Joint UNICEF-UNFPA-WHO Meeting with Manufacturers and Suppliers

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Session 9: Day 3
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unicef
for every child

About UNICEF

Updates of Unicef Quality Requirements and Tools, Demonstration of Supplier document Library




About UNICEF and Supply

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**

unicef | UNFPA | World Health Organization

Towards 2030: An Ambition Renewed

PRINCIPLES Accountability | Access | Anti-racism and Non-discrimination | Equity / Inclusion / LNOB | Gender Equality | Human Rights | Humanitarian Principles

CROSS-CUTTING PROGRAMMES Climate Action | Disability | Gender | Peacebuilding | Resilience

Enablers

- Accelerated Resource Mobilisation
- Agile and Responsive Business Model
- Decentralised and Empowered Internal Governance and Oversight
- Dynamic and Inclusive People and Culture
- Strategic Internal Communication and Staff Engagement

Change Strategies

- Advocacy and Communications
- Community Engagement, Social and Behaviour Change
- Data, Research, Evaluation and Knowledge Management
- Digital Transformation
- Gender Transformative Programming
- Innovation
- Partnership and Engagement: Public and Private
- Risk-informed Humanitarian and Development Nexus Programming
- Systems Strengthening to Leave No One Behind

Partnerships UN Working Together

Medium-Term Changes (by 2025)

Country-level

- Catalytic Child, Adolescent, Youth Engagement and Empowerment
- Child-friendly Governance, Institutions, Policies and Laws
- Comprehensive and Predictable Financing for Children
- Decision-making Based on Data and Evidence
- Equitable and Inclusive Access to Essential Supplies and Services
- Full Implementation of the CCCs for Children in Humanitarian and Fragile Settings
- Greater Public Engagement and Support to Child Rights
- Positive Behaviours, Social and Gender Norms
- Programmes that Reduce Fragility, Prevent Crisis and Build Peace
- Strategically Mobilised Business for Results

Regional- and global-level

Long-Term Results (by 2030)

Goal Area 1. Every child, including adolescents, survives and thrives, with access to adequate diets, services, practices and supplies

Goal Area 2. Every child, including adolescents, learns and acquires skills for the future

Goal Area 3. Every child, including adolescents, is protected from violence, exploitation, abuse, neglect and harmful practices

Goal Area 4. Every child, including adolescents, has access to safe and equitable water, sanitation and hygiene services and supplies, and lives in a safe and sustainable climate and environment

Goal Area 5. Every child, including adolescents, has access to inclusive social protection and lives free from poverty

DECADE OF ACTION

Impact

Realising the rights of every child, including adolescents especially the most excluded

