

Pre-Bid Webinar

RFP-DAN-2024-503726

Presenter:

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UNICEF SUPPLY Division
Medicines and Nutrition Centre

******* NOTICE *******

- Webinar will start at 10:30 AM (Copenhagen Time). Duration: around 2 hours
- This webinar is recorded. The recording will be shared with attendees and on UNGM platform for reference.
- All attendees are muted as default.
- Structure of this webinar
 - UNICEF presentation: UNICEF team will give brief introduction to UNICEF and take you through key information about this tender
 - Q&A session: You will be invited to raise your questions/concerns in Q&A session. Please write your questions in the chat room after the presentation is completed as we hope some of your questions will have been addressed to during the presentation

Agenda

- **OVERVIEW OF UNICEF SUPPLY DIVISION**
- **PROCUREMENT PRINCIPLES AND APPROACH**
- **TENDER PRODUCTS AND OBJECTIVES**
- **PROPOSAL SUBMISSION REQUIREMENTS**
 - SUBMISSION ESSENTIALS
 - COMMERCIAL PROPOSAL SUBMISSION
 - TECHNICAL PROPOSAL SUBMISSION
- **EVALUATION PROCESS**
- **Q&A – PLEASE TYPE YOUR QUESTIONS DURING THE SESSION**

OVERVIEW OF UNICEF SUPPLY DIVISION

UNICEF's Supply & Logistics
headquarters located in
Copenhagen, Denmark

It is also home to the largest
humanitarian warehouse

The UNICEF Supply Function helps
realize child rights through
continuous and equitable access to
essential supplies and services

UNICEF Vision and Mission

EVERY CHILD HAS A RIGHT TO

UNICEF advocates
to protect
children's rights

Help meet their **basic
needs** and expand
opportunities for every
child to reach **their full
potential**.



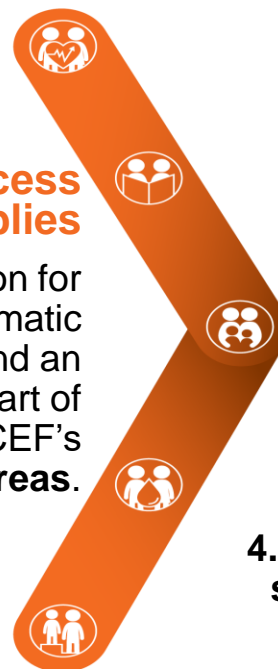
Transforming
rights into reality

Supply Division
strives to ensure that
every child has
**access to essential
supplies**.



Equitable access
to supplies

A foundation for
programmatic
interventions and an
integral part of
realising UNICEF's
five goal areas.



