

# Pre-Bid Webinar

## RFP-DAN-2023-503604: PAEDIATRIC AND ADOLESCENT CANCER MEDICINES

UNICEF SUPPLY Division  
Medicines and Nutrition Centre and  
Pan American Health Organization (PAHO)

Presenters:  
PAHO and UNICEF

## \*\*\*\*\* NOTICE \*\*\*\*\*

- Two hours webinar starting at **13:30 hours (Copenhagen Time)**
- This webinar is presented jointly by UNICEF and PAHO.
- This webinar is recorded. The recording will be shared with attendees, for reference.
- All attendees are muted as default.
- Questions and Clarifications can be raised in the Q&A session or by writing in the chat room and will be responded to after the presentation is completed.

# Agenda for this Webinar

UNICEF and PAHO team will take you through the following:

- ✓ Introduction to UNICEF Supply Division and PAHO.
- ✓ Public Procurement Principles
- ✓ Background and Purpose of this Tender.
- ✓ Proposal Submission Requirements.
- ✓ Proposal Submission Process (Instructions).
- ✓ Commercial and Technical Submission Method.
- ✓ Technical Proposal Submission Preparation and Samples Submission.
- ✓ Tender Evaluation Process.
- ✓ Questions and Answers.



# Global Platform for Access to Childhood Cancer Medicines

*Maximizing impact through  
country ownership & integration*

Pre-bid Webinar  
3 Aug 2023

# Problem statement (part 1)

>80%

children with cancer in  
**HIC** survive

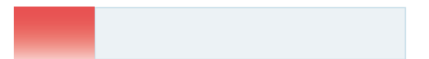
**80%** OF CHILDREN  
WITH CANCER  
WILL **SURVIVE**  
IN HIGH-INCOME COUNTRIES



<20-30%

children with cancer in  
**LMIC** survive

**ONLY ABOUT**  
**20%** OF CHILDREN  
WITH CANCER  
WILL **SURVIVE**  
IN SOME LOW- AND MIDDLE-INCOME COUNTRIES



# Global Initiative for Childhood Cancer

>60%

children with cancer survive & alleviate suffering for all

*Save 1 million children by 2030*

## GICC Objectives

- (i) ↑ capacity of countries to provide quality services for children with cancer.
- (ii) ↑ prioritization of childhood cancer at global, regional, and national levels



## Approach

- ✓ **10** priority action in CureAll with strategic investments
- ✓ Multi-sectorality:  
**>120** implementing partners
- ✓ Regional collaboration:  
**4** networks & community of practice

# Milestones: GICC after 5 years

70+

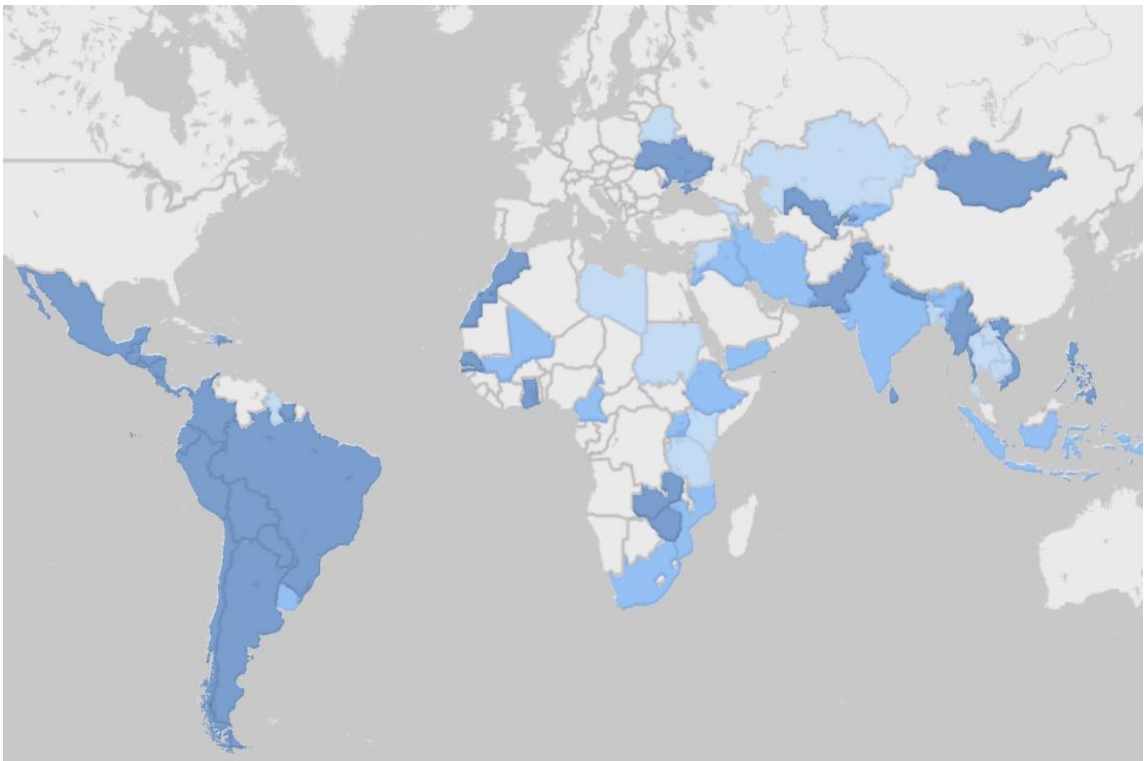
Countries participating  
in Initiative

150+

Specialized Paediatric  
Oncology Centres providing  
care across 6 WHO Regions

35,000+

Children newly diagnosed  
with cancer accessing care



70

TOTAL  
Countries

31

TOTAL  
Focus Countries

18

TOTAL  
Countries with  
Activities

21

TOTAL  
Countries in Dialogue

# Problem statement (part 2) – responding to country needs

80%

GICC countries requested action on improving access to childhood cancer medicines

75%

Low-income countries do not include essential medicines in their national benefit packages

>70%

*estimated*

children with cancer do not have access to essential childhood cancer medicines

But... different challenges for different products in different facilities in different countries



# Platform Background: value proposition

In December 2021, St. Jude Children's Research Hospital and WHO the creation of the Global Platform for Access to Childhood Cancer Medicines to provide children with cancer an uninterrupted supply of **quality cancer medicines**, with a **200M USD** investment from St. Jude.

The platform will ensure quality and effective medicines are available to treat childhood cancer and increase global visibility and predictability of the market for childhood cancer medicines.

In 6 years, approximately **120,000 children** in low- and middle- income countries should benefit.



# Vision

Platform vision: a **comprehensive** solution engaging **global partners** to provide an **uninterrupted** supply of **quality** childhood cancer medicines

|              | Development Phase | Pilot Phase |            | Growth Phase |            |            |
|--------------|-------------------|-------------|------------|--------------|------------|------------|
|              | 2022              | 2023        | 2024       | 2025         | 2026       | 2027       |
| Countries    |                   | 6           | 12         | 30           | 40         | 50         |
| Children     |                   | 5,000       | 12,000     | 25,000       | 35,000     | 45-50,000  |
| Budget (USD) | 2 million         | 11 million  | 21 million | 39 million   | 50 million | 65 million |

\* 50,000 children per year by 2027 represents approximately:

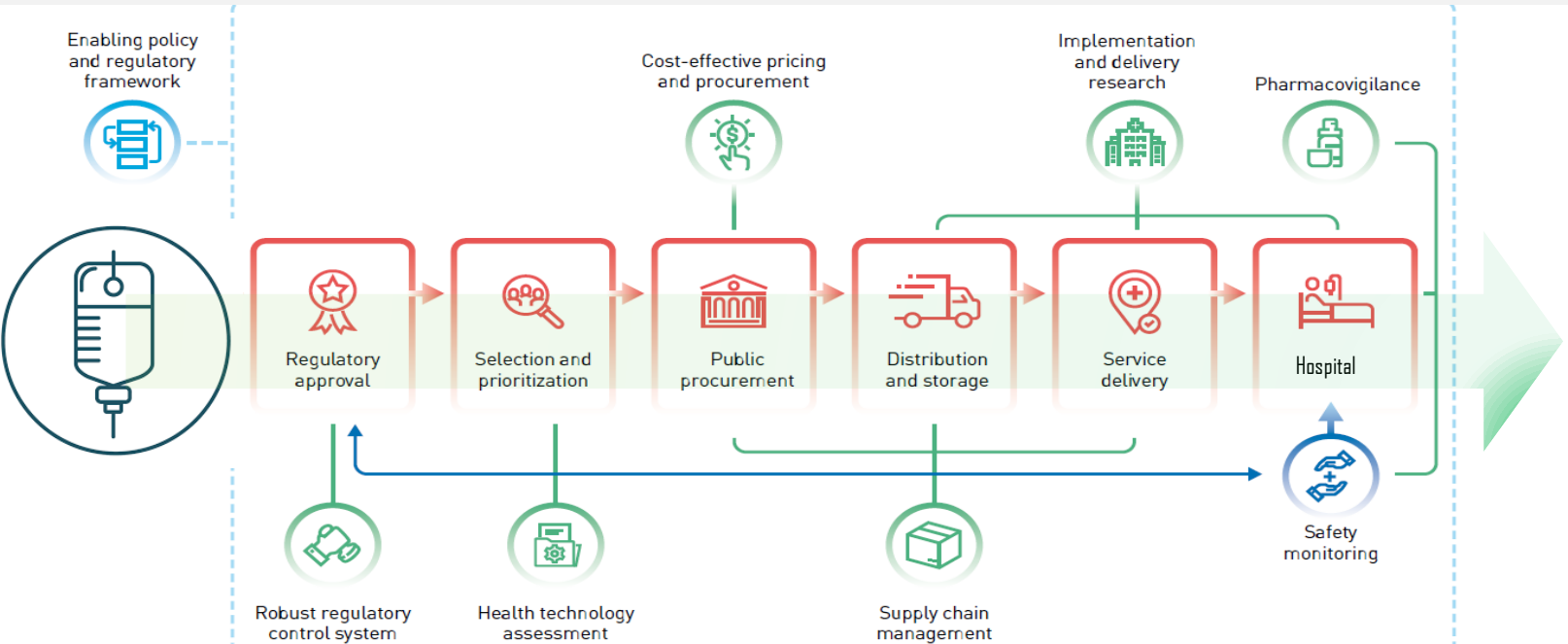
- 25% of all children with cancer in the world
- 30% of children with cancer in low and middle-high income countries
- **60% to 70% of children with cancer in low and lower-middle income countries**

**By 2027, the Global Platform will have provided medications for more than 120,000 children**

# Platform Background: providing end-to-end support

## Country support

- ✓ Preparedness
- ✓ Capacity building
- ✓ Monitoring



|                 | Pipeline analysis           | WHO EML, EDL                            | Regulatory support                                   | Forecasting, HTA                  | Diagnostic techn & administration kits | Benefit package design              | Treatment guidelines                                  | Data systems                              |
|-----------------|-----------------------------|---|--|-----------------------------------|--|-------------------------------------|---|---|
| Country support | - Clinical trial capacities | - Update nEML                           | - Facilitated approval SRA-CRP)<br>- Surveil network | (eg, - Quantification & selection | - Training material & consumables      | - Tool to support national planning | - Clinical decision-making aid (treatment guidelines) | - Strengthen registries (HMIS / LMIS)     |
| Global tools    | - Prioritized formulation   | - WHO EML/ EDL updates inform catalogue | - PQ updates, ERP                                    | - NCD med quantify tool           | - Catalogue admini kit & dx reagents   | - Dialogue with MDB re: financing   |   | - Platforms for AE reports, product track |

# Conclusion: a transformational moment

1. Unique opportunity to **build on GICC**, ensuring medicines delivered in systems and facilities providing comprehensive quality care
2. Platform is a **generational opportunity** to solve a persistent provides through a holistic approach, addressing end-to-end challenges
  - ✓ Consolidate procurement needs and address common bottlenecks
  - ✓ Apply system-based solutions employed in other programmes (eg, vaccines)
3. This Platform will transform lives for families who continue to suffer the **greatest inequities in health** because of childhood cancer
  - ✓ Thank you to St Jude Children's Research Hospital for unparalleled vision and commitment



# INTRODUCTION TO UNICEF SUPPLY DIVISION AND PAHO



for every child



# UNICEF – how we work

- Works across **190** countries and territories
- Works with **governments** based on country specific agreements to address country specific needs and contexts
- Supports global efforts and works in **partnerships** with governments, other UN organizations
- Is entirely **funded by voluntary contributions** from the public and the private sector; it does not receive funding from the UN
- Has an annual budget of approximately **USD 5 billion** to achieve results for children
- Works in **Programmes**, **Advocacy**, **Innovation**, **Technical** Assistance
- **Supplies** are an important component of this budget and are a direct expression of children's rights

# UNICEF'S MISSION AND VISION

## UNICEF advocates to protect children's rights

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



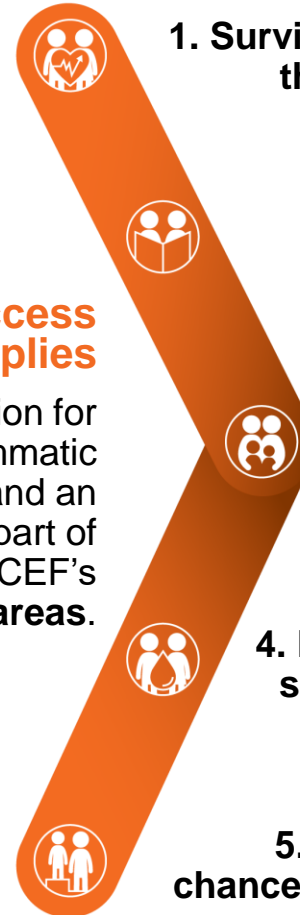
## Transforming rights into reality

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**.



Every child has a right to

1. Survive & thrive



2. Learn



3. Be protected



4. Live in a clean & safe environment



5. A fair chance in life



# SUPPLY DIVISION: CRITICAL FUNCTIONS



Supports results for children with an **effective, efficient supply operation**



Helps meet UNICEF's CCCs in emergencies by providing **rapid supply and logistics response** in emergencies



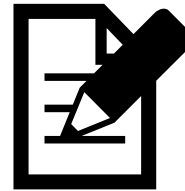
Contributes to **influencing markets** to ensure sustainable access to essentials supplies



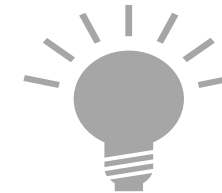
Serves as a **centre of expertise** and knowledge on essential supplies and supply chains, while **building capacities of governments**



Provides **procurement services** to governments and development partners on strategic and essential supplies