Every child

CRC

CEDAW

CRPD

Sphere of control and accountability → Sphere of influence → Vision




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**

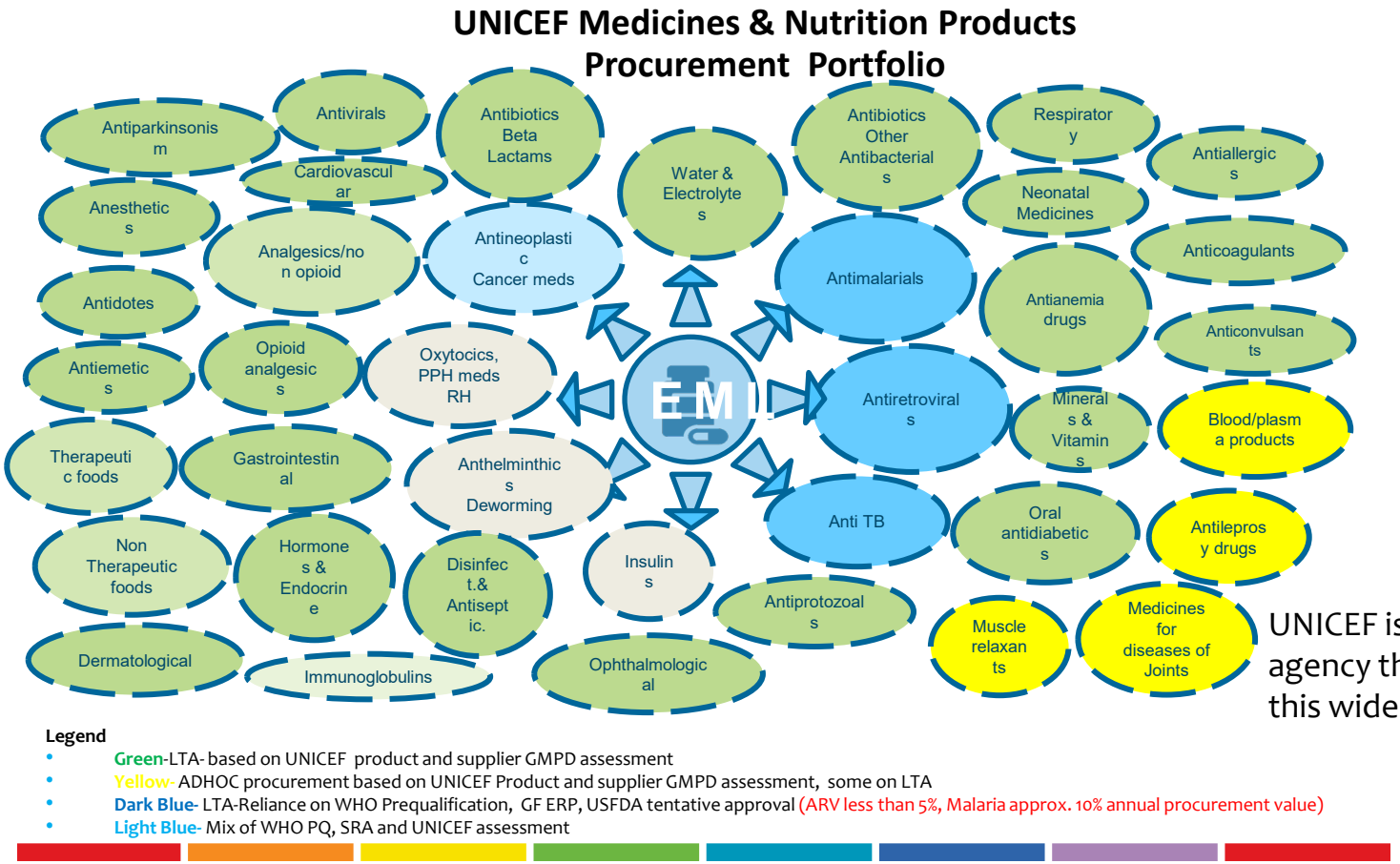
Provides **procurement services** to governments and development partners on strategic and essential supplies

Establishes **policies for supply chain** activities

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

Supply Division is UNICEF's supply and logistics headquarters and home to the largest humanitarian warehouse in the world

UNICEF Medicines Product portfolio based on WHO Model EML



UNICEF is the only UN agency that procures this wide portfolio

Legend

- **Green**-LTA- based on UNICEF product and supplier GMPD assessment
- **Yellow**- ADHOC procurement based on UNICEF Product and supplier GMPD assessment, some on LTA
- **Dark Blue**- LTA-Reliance on WHO Prequalification, GF ERP, USFDA tentative approval (ARV less than 5%, Malaria approx. 10% annual procurement value)
- **Light Blue**- Mix of WHO PQ, SRA and UNICEF assessment

Focus areas for Medicines and Nutrition

Procurement focus that addresses UNICEF **programmatic priorities**

Follow and promote **WHO recommendations** on selection and use of medicines and international guidelines on nutrition

Ensure availability of **affordable** essential medicines and nutrition supplies for primary health care and emergency relief

Develop **sources and market** for priority products

Ensure capacity to excel in **procurement activities** (quality assurance, selection, contracting, supply chain management)