1. Survive & thrive



2. Learn



3. Be protected



4. Live in a clean &
safe environment



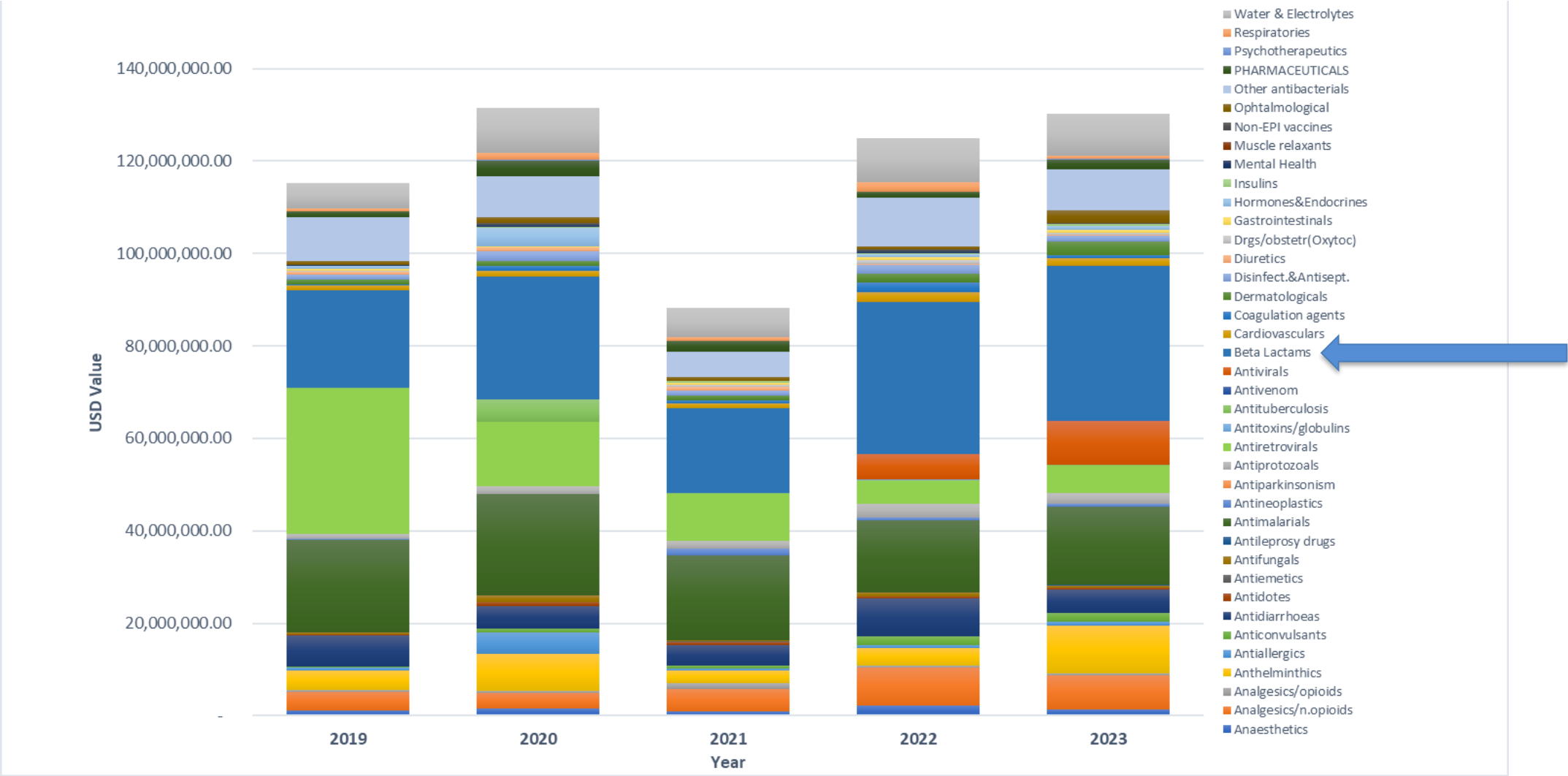
5. A fair chance in life



UNICEF Supply Division

- We work across **190** countries and territories
- We work with governments based on **country specific agreements** to address country specific needs and contexts
- We support global efforts and works in **partnerships** with governments, other UN organizations
- We are entirely **funded by voluntary contributions** from the public and the private sector
- The supplies that we provide are a **direct expression of children's rights**

UNICEF Pharmaceutical Procurement Value



Useful Links

- UNICEF Supply Division: <https://www.unicef.org/supply/>
- UNICEF Procurement Policies: <https://www.unicef.org/supply/resources/procurement-policies>
- Market Notes and Updates: <https://www.unicef.org/supply/market-notes-and-updates>
- UNICEF Price Data Overview: <https://www.unicef.org/supply/pricing-data>
- UNICEF Key Supply Markets Dashboard: <https://www.unicef.org/supply/documents/key-supply-markets-dashboard>
- UNICEF Tender Calendars: <https://www.unicef.org/supply/tender-calendars>
- Information for Suppliers: <https://www.unicef.org/supply/suppliers-and-service-providers>

PROCUREMENT PRINCIPLES AND APPROACH



UNICEF Procurement Principles and Approach

PRINCIPLES

- Promotion of objectives of UNICEF
- Fairness, integrity and transparency through competition
- Economy and effectiveness
- Best value for money

NOTE

- Suppliers must be registered on the **UNGM**
<https://www.ungm.org>
- More information on how to do procurement with UNICEF can be accessed via the links below:
 - <https://www.unicef.org/supply/suppliers-and-service-providers>
 - <https://www.unicef.org/supply/documents/general-terms-and-conditions-contract>

APPROACH

- Procurement is guided primarily by WHO EML (<https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>)
- Purchases medicines products primarily directly from manufacturers
- Uses competitive tendering process
- **Does not purchase** from companies employing child labour nor manufacturers of land mines and their components;
- **Does not purchase** from companies found to have undertaken unethical, unprofessional or fraudulent activities.