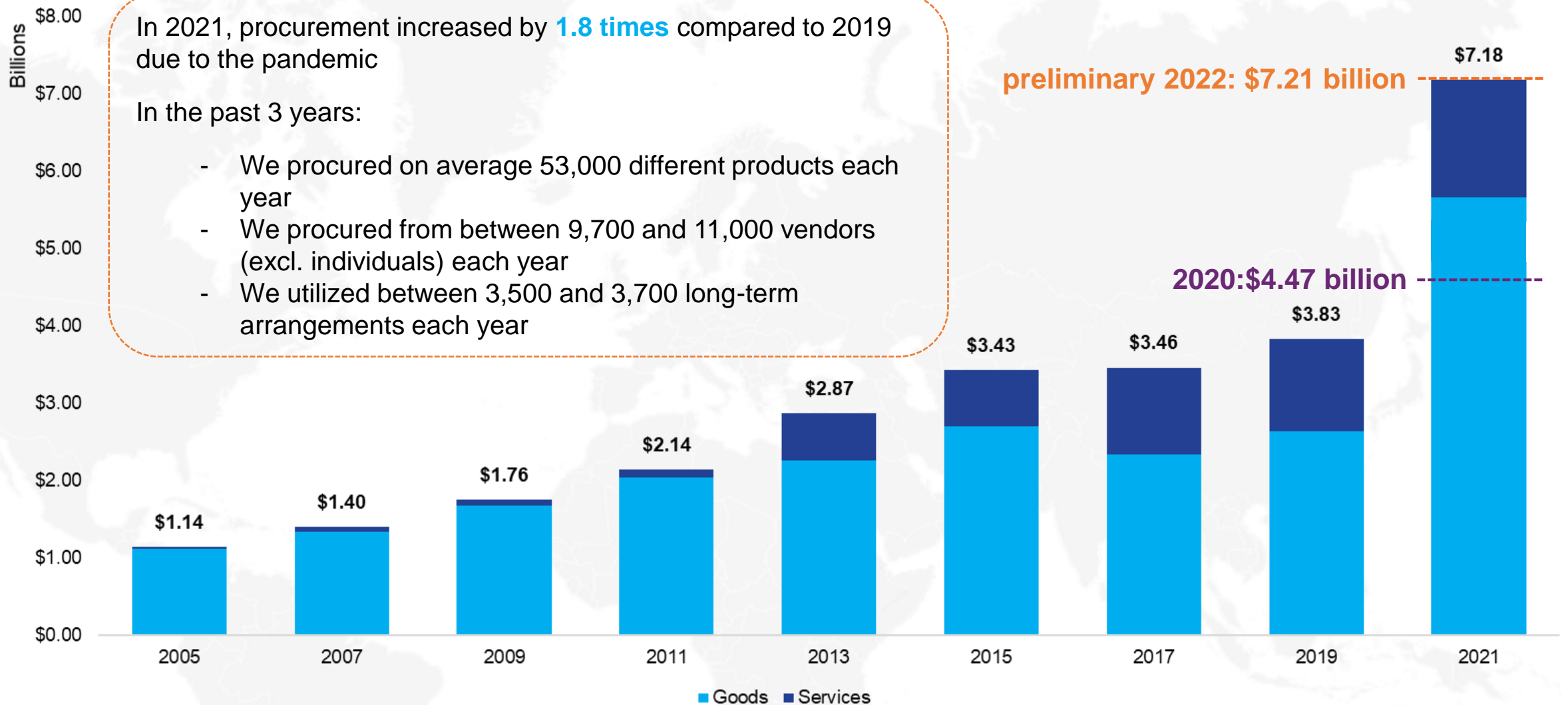


Establishes **policies for supply chain** activities



Uses **product innovation** to increase results and decrease costs

# UNICEF PROCUREMENT 2005-2021



# LINKS TO USEFUL UNICEF RESOURCES

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



# PAN AMERICAN HEALTH ORGANIZATION IN TIME

01



**1902**

In 1870, a yellow fever epidemic struck Brazil, Paraguay, Uruguay, and Argentina and, within eight years, had spread to the United States, where it killed more than 20,000 people. Maritime transport, which was expanding rapidly along with international trade, was the main channel for the international spread of disease at the end of the 19th century. The need to control the spread of epidemics from one country to another to protect people's health and countries' economies led to the creation in December 1902 of what is today known as the Pan American Health Organization (PAHO).

02



**1949**

In 1949, PAHO Director Dr. Fred Soper signs an agreement with the World Health Organization (WHO) making PAHO the Regional Office for the Americas of WHO.

03



**1950**

Becomes the health agency for the Inter-American System, reporting to the Organization of American States (OAS).

04



**1979 & 2000**

The PAHO Revolving Fund for Vaccine Procurement is a mechanism developed in 1979 for the purchase of vaccines.

The Revolving Strategic Fund for medicines since its creation in 2000 has offered a wide range of comprehensive support and capacity-strengthening services for priority health programs across several infectious and chronic diseases.



# PAHO STRATEGIC FUND (2018-2023)

Improving **access** and **availability**  
to essential public health supplies



Over  
**120 Million**  
people supported



Over  
**\$850 Million**  
products procured

**55**  
Participating entities



35 countries and territories



20 health agencies



# WHAT ARE THE PAHO REGIONAL REVOLVING FUNDS LOOKING FOR?





# IF YOU WANT TO KNOW MORE ABOUT PAHO STRATEGIC FUND:



*Contact us:*  
**strategicfund**  
**@paho.org**



Solidarity  
Equity  
Transparency  
Quality  
Panamericanism

**PAHO**  
**Revolving**  
**Fund** For Access  
to Vaccines





# **PUBLIC PROCUREMENT PRINCIPLES**





# Guiding Procurement principles

---

- **Promotion of objectives of UNICEF**  
*(fulfilling the mandate, goals and objectives)*
- **Fairness, integrity and transparency through competition**  
*(clear & appropriate regulations/rules applied to all suppliers, fair process, equal treatment of suppliers, transparent system)*
- **Economy and effectiveness**  
*(meet requirement in terms of quantity, quality, timeliness at the right place. Economy=minimize cost, Effectiveness=meet end-user interest)*
- **Best value for money**  
*(Consider the optimum combination of factors in meeting the end user needs)*

# BACKGROUND AND PURPOSE OF THE TENDER



# BACKGROUND

- WHO and St. Jude Children's Research Hospital have established a platform that aims at dramatically increasing access to oncology treatment to approximately 120,000 children in 50 countries around the world between 2023 and 2027.
- The Global Platform for Access to Childhood Cancer Medicines (GPACCM), the first of its kind, aims at providing an uninterrupted supply of quality-assured childhood cancer medicines to countries.
- The Global Initiative for Childhood Cancer (GICC) launched by WHO to provide assistance to governments and support them with the aim of achieving at least 60% survival rate for all children with cancer by 2023.
- UNICEF and PAHO aim to contribute to the GICC and support the GPACCM by increasing access to medicines and thus increasing survival rate of children.

# PURPOSE

- The aim of launching this tender is to increase the access to quality, efficacious, affordable and safe Paediatric cancer medicines that are included in the WHO Essential Medicines List and that can be used to treat commonly occurring Paediatric cancer conditions.
- The tender aims at establishment of Long Term Agreement ( LTAs) by each UNICEF an PAHO separately for a duration of 12 months with possibility of extension for another 12 months.
- UNICEF for this joint tender is administratively managing the tender process.

# FORECAST

| Region                      | Country    | Estimated # of children with cancer per year |
|-----------------------------|------------|--|
| African (AFRO)              | Zambia     | 150-200                                      |
| Americas (AMR/PAHO)         | Ecuador    | 800-1000                                     |
| Eastern Mediterranean (EMR) | Jordan     | 250-500                                      |
| European (EUR)              | Uzbekistan | 900-1000                                     |
| South-east Asia (SEAR)      | Nepal      | 200-400                                      |
| Western Pacific (WPR)       | Mongolia   | 150-200                                      |

- The first 6 countries to start in the pilot phase in 2023 are listed in the table. An additional six countries are planned to join the initiative in the second year of the pilot phase.