Engagement with pharma companies in Africa

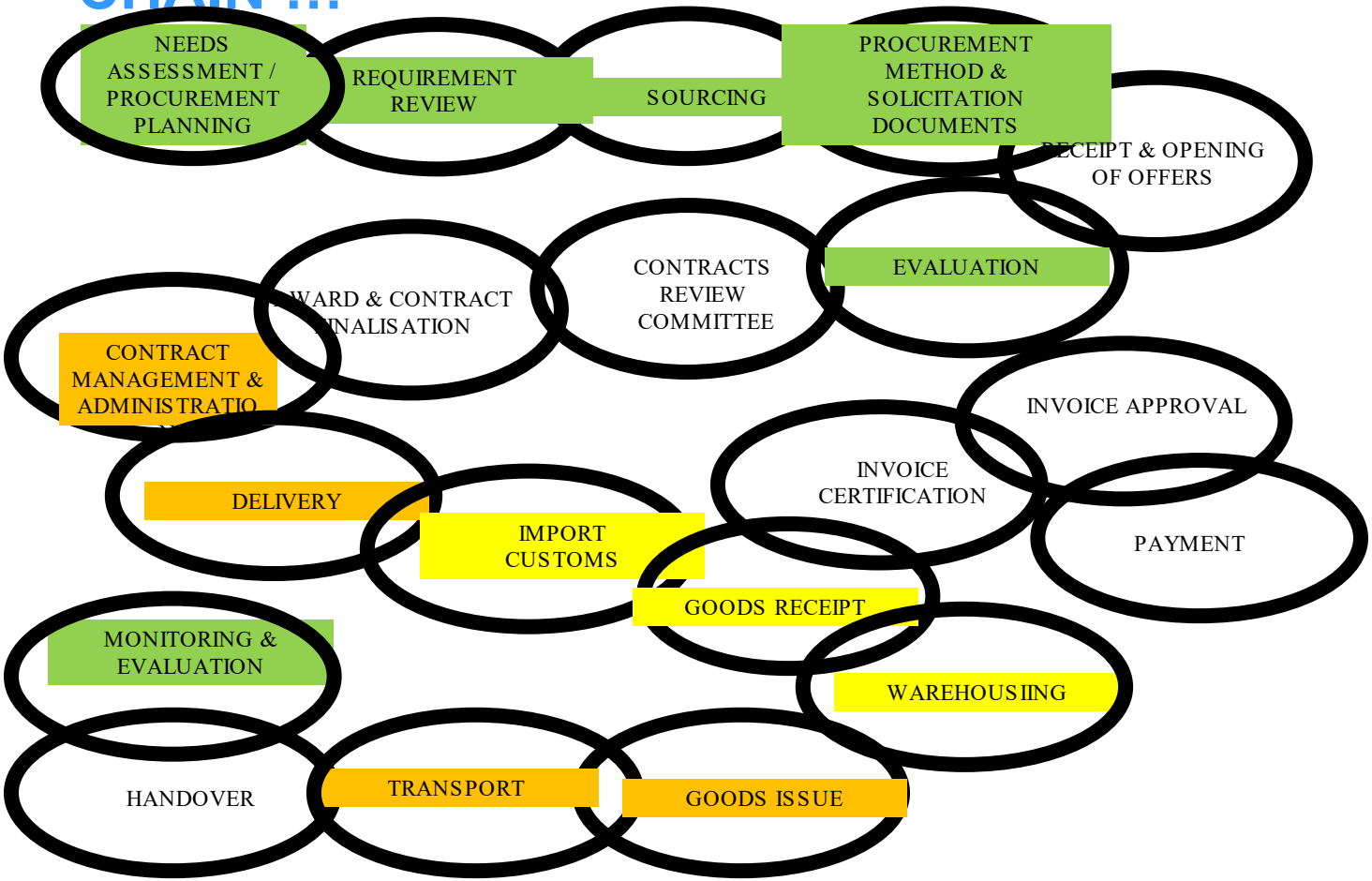
Company	Country	Product	Contracts	What worked and what did not
SXXXXS	TNZ	ORS	$338,040 (2009)	GMP non-compliant
VXXXXXM	ZIM	ARV	$1,103,333 (2011-2012)	WHO PQ- delisted
UXXXXXL	KEN	ORS, Zinc, Antimalarials, ODS	$48,454,280 (2012-2023)	Active, major supplier to UNICEF, WHO PQ
XXXXX	NIG	ORS+Zn, Zn	$2,081,255 (2016-2018)	GMP failure (WHO/UNICEF)
DDDD	SA	ARVs	$2,438,041 (2006-2013)	No longer needed
DDDDD	SA	LVP/IN FLUIDS	$111,091 (2007-2011)	Limited interest
ffdfdfff	SA	Vit B3	$11,091 (2019-2021)	Ad-hoc source, active