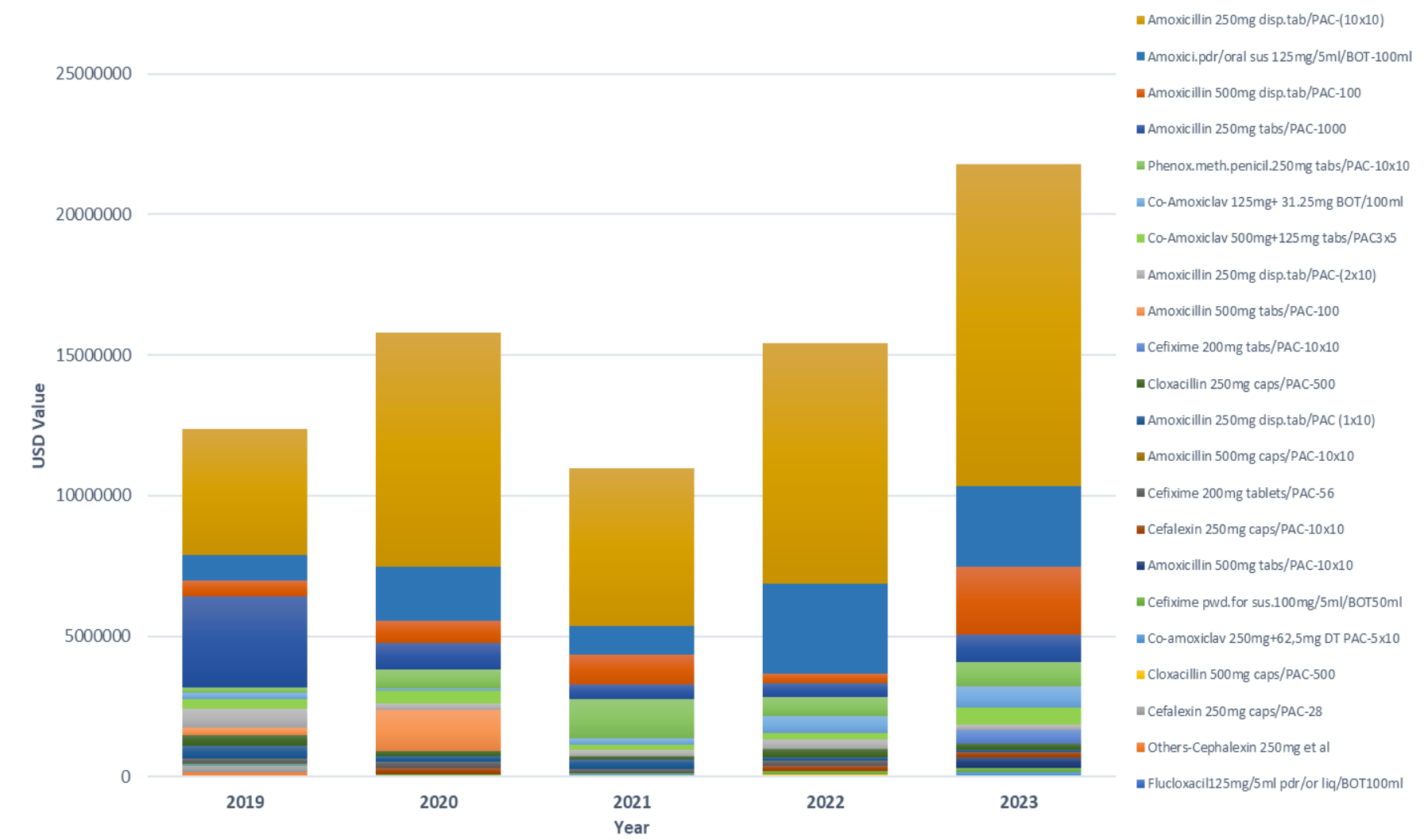
TENDER PRODUCTS AND OBJECTIVES



Tender Products and Objectives

Product Category	Objectives
<div>Beta Lactam Antibiotics (Oral)</div>	<ul style="list-style-type: none">• To facilitate sustainable supply of life saving medicines without supply interruptions to support both regular UNICEF program work as well as Emergency response .• To establish Long Term Arrangements (LTAs) with manufacturers / wholesalers for the supply of these medicines for an initial period of 24 months with an option of renewal for initially 24 months and then a further 12 months. (subject to mutual agreement)

Procurement Trend 2019-2023 - Beta Lactams Oral



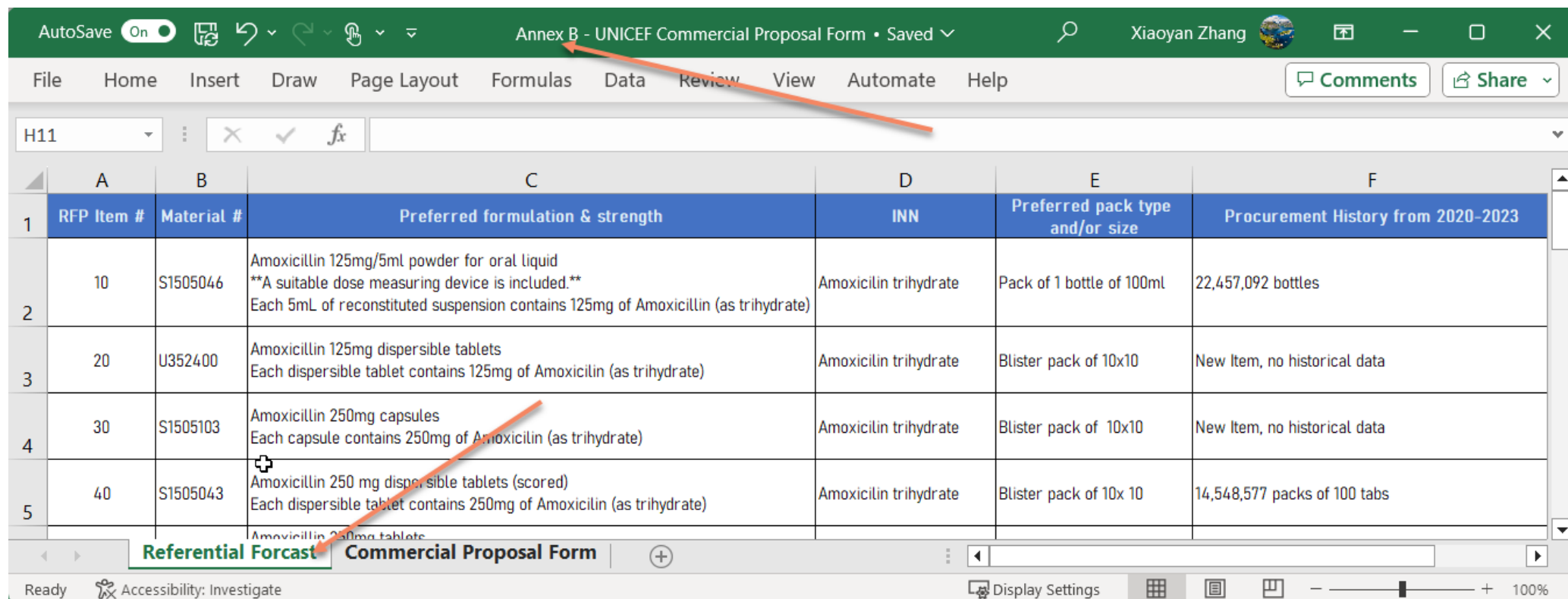
- Warehouse deliveries to Supply Division, Denmark
- Direct Deliveries to 38 countries

Receiving Country Name	
Afghanistan	Malawi
Botswana	Mali
Burkina Faso	Mozambique
Central Afr.Rep	Myanmar
Chad	Niger (the)
Congo (the)	Nigeria
Cote d'Ivoire	Pakistan
Djibouti	Pap. New Guinea
DPR of Korea	Sierra Leone
DR of the Congo	Somalia
Eritrea	South Sudan
Ethiopia	Sudan (the)
Ghana	Tanzania
Guinea	Timor-Leste
Haiti	Uganda
Kenya	Venezuela
Lebanon	Yemen
Liberia	Zambia
Madagascar	Zimbabwe

Tender Products and Referential Forecast

Product List and Referential Forecast: Refer to the 1st spread sheet of the Annex B - UNICEF Commercial Proposal Form

- Item 270 is added to this tender. You can find the updated Annex B in UNGM
- This forecast is based on the historical procurement quantity from 2020-2023
- Some tendered products are new to UNICEF and thus no procurement history