# PROPOSAL SUBMISSION REQUIREMENTS



# Proposal Submission Key Requirements (MANDATORY)

**1- Bid Declaration Form: on pages 3-5 of the solicitation documents.**

**2- Commercial Proposal ( Mandatory Submissions):**

- Annex D Commercial Offer Template
- Annex F Information about environmental sustainability

**3-Technical Proposal ( Mandatory Submissions – *page 12 of the RFP-DAN-2023-503604 Cancer medicines*):**

**a) Site Documents**

- Annex 2a UNICEF Technical Questionnaire for pharmaceutical manufacturers
- Annex 2b UNICEF Technical Questionnaire for pharmaceutical wholesalers

**b) Product Documents**

- Annex 2c Interagency finished pharmaceutical product questionnaire (Automated form);
- Annex 2d IAFPPQ Commitment and authorization - Section 5;
- Annex 2e UNICEF API Declaration form to be filled by FPP manufacturer;
- Annex 2f UNICEF Technical offer form (for SRA/WHO PQ products);
- Annex 2g UNICEF Technical commitment declaration form (for SRA/WHO PQ products);
- Annex 2h Interagency finished pharmaceutical product questionnaire for BTPs and SBPs (for biologicals and biosimilars),
- Annex 2i Letter of authorization permitting UNICEF and PAHO to access information submitted to the tender

➤ **Deadline for submission: 22nd August 2023 at 23:59 hours Copenhagen time.**



# PROPOSAL SUBMISSION PROCESS



# PROPOSAL SUBMISSION INSTRUCTIONS

- ✓ UNGM registration;
- ✓ Acknowledgement and intent to submit a proposal;
- ✓ Commercial and Technical Proposal must be signed and stamped by an authorized person;
- ✓ Two separate proposal submission shall be made:
  - Technical Submission
  - Commercial Submission
- ✓ Technical Proposal **MUST NOT** contain any pricing information;
- ✓ Proposals **MUST NOT** be sent to any individual e-mail address;
- ✓ Currency of proposals shall be in USD or Euro;

# PROPOSAL SUBMISSION INSTRUCTIONS

- ✓ Proposers shall submit their proposal with their legal authorized entity that shall be the same main entity with whom, in case of award, an LTA shall be signed.
- ✓ Bid validity shall be **(365)** days after the Submission Deadline.
- ✓ There is no public bid opening.
- ✓ Any amendments shall be publicly announced and participating Proposers shall be notified.
- ✓ Additional request for clarifications “received after this webinar” shall be sent to Ilona Schioler [ischioler@unicef.org](mailto:ischioler@unicef.org) with copy to Zainab Rashan [zrashan@unicef.org](mailto:zrashan@unicef.org) not later than 7 days before submission deadline



# **COMMERICAL AND TECHNICAL SUBMISSION METHOD**



# Commercial Proposal Submission Method

## ➤ COMMERCIAL PROPOSAL SUBMISSION METHOD:

- The Commercial Proposal templates consisting of ***Annex D***, ***Annex F*** and the ***Bid Declaration Form*** shall be all signed and stamped and submitted in both pdf. and excel formats.
- The Commercial Proposal **MUST BE submitted only to** **supplybid@unicef.org**
- The Commercial Proposal **SHALL BE INVALIDATED** if another e-mail address is being copied or if the Commercial Proposal is sent to another e-mail address!
- E-mail subject box shall make reference to the **Tender Number and Tender Subject “RFP-DAN-2023-503604 – Supply of Paediatric and Adolescent Cancer Medicines”**

# How to Complete the Commercial Proposal Form

- **Completeness:** All columns should be filled
- **Alternative Products:** Add additional row per each different strength, pack size, surface transport mode as applicable.
- **Unit Price:** Please add numerical values in **two decimals** only.
- **Quoted Unit Price:** Please use decimals, do not use commas.

✓ \$1.50  Yes

✓ \$1,50  No

- **FCA Lead time:**
  - ✓ realistic production and delivery lead-time based on FCA Incoterms- named airport/seaport.
  - ✓ Shall be indicated in **Calendar days and** in figures only **(no words)**
- **Minimum Order Quantity (MoQ):** must be declared if applicable.
- Do not merge neither cells, nor rows or columns.

# How to Complete the Bid Declaration Form

## Declaration

The undersigned, being a duly authorized representative of the Company, represents and declares that:

|    |  | YES                      | NO                       |
|----|--|--------------------------|--------------------------|
| 1. | The Company and its Management <sup>1</sup> have not been found guilty pursuant to a final judgment or a final administrative decision of any of the following:  |                          |                          |
|    | a. Fraud;  | <input type="checkbox"/> | <input type="checkbox"/> |
|    | b. Corruption;   | <input type="checkbox"/> | <input type="checkbox"/> |
|    | c. conduct related to a criminal organisation;   | <input type="checkbox"/> | <input type="checkbox"/> |
|    | d. money laundering or terrorist financing;  | <input type="checkbox"/> | <input type="checkbox"/> |
|    | e. terrorist offences or offences linked to terrorist activities;  | <input type="checkbox"/> | <input type="checkbox"/> |
|    | f. sexual exploitation and abuse;  | <input type="checkbox"/> | <input type="checkbox"/> |
|    | g. child labour, forced labour, human trafficking; or  | <input type="checkbox"/> | <input type="checkbox"/> |
|    | h. irregularity (non-compliance with any legal or regulatory requirement applicable to the Company or its Management).   | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. | The Company and its Management have not been found guilty pursuant to a final judgment or a final administrative decision of grave professional misconduct.  |                          |                          |
| 3. | The Company and its Management are not: bankrupt, subject to insolvency or winding-up procedures, subject to the administration of assets by a liquidator or a court, in an arrangement with creditors, subject to a legal suspension of business activities, or in any analogous situation arising from a similar procedure provided for under applicable national law.                             | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. | The Company and its Management have not been the subject of a final judgment or a final administrative decision finding them in breach of their obligations relating to the payment of taxes or social security contributions.   | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. | The Company and its Management have not been the subject of a final judgment or a final administrative decision which found they created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration, or principal place of business ( <i>creating a shell company</i> ). | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. | The Company and its Management have not been the subject of a final judgment or a final administrative decision which found the Company was created with the intent referred to in point (5) ( <i>being a shell company</i> ).   | <input type="checkbox"/> | <input type="checkbox"/> |



Tick **Yes** or **No** as applicable

<sup>1</sup> "Management" means any person having powers of representation, decision-making or control over the Organization. This may include, for example, executive management and all other persons holding downstream managerial authority, anyone on the board of directors, and controlling shareholders.

# Technical Proposal Submission Method

## ➤ TECHNICAL PROPOSAL SUBMISSION METHOD:

- Proposers shall send a request for creation of a folder in UNICEF SharePoint library for the submission of the Technical Proposal by sending an e-mail to **Rennie Shonhiwa-Chikwanha** @ [rshonhiwa@unicef.org](mailto:rshonhiwa@unicef.org)
- Proposers shall provide the following information in the e-mail:
  - Full name and address of the Proposer
  - INN description of products offered
  - Contact person(s) in the company to access the SharePoint library
  - Manufacturing site information for each product offered
- Proposers **MUST NOT** upload any commercial offer or commercial information to the SharePoint library. If this happens, the offer will be INVALIDATED.
- Please read ***Annex 2 Instructions for technical proposals and offers*** and ***Annex 3 Instructions for uploading Technical Documents to SharePoint.***

Page 14 and 19 of the RFP-DAN-2023-503604 Cancer medicines



# Technical Proposal Submission Method

## ➤ Continued TECHNICAL PROPOSAL SUBMISSION METHOD:

- List of documents to be uploaded into Site Documents & Product Documents folders are in the Annex 3.
- Tag the documents appropriately as shown in Annex 3.
- 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 it e.g. ***Not applicable*** or ***Will submit the document later (by XXXX date) etc.*** in lieu of the Annex. Page 2 of the Annex 3 Instructions for uploading Technical Documents to SharePoint