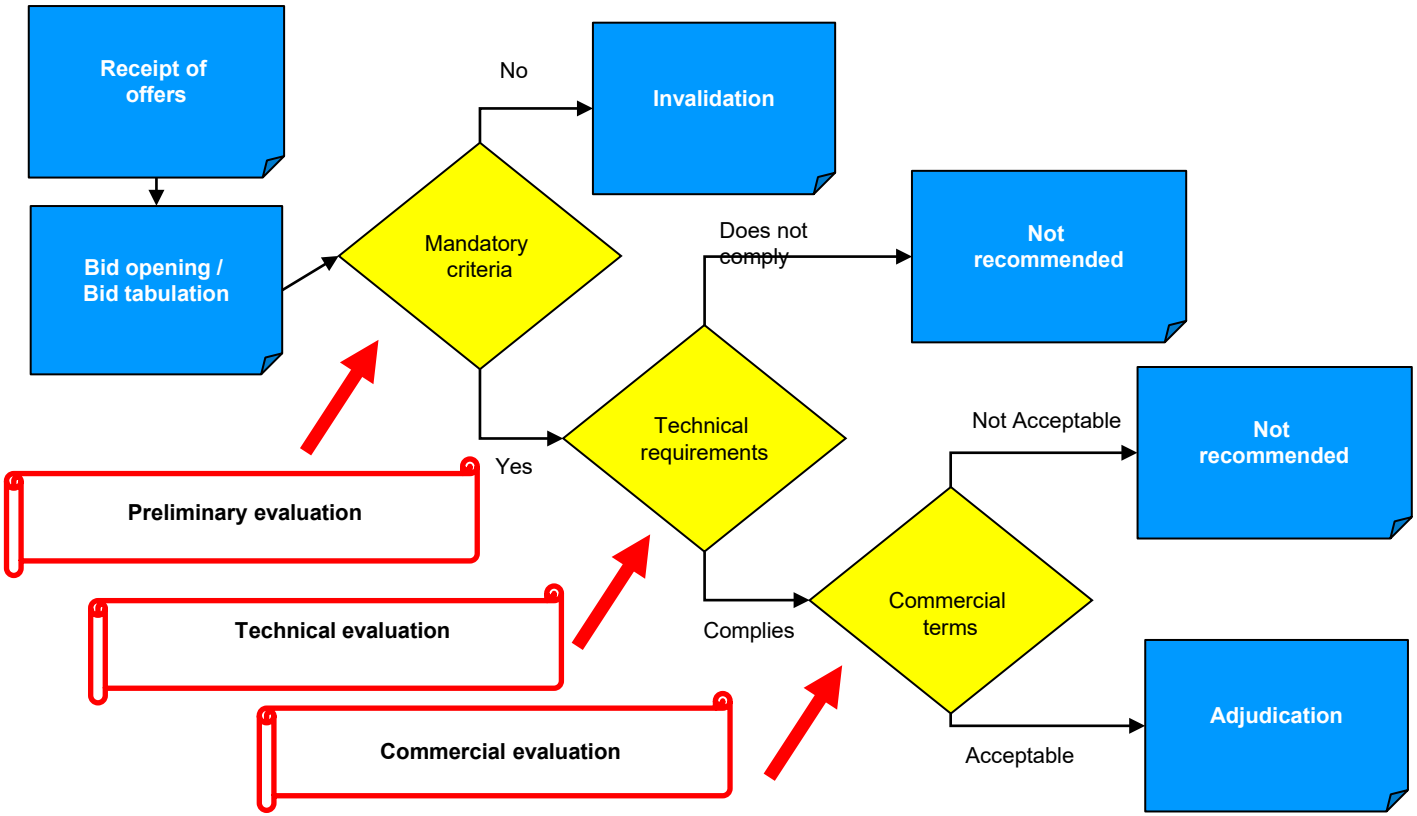
Guiding principles

Quality Risk Management




Technical &Quality roles in the SUPPLY CHAIN …




Receipt of offers
Bid opening / Bid tabulation
Mandatory criteria
No
Invalidation
Does not comply
Not recommended
Technical requirements
Not Acceptable
Not recommended
Yes
Preliminary evaluation
Technical evaluation
Commercial evaluation
Complies
Commercial terms
Acceptable
Adjudication