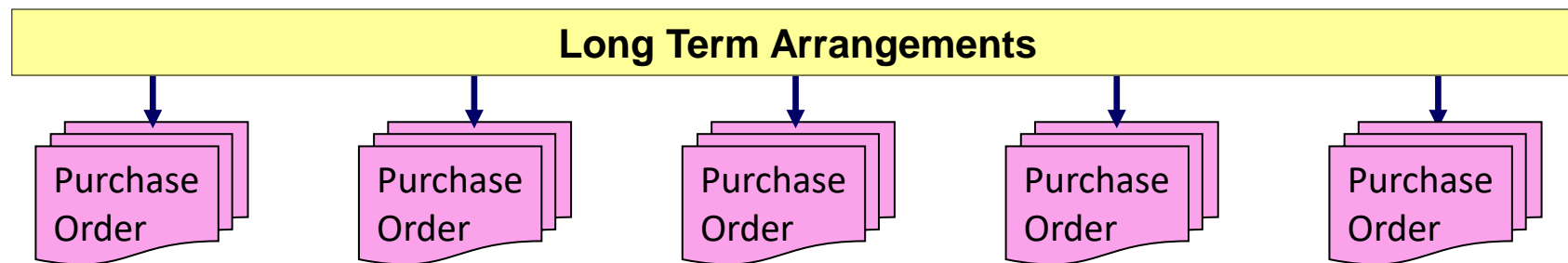
	A	B	C	D	E	F
	RFP Item #	Material #	Preferred formulation & strength	INN	Preferred pack type and/or size	Procurement History from 2020-2023
1	10	S1505046	Amoxicillin 125mg/5ml powder for oral liquid **A suitable dose measuring device is included.** Each 5mL of reconstituted suspension contains 125mg of Amoxicillin (as trihydrate)	Amoxicilin trihydrate	Pack of 1 bottle of 100ml	22,457,092 bottles
2	20	U352400	Amoxicillin 125mg dispersible tablets Each dispersible tablet contains 125mg of Amoxicilin (as trihydrate)	Amoxicilin trihydrate	Blister pack of 10x10	New Item, no historical data
3	30	S1505103	Amoxicillin 250mg capsules Each capsule contains 250mg of Amoxicilin (as trihydrate)	Amoxicilin trihydrate	Blister pack of 10x10	New Item, no historical data
4	40	S1505043	Amoxicillin 250 mg dispersible tablets (scored) Each dispersible tablet contains 250mg of Amoxicilin (as trihydrate)	Amoxicilin trihydrate	Blister pack of 10x 10	14,548,577 packs of 100 tabs

Tender Outcome: LTAs & POs

Long Term Agreements

- LTAs will be issued for a time-bound (open quantity) agreement
- For each product there will be multiple LTA awarded. Based on multiple criteria, LTA with various vendors for the same product will be given a PO value allocation. This allocation will be an **internal** guideline when we award individual PO.

Purchase Orders POs will be placed against LTAs within the LTA validity period when request is received in Supply Division from programs & partners



PROPOSAL SUBMISSION REQUIREMENTS



Submission Essentials

Step 1. Commercial Proposal



Deadline: 30 September 2024, 23:59 Copenhagen Time



Email to: supplybid@unicef.org



DO NOT copy ANY other UNICEF staff when submitting Commercial Proposal



As soon as Commercial Proposal is submitted, please send separate email to Rennie Shonhiwa-Chikwanha (email: rshonhiwa@unicef.org) for access to SharePoint Library

Step 2. Technical Proposal



Deadline: 15 October 2024, 23:59 Copenhagen Time



Upload to: [SharePoint Library](#)



DO NOT upload commercial proposal content in SharePoint Library

Commercial Proposal Submission - Overview

Commercial Proposal must include **ALL** documents listed below:

- Completed and signed **Bid Form/Declaration Form** in .pdf format. The Forms are in page 3-5 of the tender document named RFP-DAN-2024-503726

*Note: For the Declaration, if you are not found guilty of the crimes listed in the form, you should tick “**YES**”.*

- Completed and signed **Commercial Proposal Form** spreadsheet in Annex B (please use the updated version) in both .pdf & .xls format

*Note: This form is the **2nd spreadsheet of Annex B***

- 1st Spreadsheet (Referential Forecast): This is for a reference on our historical procurement data from 2020-2023
- 2nd Spreadsheet (Commercial Proposal Form): This is the spreadsheet bidder needs to complete and sign
- Completed and signed Annex C **Information about sustainability** in both .pdf and .doc format

Note: Bidder is required to show all the efforts you are already making toward sustainability.

*Please also include all **supporting document** to substantiate these efforts made. No requirement to translate to English if these document is in other languages.*

- ✓ Email Commercial Proposal to supplybid@unicef.org, email subject should be “RFP-DAN-2024-503726 - [Company Name]”
- ✓ Copy or BCC any other UNICEF email address when submitting commercial proposal will result in bid invalidation

Commercial Proposal Form – Deep Dive 1/2

- Column A-D: These are details the product we are looking for.
Note: Please pay attention to our preferred strength and pack size
When available, please offer as per our preferred perimeters to maximize your opportunity. We consider other strength and pack size when we do not have enough bid for our preferred perimeters or other strength/pack size represent overwhelming majority on market.

	A	B	C	D
5				
6	RFP-DAN-2024-503726			
7	Request Details			
8	RFP Item #	Material #	Preferred formulation & strength	Preferred pack type and/or size
9	10	S1505046	Amoxicillin 125mg/5ml powder for oral liquid **A suitable dose measuring device is included.** Each 5mL of reconstituted suspension contains 125mg of Amoxicillin (as trihydrate)	Pack of 1 bottle of 100ml

- Column E-Q: Bidder to fill in the details of the product offered
Note:
 - When you fill in information, please pay attention to the requirement on row 8.
 - There are pop up instruction when you click on cells regarding format to use etc. Please pay attention and follow instruction
 - When you have different pricing for product produced in different manufacture site for the same tender item, please add row to the item.