# How to Submit Technical Proposal

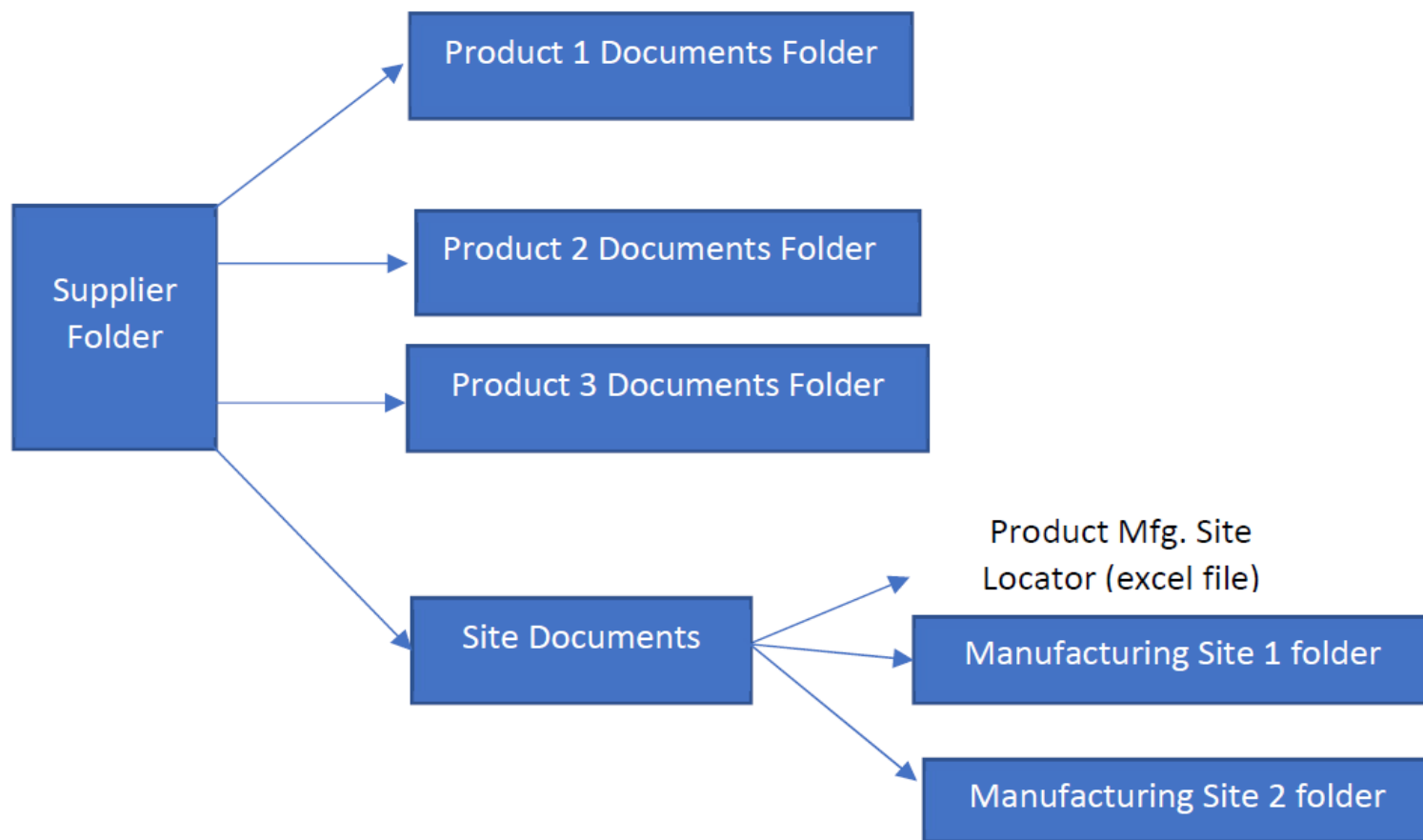
## UNICEF WILL ACCEPT

Electronic files named appropriately and uploaded to the UNICEF Supplier SharePoint library  
(Please refer to Annex 3 for detailed instructions)

## UNICEF WILL NOT ACCEPT

- Any paper documentation – except for Certificate of Analysis (CoA) and Patient Information Leaflet (PIL) accompanying the samples when they are asked for.
- CDs or USB memory sticks
- Documentation sent via large-size emails or multiple emails
- Zipped folders in the share point library

# Proposer/Supplier Folder Structure



# TECHNICAL PROPOSAL SUBMISSION PREPARATION AND SAMPLES SUBMISSION








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





ANNEX C - Overview of the Product List to be Procured

RFP-DAN-2023-503604 - Supply of Peadiatric and Adolescent Cancer Medicines

| Item  | Short description  | General description  | Route of Administration  | Technical specification                             | INN  | Indicative pack size and type<br>(Other pack sizes/types will be considered)  |
|--|---|---|---|--|---|--|
| 10   | Ca folinate 5mg tabs  | Calcium folinate 5mg tablets  | Oral  | Each tablet contains calcium folinate, which is equivalent to 5mg folinic acid (leucovorin)  | Calcium folinate  | Blister pack of 28   |
| 20   | Ca folinate 15mg tabs   | Calcium folinate 15mg tablets   | Oral  | Each tablet contains calcium folinate, which is equivalent to 15mg folinic acid (leucovorin).<br>Functionally scored tablets preferred | Calcium folinate  | Bottle of 10   |
| 30   | Cyclophosphamide 25mg tabs  | Cyclophosphamide 25mg tablets (as monohydrate)  | Oral  | Each tablet contains cyclophosphamide monohydrate equivalent to 25 mg anhydrous cyclophosphamide                                       | Cyclophosphamide  | Pack of 50   |
| 40   | Cyclophosphamide 50mg tabs  | Cyclophosphamide 50mg tablets (as monohydrate)  | Oral  | Each tablet contains cyclophosphamide monohydrate equivalent to 50 mg anhydrous cyclophosphamide                                       | Cyclophosphamide  | Blister pack of 100  |
| 50   | Dasatinib 20mg tabs   | Dasatinib 20mg tablets  | Oral  | Each tablet contains 20mg of dasatinib   | Dasatinib   | Blister pack of 60   |
| 60   | Dasatinib 50mg tabs   | Dasatinib 50mg tablets  | Oral  | Each tablet contains 50mg of dasatinib   | Dasatinib   | Blister pack of 60   |
| 70   | Dasatinib 70mg tabs   | Dasatinib 70mg tablets  | Oral  | Each tablet contains 70mg of dasatinib   | Dasatinib   | Blister pack of 60   |
| 80   | Dexamethasone 2mg tabs  | Dexamethasone 2mg tablets   | Oral  | Each tablet contains 2mg of dexamethasone  | Dexamethasone   | Blister pack of 50   |
| 90   | Dexamethasone 4mg tabs  | Dexamethasone 4mg tablets   | Oral  | Each tablet contains 4mg of dexamethasone  | Dexamethasone   | Blister pack of 50   |

# Criteria

- Marketing Authorization (MA) issued by the SRA in the country of the SRA (registered and marketed in the country of SRA). "for export only" NOT acceptable
- WHO Prequalification
- Approval by the SRA, based on scientific opinion on high priority human medicines intended for markets outside of their jurisdiction

Exceptionally:

- PAHO – medicines approved by any of the Regional Reference National Regulatory Authorities (NRAr)  
[https://www3.paho.org/hq/index.php?option=com\\_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=0&lang=en#gsc.tab=0;](https://www3.paho.org/hq/index.php?option=com_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=0&lang=en#gsc.tab=0;)
- UNICEF – Assessment results of the WHO Expert Review Panel (ERP)  
<https://extranet.who.int/pqweb/medicines/expert-review-panel>

# Stringent Regulatory Authority (SRA)

- As a Stringent Regulatory Authority (SRA), it is considered:
  - A member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015) or
  - An ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015) or
  - A regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein, and Norway (as before 23 October 2015).

*3. Statement of quality, page 10 of the RFP-DAN-2023-503604 Cancer medicines*

# Technical Proposal Requirements

## **GMP Assessment of Manufacturing site**

- Annex 2a - Technical questionnaire for pharmaceutical manufacturers
  - To be completed by all manufacturers (including the contract manufacturers)
  - One form to be completed per manufacturing site where FPPs offered are manufactured.

