder having different strengths e.g., you need to again upload the same documents (if applicable) in each strengths folder for e.g., Amoxycillin 250 mg and Amoxycillin 500 mg for e.g. even if API, mfg. site is same for both the strengths.

5. *For each* Named Product folders (*for each INN and strength) please upload the required documents as mentioned in the Table 1 below in the section "Product Documents".*

6. *Product Mfg. Site Locator (excel file located in Site Documents folder) needs to be completed. This file is used for locating specific Manufacturing Site (e.g., 1 or 2 or 3) for a specific product and its strength. The product and its mfg. site must match with the details mentioned in the Product (Annex 2c Interagency Pharmaceutical Product Questionnaire (IAFPPQ)-Automated pdf version).*

7. *For each manufacturing site – please upload the required documents as mentioned in Table 1 below in the section "Site Documents (for each mfg. Site)".*

8. Please upload only pdf or word Doc or Jpeg (for pictures/ Images) files in Product documents and Site documents folder. Do not upload any "zip folders" or "folders" in Product documents and Site documents folder. (e.g., COA's or stability reports for 3 batches should be scanned as one file). Scanned files for the annexes of the IAPPQ can be uploaded.

9. If you do not have any Annex (for product or site or other documents) to upload for any reason, please mention the specific reason for the same on a word /pdf file and upload the same in that respective Annex upload. e.g. Not Applicable or Will submit the document later (by XXXX date) or Document cannot be provided or Not available or any other reason as applicable.

Table 1: Documents to be provided by Suppliers

| Site Documents (for each mfg. Site) (for a specific manufacturing site where the product is produced)	Product Documents (refers to product specific documents)
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 C Secondary Packaging
For Wholesalers Only	Annex D Manufacturing License (FPP & API)
Annex 2b UNICEF Technical Questionnaire for wholesalers (required only for wholesalers)	Annex D1 Copy of product registration & market status-License No.
Evidence from wholesaler that they are authorized by manufacturer to distribute the product.	Annex E CoPP (Certificate of Pharmaceutical Product)
	Annex F Acceptance/Deficiency letter issued by PQP/SRA
	Annex G WHO Prequalification letter
	Annex H WHO acceptance letter for Product Dossier
	Annex I Labelling (Primary & Secondary)
	Annex J SmPC and PIL
	Annex K API GMP certificate
	Annex L API specification (FPP Mfgr. Internal specif.)

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	Annex M Method Validation for API
	Annex N Data on validation for sterile API
	Annex O API COA (API Mfgr. & FPP Mfgr.)
	Annex P1 CEP certificate for API
	Annex P2 Technical file (DMF)
	Annex Q FPP GMP certificate
	Annex R FPP Specifications (release & shelf life)
	Annex S FPP COA (3 batches)
	Annex T Process Flow Sheet (FPP- mfg. process)
	Annex U Data on validation of sterile aspects for sterile FPP products
	Annex V Stability Data -FPP (long term & Accl.)
	Annex W Stability Declaration (API used)
	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.

10. 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".
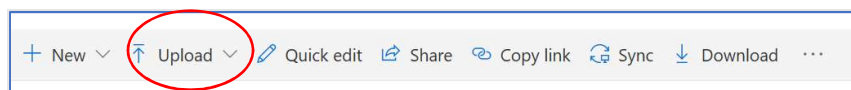
    iv. Select "Files" and choose the file you want to upload.
    v. Once the file is uploaded, select the file by ticking the circle that appears on left when you mouse over the files and click on the "i" icon (*open details pane*) on the top right corner.
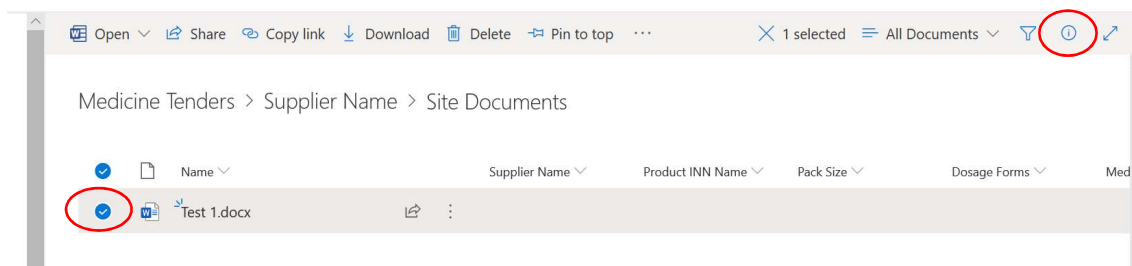
vi.   Using the vertical slide bar at the far right, scroll down to "Properties" and click on "Edit All".
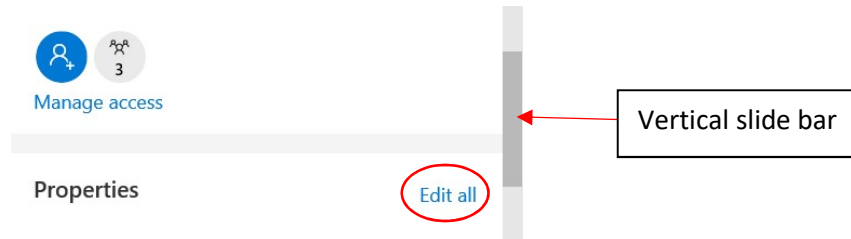
vii.   Complete the relevant fields. *NB ensure to complete only the Medicine Product Documents field for medicines or Medicine Site Documents for manufacturing site but do not complete both fields for one document.*

viii.   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 e.g. 100, 1000 etc. Also indicate whether it's a vial, ampoule, bag etc.

ix.   Click on "Save".

x.   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.

xi.   When uploading documents for more than one product, please ensure that you upload the files in the correct product folder.