	E	F	G	H	I	J
5						
6	Details of Offered Products					
7	Bidder Name	INN/BAN/ Generic Name	Dosage Form	Concentration	Pack Size	Commercial Pack Size (offered price is based on this pack size)
8						
9						

Commercial Proposal Form – Deep Dive 2/2

- Column R-AC: Bidder to fill in on pricing and price conditions

Note:

- Please pay attention to the requirement on row 8.
- Offer price shall be either USD or EUR. Offered price shall not exceed 2 decimal places. Use dot to separate round number and decimal number
- There are pop up instruction when you click on cells regarding format to use etc. Please follow instruction
- Price: Bidder is encouraged to include both FCA and DAP price. DAP location is our WH in Copenhagen. For FCA location, please state clearly the name of your nearest international airport/seaport in the relevant cells
- MOQ: Bidder is free to calculate offered price on base of batch size, container size or pallet size etc. When there is requirement for MOQ please state it clearly in the relevant column. Please note that both price and MOQ are part of the evaluation perimeter we look at when deciding LTA reward or PO allocation.
- Tiered pricing is accepted. When offer tier pricing based on different PO quantity, please add row to the tender item
- Offer validity is 365 days counting from commercial proposal submission deadline

	R	S	T	U	V	W
5						
6		DAP UNICEF Copenhagen Warehouse (Incoterms 2010)				
7		By Sea/Truck				
8	Currency	DAP Price/Pack (Reefer Container Sea, /Road)	DAP Price/Pack (Dry Container Sea, /Road)	MoQ: # of Commercial Pack (DAP Sea/Road)	Lead Time (Day) (DAP Sea/Road)	DAP Price/Pack (Air)
9			+	Offer should be calculated based on MOQ		

Referential Forecast Commercial Proposal Form ...

Last but not least: Please do NOT add column or merge cells when filling this form

HOW TO SUBMIT TECHNICAL PROPOSAL AND SAMPLES

Quality assessment is done principally via technical assessment of pharmaceutical product dossiers, evaluation of samples and manufacturer Good Manufacturing Practices (GMP).



UNICEF Supplier SharePoint Library

- A commercial proposal must be submitted **first** by the Proposer before requesting for a link to their SharePoint folder.
- For a link to your SharePoint folder send a request to Rennie Shonhiwa-Chikwanha (email: rshonhiwa@unicef.org); include the following information: full name and address of Proposer, INN descriptions of products of interest and their respective manufacturing sites.
- List of documents to be uploaded into Site Documents & Product Documents folders are listed in Annex 2h.
- Tag the documents appropriately as shown in Annex 2h.
- If you do not have any of the annexes (for product or site or other documents). Upload a word document mentioning the specific reason for not having e.g. Not applicable or Will submit the document later (by XXXX date) etc. in lieu of the Annex.

How to Submit Technical Proposal

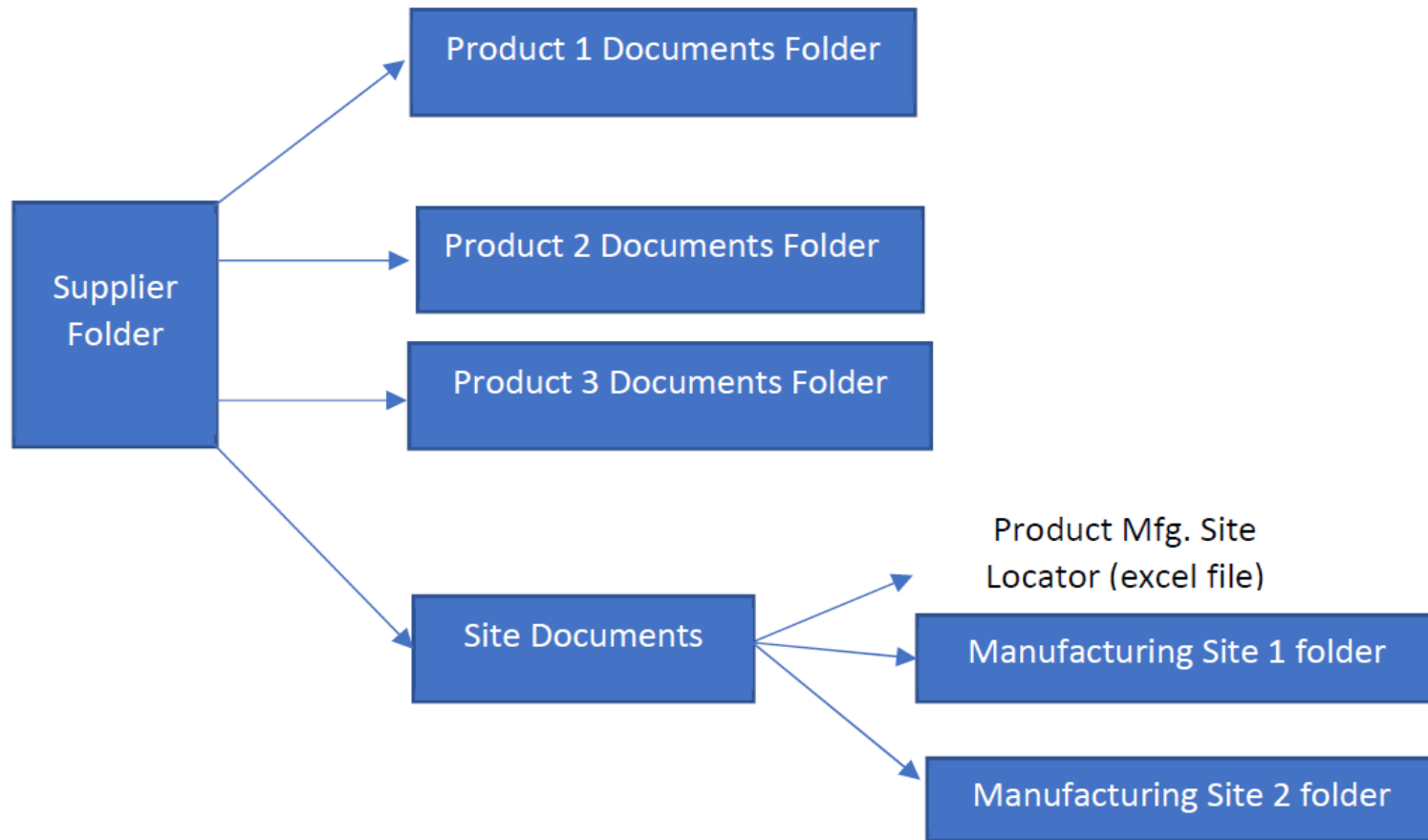
UNICEF will only accept

Electronic files named appropriately and uploaded to the UNICEF Supplier SharePoint library
(Please refer to Annex 2h for detailed instructions)