## **GDP Assessment**

- Annex 2b - Technical questionnaire for pharmaceutical wholesalers
  - To be completed by wholesalers and distributors only.

*5.2.4 Technical Questionnaires and Forms, page 12 of the RFP-DAN-2023-503604 Cancer medicines*



# Technical Proposal - **SRA products** - Annexes to be submitted

- For medicines manufactured, registered and actively marketed in **the country of Stringent Regulatory Authority (SRA)**, WHO Prequalified medicines and medicines with SRA approval for high priority medicines, please provide the following:
  - **DULY FILLED/SIGNED Annex 2a Technical Questionnaire for pharmaceutical Manufacturers** (for manufacturers only) or **Annex 2b Technical Questionnaire for Pharmaceutical Wholesalers** (for wholesalers only).
  - **DULY FILLED/SIGNED Annex 2f UNICEF Technical Offer Form** (for each product).
  - **DULY FILLED/SIGNED Annex 2g UNICEF Technical Commitment Declaration Form** (for each product).

Annex 2 Instructions for technical proposals and offers

# Technical Proposal - **SRA products** - Annexes to be submitted cont.

- **Annex 2i Letter of Authorization** permitting **UNICEF** and **PAHO** to access information submitted to the tender
- Submit **documents** mentioned in the Annex 2f - CoA, CoPP (copy of product registration & marketing status), label artwork (primary & secondary packaging), SmPC and PIL (Patient Information Leaflet) (for each product offered as well as for diluent if applicable)
- Commercial **samples** might 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
  - In lieu of samples, closeup photos of the carton (all sides), primary package and PIL/package insert should be submitted
- The following documents may be required during the supply of products to countries (PAHO):
  - Certificate of Origin (CoO); Good Manufacturing Practice (GMP) certificate(s) issued by the NRA of the country of manufacture for site(s) involved in the production of the finished product; Free Sale Certificate (FSC), if applicable; Proof of therapeutic equivalence (i.e. Bioequivalence/Bioavailability studies, when applicable, or comparative in vitro dissolution tests)

# Technical Proposal Guidance for Wholesalers only

- SRA products must be packaged and labelled according to the country of SRA registration only.
- If SRA products are offered from Non-EU origin e.g., products having valid Marketing Authorization (MA)/registration in the USA, Canada, Australia, **THEN**
  - The wholesaler will be required to submit/provide Marketing Authorization Holder (MAH) authorization from MAH holder based in a country of SRA to wholesaler offering the product or proof of supply chain from MAH based in a country of SRA to wholesaler offering the product.
- The offered SRA products (including SRA products offered from Non-EU origin but only from country of SRA), must be supplied directly from the country of SRA where MAH holder is based or from any country of SRA.
- All SRA products (from country of SRA or Non-SRA) must be released from country of SRA only and must be supplied with Finished Product CoA (Certificate of Analysis) issued by country of SRA only.
- CoC (Certificate of Compliance) will not be accepted in lieu of FPP CoA

# Technical Proposal Guidance for Wholesalers only cont.

- If SRA products are manufactured in Non-SRA country they would be considered as SRA products, **ONLY if**
  - Are packaged and labelled according to the SRA in the country of registration
  - Product/s is actively marketed and released in SRA market
  - Supplied with Finished Product CoA from country of SRA of MAH (Marketing Authorization Holder) or from QP responsible for release within SRA country
- If SRA products are manufactured and supplied directly/offered from Non-SRA country, then such products would be considered as Non-SRA products and then wholesaler will have to submit all the technical documentation required for Non-SRA product assessment. e.g. Annex 2c and other documents.
- Non-English labelled SRA Products that are manufactured, registered, actively marketed and released from country of SRA may be considered, if label/packaging material is translated to English text and must provide declaration of equivalence issued by MAH from country of SRA. The translated English label pack may be accepted without the SRA Marketing Authorization /registration number on the pack.

# Technical Assessment of **Biological Product Dossiers** - potential ERP process

- **Annex 2h Interagency finished pharmaceutical product questionnaire for BTPs and SBPs**
  - All biologicals and biosimilars
- **Annex 2d - Commitment and authorization** (section 5)
- **Annex 2e - UNICEF API declaration form**
- **Annex 2i Letter of Authorization permitting UNICEF and PAHO to access information submitted to the tender**
- In lieu of samples, closeup photos of the carton (all sides), primary package and PIL/package insert should be submitted



# Technical Proposal - **Non-SRA products** - Annexes to be submitted - potential ERP process

**For products manufactured and/or marketed in the country of Non-Stringent Regulatory Authority (Non-SRA) please provide the following:**

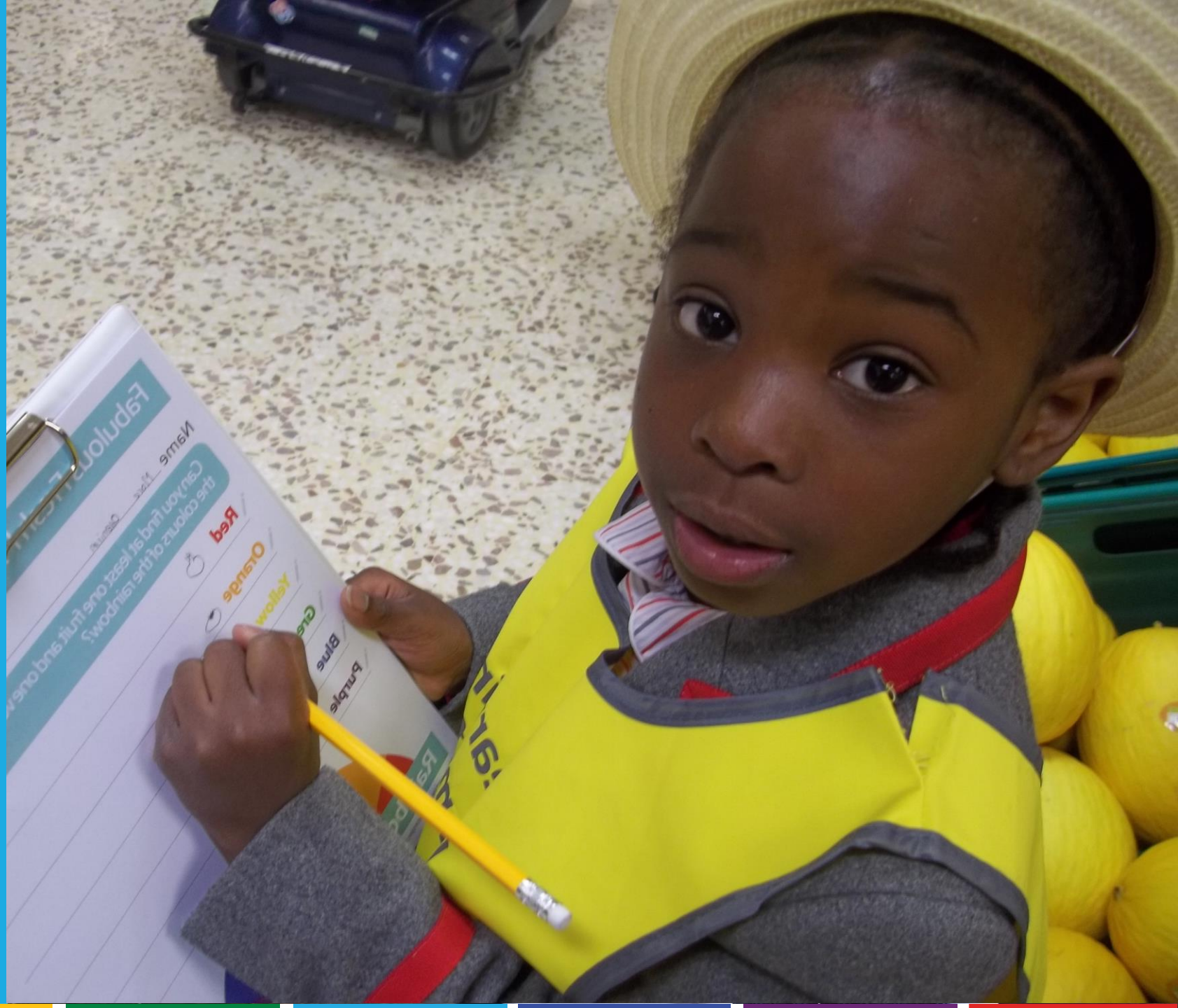
- **DULY FILLED/SIGNED Annex 2a Technical Questionnaire for pharmaceutical Manufacturers** (For manufacturers only- To be filled and signed by Manufacturers even if the products is offered via wholesaler)
- **DULY FILLED Annex 2c Interagency finished pharmaceutical product questionnaire** (Automated form) - to be completed for non-SRA registered products
  - All relevant annexes as a separate pdf files, according to Annex 3 Instructions for uploading Technical Documents to SharePoint
- **DULY FILLED/SIGNED Annex 2d IAFPPQ Commitment and authorization** - Section 5
- **DULY FILLED/SIGNED Annex 2e UNICEF API Declaration form** to be filled by FPP manufacturer. If there is more than one source for any API, a separate form should be filled for each source
- **Annex 2i Letter of Authorization permitting UNICEF and PAHO to access information submitted to the tender**
- Artwork (primary & secondary packaging), SmPC and PIL (Patient Information Leaflet) (for each product offered).
- Sample might be required. In lieu of samples, closeup photos of the carton (all sides), primary package and PIL/package insert should be submitted