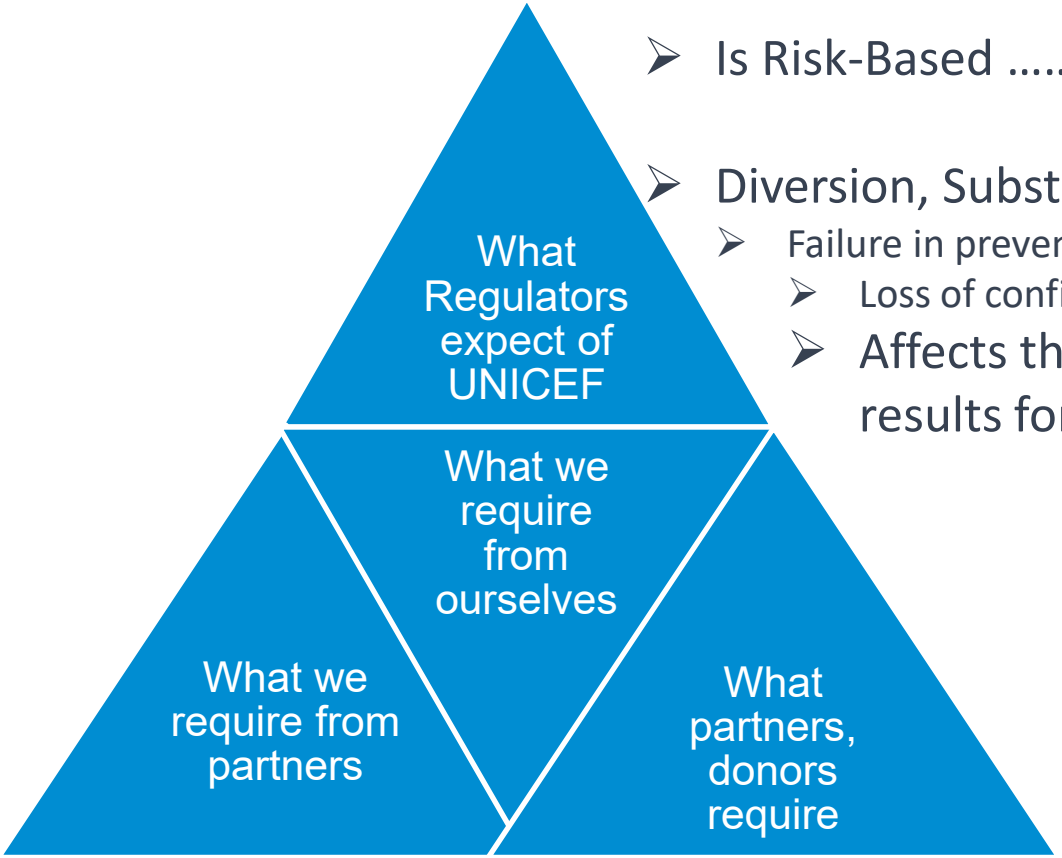
Guiding principles
UNICEF implements and maintains a Quality Management System (QMS)

Based on ISO 9001, 2015
WHO Model QA Scheme,

Partner Requirements/ End Users Needs

QMS Includes:
Documentation management system
Complaints management system
Corrective actions
Problem solving tools and training
Internal assessment/spot checking