UNICEF will NOT accept

- Any paper documentation – except from CoA and PIL accompanying the samples.
- Handwritten technical documentation
- CDs or USB memory sticks
- Documentation sent via large-size emails or multiple emails
- Zipped folders in the share point library

Supplier Folder Structure



Technical Proposal/Sample Requirements (1/3)

- **GMP Assessment of Manufacturing site**
 - Annex 2a - Technical questionnaire for pharmaceutical manufacturers
 - To be completed by all manufacturers (including the contract manufacturer)
 - One form (Annex 2a) to be completed per manufacturing site where FPPs offered are manufactured.
 - Annex 2b - Technical questionnaire for pharmaceutical wholesalers (GDP assessment)
 - To be completed by wholesalers and distributors only. (based in EU and offering SRA products)

Technical Documents/Sample Requirements (2/3)

2. Technical Assessment of Pharmaceutical Product Dossiers

- Annex 2c - Interagency Finished Pharmaceutical Product Questionnaire (automated)
 - First time Proposer (Non-SRA product i.e., product without SRA market authorization).
 - Bidders whose FPP & API specs changed since last submission.
 - Product is manufactured & released or sourced from non-SRA country.
 - UNICEF has limited or no prior procurement experience of the product(s) irrespective of country of manufacture or marketing authorization status. (requested on cases by case basis)
- Annex 2d - Commitment and signature (section 5)
- Annex 2e - UNICEF API declaration form
 - To be filled out by FPP manufacturer
 - If there is more than one source for any API, a separate form should be filled for each source.

Technical Document/Sample Requirements (3/3)

- Annex 2f - UNICEF technical offer form
 - Product has Marketing Authorization from a Stringent Regulatory Authority (SRA). (released and supplied from country of SRA)
 - Product(s) and manufacture site(s) has been technically assessed and approved by the partners below: WHO PQ, MSF international & Other agencies stated in the IAFPPQ (Annex 2c).
- Annex 2g - UNICEF technical commitment declaration form
 - If the Proposer has supplied the same product to UNICEF within the past 4 years with no major changes.
 - Product has Marketing Authorization from a Stringent Regulatory Authority (SRA).
 - Product(s) and manufacture site(s) has been technically assessed and approved by the partners below: WHO PQ, MSF international & Other agencies stated in the IAFPPQ (Annex 2c).

3. Evaluation of Samples

- Commercial samples will be requested from Proposers.
- Proposers will be contacted to provide such samples and a deadline for the submission of samples will be indicated at the time of request.

Technical Proposal

For SRA marketed products and products qualifying as WHO PQ or WHO Listed Authority (WLA), or WHO Emergency Use Listing (EUL) approval/status

Technical proposal to include the following:

- DULY FILLED/SIGNED Annex 2a Technical Questionnaire for pharmaceutical Manufacturers (for manufacturers only).
- DULY FILLED/SIGNED Annex 2b Technical Questionnaire for Pharmaceutical Wholesalers (for wholesalers only).
- DULY FILLED/SIGNED Annex 2f UNICEF Technical Offer Form 2019 (for each item).
- DULY FILLED/SIGNED Annex 2g UNICEF Technical Commitment Declaration 2019 (for each item).
- Artwork (primary & secondary packaging), SmPC and PIL (Patient Information Leaflet) (for each product offered).
- Closeup photos of the carton (all sides), blister, bottle, measuring device, PIL/package insert.
- Additional documents may be requested if required.

Technical Proposal

For Non-SRA marketed products

Technical Proposal to include the following:

- DULY FILLED/SIGNED Annex 2a Technical Questionnaire for pharmaceutical Manufacturers (For manufacturers only- To be filled and signed by Manufacturers even if the products is offered via wholesaler)
- DULY FILLED/SIGNED Annex 2b Technical Questionnaire for Pharmaceutical Wholesalers
- DULY FILLED/Annex 2c Interagency finished pharmaceutical product questionnaire (Automated form -version 4 Marts 2019)
- DULY FILLED/Annex 2d IAFPPQ Commitment and signature - Section 5 for non-SRA registered products
- DULY FILLED/ Annex 2e UNICEF API Declaration form to be filled by FPP manufacturer
- Artwork (primary & secondary packaging), SmPC and PIL (Patient Information Leaflet) (for each product offered).
- Closeup photos of the carton (all sides), blister, bottle, measuring device and PIL/package insert.

Technical Proposal

For Wholesalers/Distributors

Product offered qualifies as:

- WHO PQ or WHO Listed Authority (WLA), or WHO Emergency Use Listing (EUL) approval /status.
- SRA

Technical proposal to include the following:

- DULLY FILLED/SIGNED Annex 2b Technical Questionnaire for Pharmaceutical Wholesalers (for wholesalers only)
- DULLY FILLED/SIGNED Annex 2f UNICEF Technical Offer Form 2019 (for each item)
- DULLY FILLED/SIGNED Annex 2g UNICEF Technical Commitment Declaration 2019 (for each item)
- Additional documents may be requested if required.