# Deep-Dive for Annex 2c

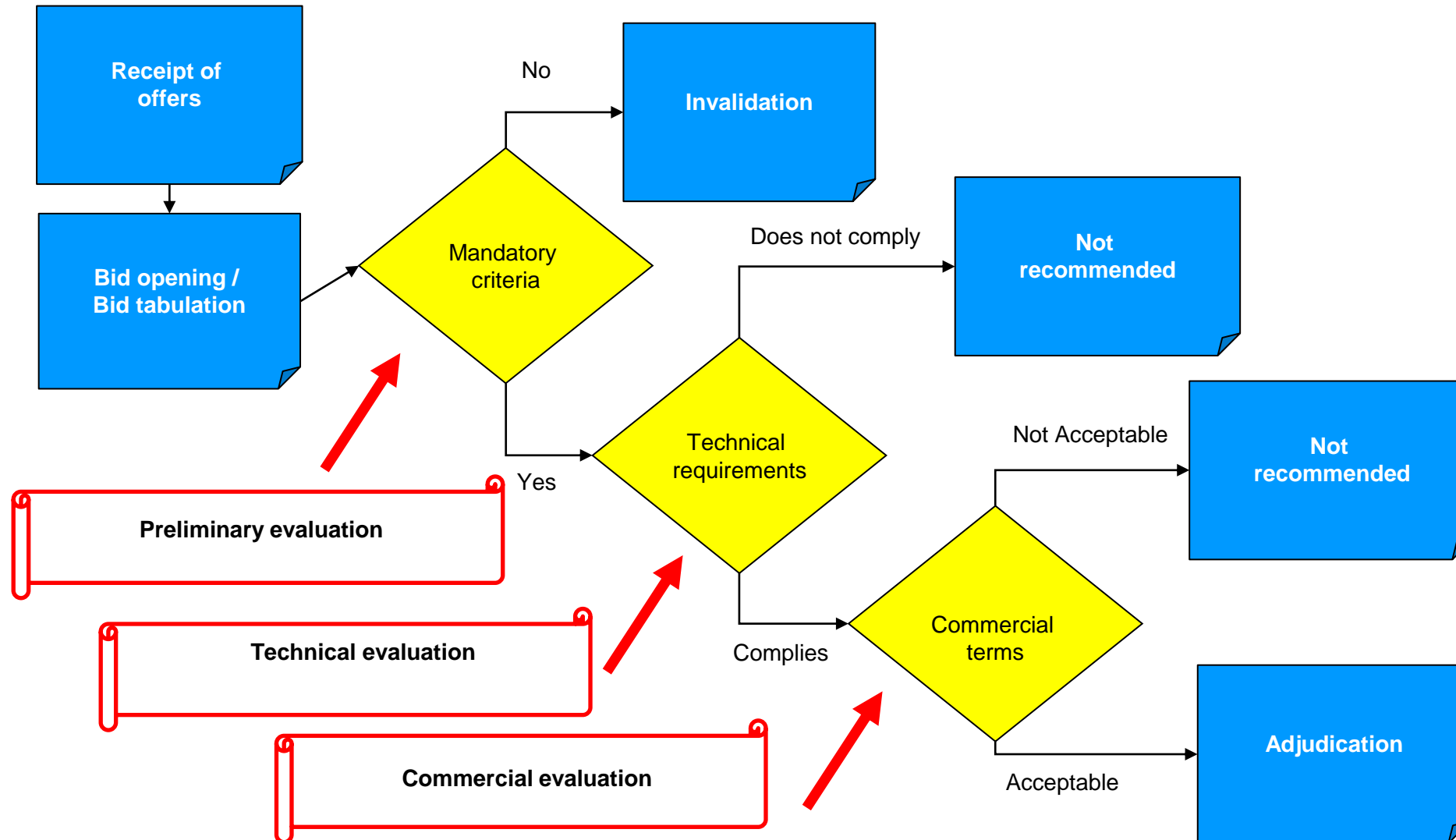
## **Annex 2c - Interagency Finished Pharmaceutical Product Questionnaire (IFPPQ)**

- This annex is to be completed for EACH FPP not eligible for Annex 2f & 2g (i.e. for products not having WHO PQ/SRA market authorization).
- The annexes to the IFPPQ should NOT be merged into a single pdf document.
- Ensure that each of the annexes are named appropriately and uploaded as separate pdf files.
- Please ensure you upload Annex 2c (Interagency Questionnaire) in its original format. (i.e. please DO NOT upload printed/scanned versions. The form is automated hence cannot be processed if a scanned version is uploaded.