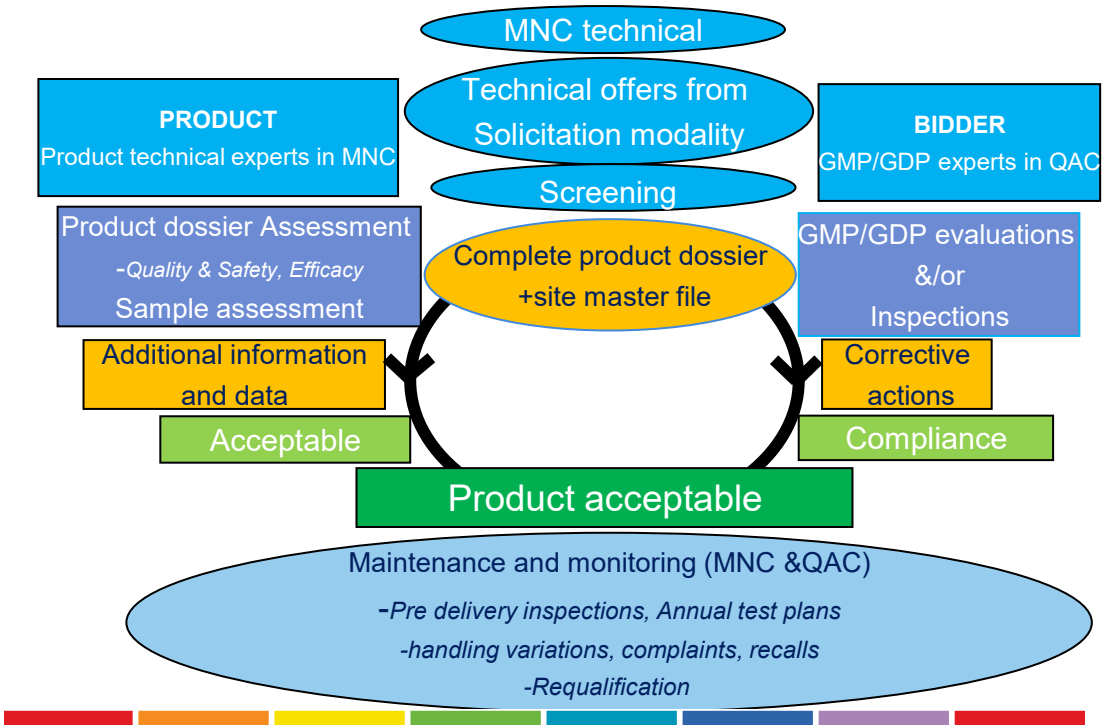
Guiding principles
UNICEF Quality assurance in (Pharmaceutical) Supply Chains….



- Is Risk-Based ……Risk register
- Diversion, Substandard, Falsified products cause harm
  - Failure in preventing/managing the diseases
    - Loss of confidence in medicines, vital health systems..
  - Affects the way we work together to obtain results for children

Processes influencing
RELIANCE
Who can we rely on ?
Whose data can be used ?
Risk based approach per Product…
Risk based approach per Supplier…

UNICEF Prequalification of Medicines Framework



Product assessment Framework

RELIANCE: For product approved by SRA and or WHO Prequalified, abridged review is conducted focusing on tender specific requirements

FULL DOSSIER ASSESSMENT: For Non SRA, Non WHO PQ products. Challenge with BE

ASSESSORS; UNICEF has Both regulatory and pharmacy practice experts. They undergo regular training on assessment to ensure they have skills and knowledge commensurate to current regulatory science needs- **8 technical experts doing dossier assessments & 3 GMP inspectors all with over 10 years experience**

Apply unified standards of acceptable quality, safety and efficacy

WHO, ICH, Monographs

UNICEF Technical requirements for pharmaceutical products

Products are considered acceptable based on assessment of their quality, safety and efficacy, based on information submitted by the manufacturers, and inspection of the corresponding manufacturing sites

Reliance where Applicable

- WHO Prequalification (PQS)
- Stringent regulatory Authorities (SRA)
- Pharmaceutical Inspection Cooperation Scheme (PICs)- for GMP; UNICEF is an observer PIC/s
- Product is manufactured at a site that is compliant with all standards of GMP-by UNICEF or by SRA, WHO PQ or collaborating partners
- WLA

- **Expert input- EMA, WHO PQ (Antivenoms, Igs)**
- **Relevance of WHO Maturity Leve 3&4 to procurement?**