Product offered qualifies as

- Non-SRA

Technical proposal to include the following:

- DULLY FILLED/SIGNED Annex 2a Technical Questionnaire for pharmaceutical Manufacturers (To be filled by manufacturer of the product)
- Letter of Authorization from MAH
- DULLY FILLED/SIGNED Annex 2b Technical Questionnaire for Pharmaceutical Wholesalers (To be completed by the wholesaler/distributor).
- DULLY FILLED/Annex 2c Interagency finished pharmaceutical product questionnaire (Automated form -version 4 Marts 2019)
- DULLY FILLED/Annex 2d IAFPPQ Commitment and signature - Section 5 for non-SRA registered products
- DULLY FILLED/ Annex 2e UNICEF API Declaration form to be filled by FPP manufacturer.

Technical Proposal

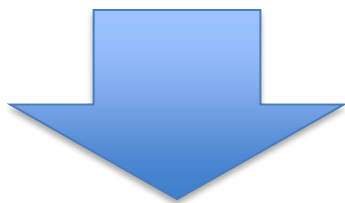
Amoxicillin Dispersible Tablets

When the amoxicillin dispersible tablets offered **are not**:

- WHO prequalified
- SRA marketed/registered
- Approved/registered by a regulatory Authority that is listed as WHO Listed Authority(WLA) for **BOTH** Marketing Authorization and Regulatory inspections

AND

No application has been submitted to the WHO prequalification programme or an SRA or WHO ERP or WLA and accepted for review.



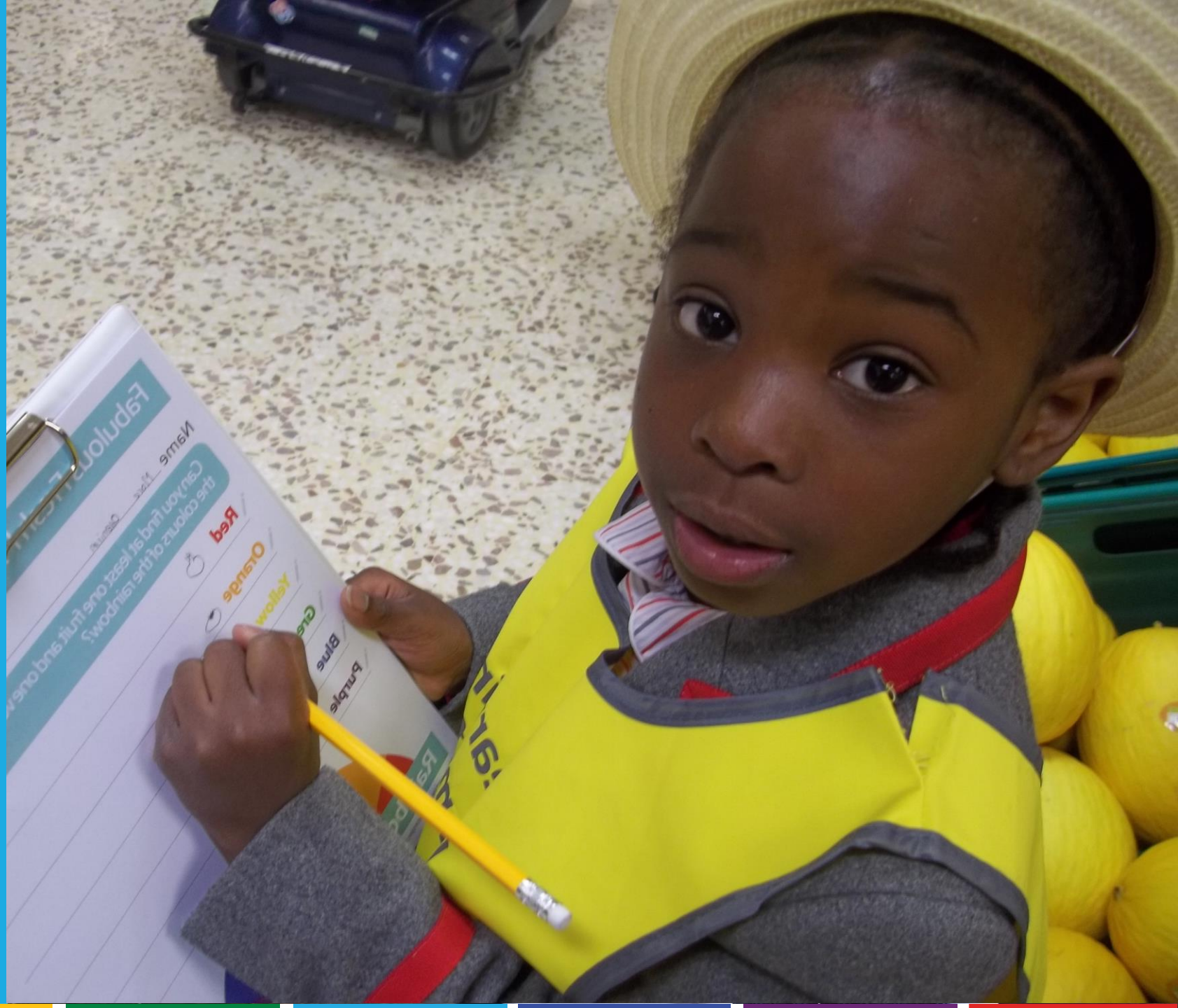
Technical offers will be assessed by WHO Expert Review Panel (ERP).