# TENDER EVALUATION PROCESS



# Evaluation Flowchart



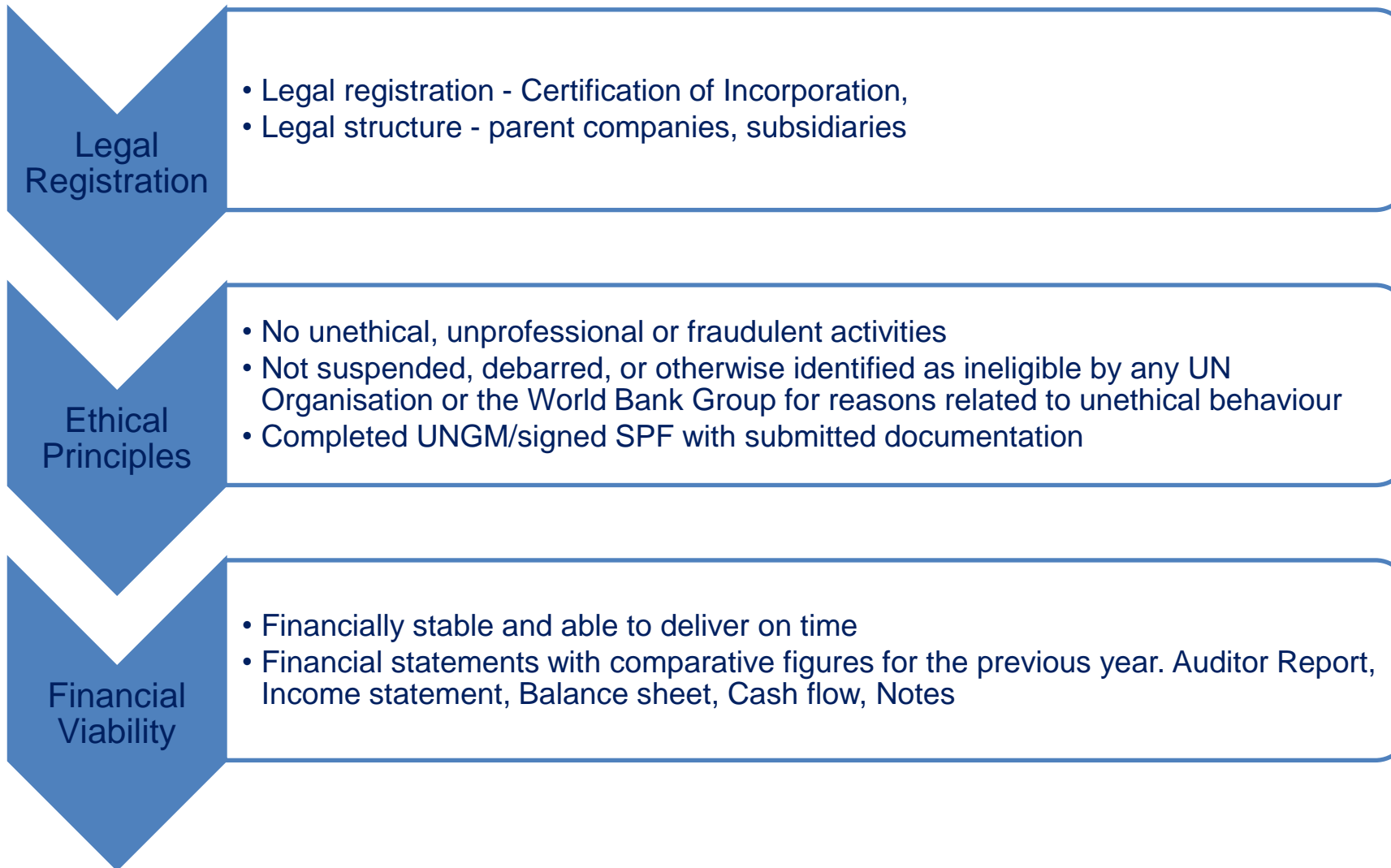
# Preliminary Evaluation

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

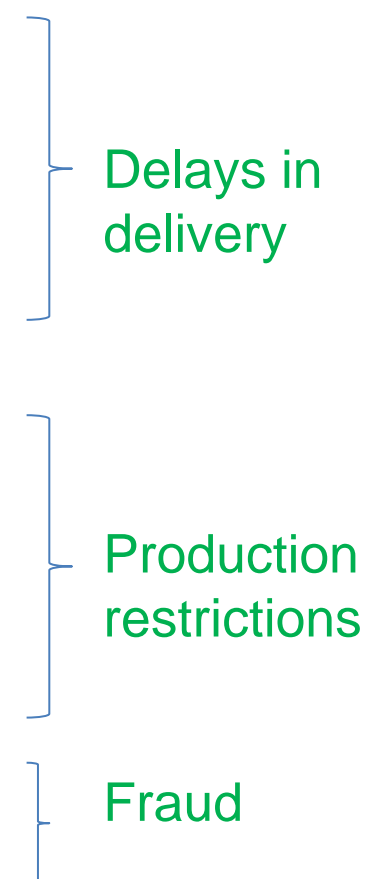
- Compliance with eligibility conditions.
- Compliance with the bid submission deadline
- Completeness of the proposals
- Acceptance of UNICEF/PAHO Terms and Conditions
- Compliance with the requested Incoterms
- Compliance with UNICEF payment terms & currency
- Compliance with the requested validity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



# Other Aspects of Supplier Eligibility Evaluation



# Supplier Eligibility Evaluation Elements

- Supplier bankruptcy
  - Supply shortages (stock outs) & delays
  - Constrained cash flow
  - Financial instability and crisis
  - Reputational damage due to unethical conduct
- 
- The diagram uses blue curly braces to group the list items into three categories on the right:
- Delays in delivery** (includes Supplier bankruptcy and Supply shortages)
  - Production restrictions** (includes Constrained cash flow and Financial instability)
  - Fraud** (includes Reputational damage)

# 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 (and mentioned above).
- Different pack type/size will be considered
- Different dosage forms will be considered (capsules instead of tablets, powder for injection instead of solution for injection)
- In-use stability/shelf life must be mentioned on the Pack and PIL/pack insert e.g., the product must be discarded “number of days” after opening.
- If the product contains diluent, it should have longer shelf-life than the medicine
- All the products should comply with the monograph of one of the following pharmacopeias (if applicable): BP, Ph. Eur., USP, Ph. Int.
- As a minimum, labeling text should be in English. Packing with English and other language text would be also considered.
- Finished Product Certificate of Analysis (CoA) must be in English and must be provided

# Commercial Evaluation

- Acceptance of and compliance with UNICEF and PAHO General Terms and Conditions.
- Compliance of Proposals with all instructions in the RFP-DAN-2023-503604.
- Compliance with UNICEF's Financial requirements.
- Lowest offered price.
- Product Registration Status.
- Longest shelf life, i.e., preference will be given to Proposals for products with total of 36 months shelf life or more at Zone IVA and/or Zone IVB conditions.
- Shortest lead time.
- Minimum order Quantity (MoQ). Proposers must declare in their Proposals if there will be any minimum order quantity(-ies) for the item(-s) detailed in the schedule to this Solicitation Document. Any such minimum order quantities will be considered as part of the evaluation process. Smallest minimum order quantities are preferred.
- Optimal supply chain management.
- Satisfactory historical performance of past delivery on previous orders, if applicable.
- Satisfactory reference check as applicable.

# Key Criteria for LTA Award

Best value for money { Quality  
Price  
Delivery Time / Speed

Market development

Supplier past performance

The tender outcome is reviewed by Contracts Review Committee who recommends approval to UNICEF SD Director.

SD publishes monthly contract awards online.



# Type of Contracts and Agreements

- **UNICEF and PAHO will each establish their own Agreements separately.**

## ➤ **UNICEF Long Terms Agreement(s) LTAs:**

Multiple time bound LTAs shall be signed with the successful proposers against which Purchase Orders shall be raised as and when required through out the validity of the LTA.

## ➤ **PAHO Notification Agreement Form:**

Multiple agreements shall be established against which Purchase Orders shall be raised as and when required through out the validity of the agreement.

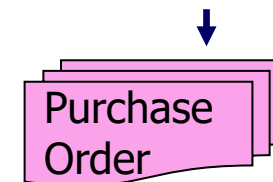
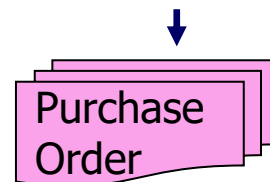
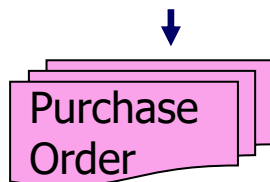
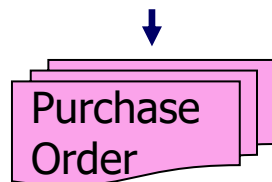
## ➤ **Duration of Agreements:**

Agreements shall be valid initially for a **period of 12 month with possibility of extension for further 12 months.**

**1**

**Establishment of Long Term Agreements for 1 to 2 years**

**2**



# Contract Management

- Contract Management: is the process that enables both parties of the Contract to meet their obligations in order to deliver the objectives required from the Contract.
- Key Enabling Factors:
  - ✓ Communication
  - ✓ Monitoring (including performance)
  - ✓ Feedback

UNICEF values the relation it has with suppliers and makes priority by establishing effective processes to manage it.



Thank You

# Q&A

---