COLLABORATION ON QUALITY

- ✓**Interagency Pharmacists Group (IAPG)**
  - ✓ Membership by application
  - ✓ Minimum requirement- agency has implemented MQAS, duly qualified assessors
  - ✓ Exchange of information between the Interagency pharmacists group, joint inspections
- ✓**UN Quality Assurance Group- in formative stages**
- ✓**UNICEF is PIC/s observer member**

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Interagency Finished Pharmaceutical Product Questionnaire

- Annexed to WHO MQAS

Finished Pharmaceutical Product questionnaire for biotherapeutics*

- Done by WHO PQ, IAPG reviewing it, recently used in UNICEF tender for bio-oncology products

UNICEF Technical Requirements for Pharmaceuticals – 5th Edition

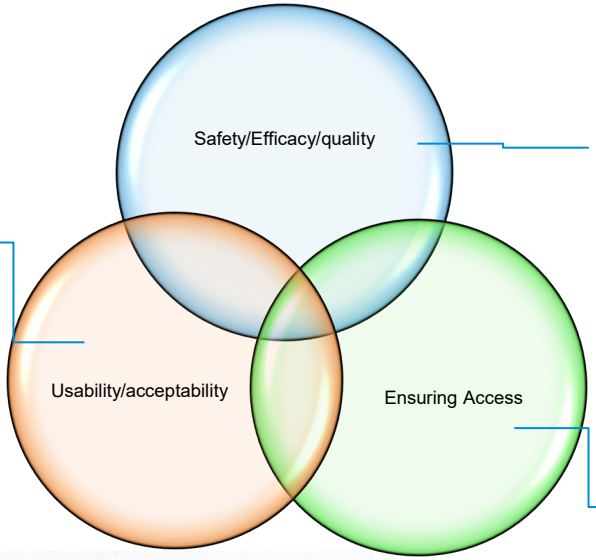
Aligned with WHO TRS norms and standards and ICH guidelines

Annexes accompanying the IAPPQ should be uploaded individually and named appropriately in the manner shown below:

Annex-A - Batch Formula
Annex-AA - Graphic summary of BE results
Annex-AB - BE Study Report
Annex-B - Primary Packaging
Annex-C - Secondary Packaging
Annex-D- Manufacturing licence
Annex-E-CPP
Annex-G-WHO prequalification letter
Annex-I-Labeling
Annex-J- SmPC and PIL
Annex-K - API GMP certificate
Annex-L - API specification
Annex-M - Method validation
Annex-O - API COA
Annex-P1 - CEP certificate
Annex-P2 - Technical File
Annex-Q - FPP GMP certificate
Annex-R - FPP Specifications
Annex-S - FPP COA
Annex-T - Process Flow Sheet
Annex-V - Stability Data
Annex-W - Stability Declaration
Annex-X - Status of On-going Stability
Interagency Finished Pharmaceutical Product questionnaire
Other doccuments - API Declaration form
Other documents - Indicate name of document here
Signed pages

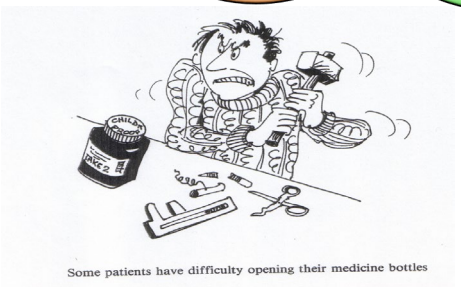
Dossier assessment; Benefit/risk approach

USABILITY
Supports adherence
Dose flexibility
Appropriate size/volume
Appearance& taste]
Handling, administration
Use instructions, Language
Frequency of administration
Minimal impact on lifestyle, dosing and



Bioavailability(BE)
Physicochemical properties
Tolerability
Dosage form, pack size/QTY
Packaging , leaflets
Formulation, product design
Excipients
Stability during shelf-life, in-use stability
Quality against standards
Minimal risk of medication error

Robust manufacturing process
Validation of manufacture process, analytical methods
Adequate qualified API sources
Easily transported and stored
Low environmental impact
Value for money