For more information on the ERP process refer to:

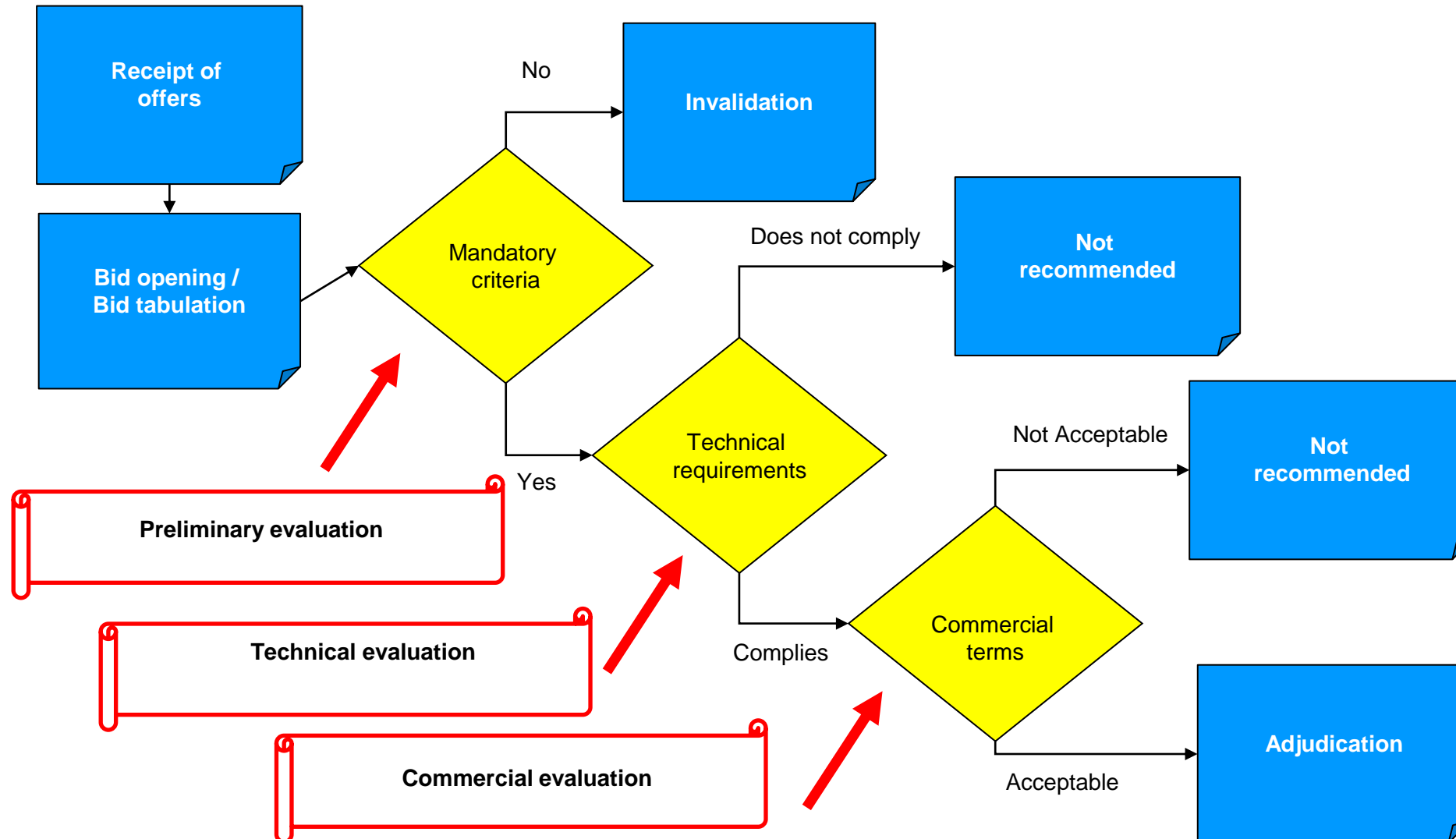
<https://extranet.who.int/prequal/medicines/expert-review-panel>

Bidders are required to prepare an ERP dossier based on the Interagency Finished Pharmaceutical Product Questionnaire (Annex 2c).

EVALUATION PROCESS



Evaluation Flowchart



Preliminary Evaluation 1/2

Preliminary evaluation is to ensure compliance to the mandatory criteria of the solicitation document including:

- Compliance with the bid submission deadline
- Completeness of the proposals
- Acceptance of UNICEF Terms and Conditions
- Compliance with the requested Incoterms
- Compliance with UNICEF payment terms & currency
- Compliance with the requested validity period of the Proposal

Preliminary Evaluation 2/2



Technical Evaluation

During the technical evaluation stage, the proposals will be evaluated for compliance with:

- [UNICEF technical requirements for pharmaceuticals](#) (Annex 1).
- Technical and quality criteria as outlined in the solicitation document.
- All the products must comply with the monograph of one of the following pharmacopeias: BP, Ph. Eur., USP, Ph. Int.
- Preference will be given to proposals for products with 36 months total shelf life or more at zone Iva &/or zone Ivb conditions.
- Shorter shelf life may also be considered for direct deliveries.
- Blister packs are preferred for tablets and capsules.
- Preference will be given to the preferred pack sizes, strengths and dosage forms as outlined in the solicitation document. Alternative pack sizes, strengths and dosage forms will only be considered and evaluated provided we do not receive adequate offers for our preferred pack size, strength and dosage form.

Commercial Evaluation

- Competitive Price (including Volume discounts).
- Longest product shelf life
- Guaranteed shortest Lead-time
- Lowest Minimum order Quantity (MoQ).
- Compliance with packing and shipping marking requirements
- Highest available monthly production capacity indicated for UNICEF procurements.
- Past supplier performance for previous LTA holders
- Compliance to international/national environmental management standards as shown in Annex C (Unsafe discharge of solid waste from the production process of beta lactam can lead to environment pollution and result in development of anti-microbial resistance. Preference in the award will therefore be given to suppliers that can demonstrate compliance with national environment management standards).
- UNICEF intends to award multiple LTA-Gs in support of the tender objectives to ensure sustainable access to quality and affordable beta lactam medicines in different geographical areas. Therefore, location of manufacturing site and production capacity will be considered in the final overall award strategy.

Supplier Evaluation Risk Elements

- Supplier bankruptcy
 - Supply shortages (stock outs) & delays
 - Constrained cash flow due to price fluctuations
 - Financial instability and crisis
 - Reputational damaged by unethical conduct
- Delays in delivery
- Production restrictions
- Fraud

Q&A





Thank You