Some patients have difficulty opening their medicine bottles

Source: UNICEF Supply Division

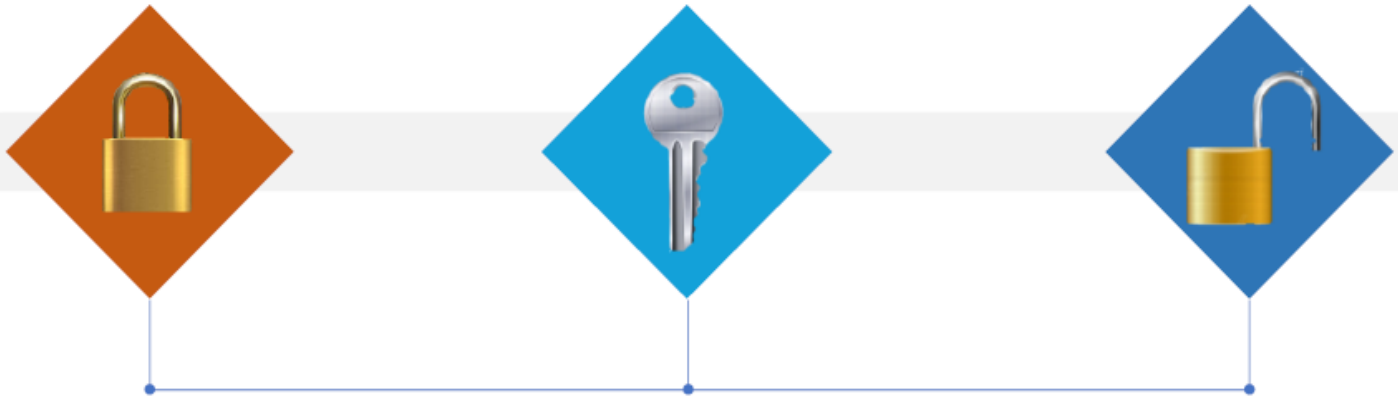
The Future is reliance

WHO Listed Authorities




WHO Listed Authorities

A new concept introduced to replace SRAs



Following ICH structural changes in 2015, need for replacing the term Stringent Regulatory Authority (SRA) and eligibility criteria based on the pre-reform membership to ICH

ICDRA 2016 & 2018 *Recommendations regarding SRAs*

Recommendations from 51st ECSPP in 2017 and 61st ECBS in 2018

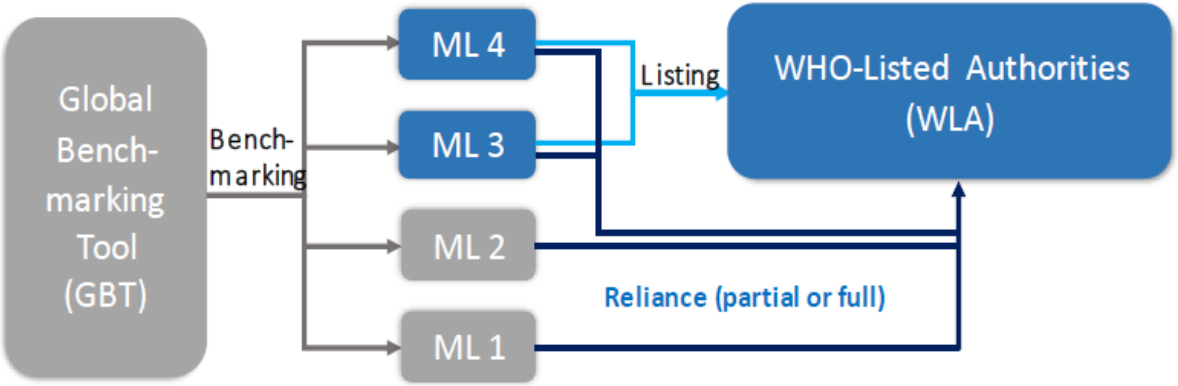
Feedback *from international consultations and virtual meetings on developing the GBT*

WLA

Authorities listed by WHO following a **consistent, documented, transparent and accountable** assessment

WHO Listed Authorities

...and to promote reliance



- ***LISTING*** can be achieved by ML3 and ML4 NRA/RRS and implies *ADVANCED PERFORMANCE*

i.e., **consistent** adherence to international standards and guidelines, as well as **good regulatory practices**, by ensuring the attainment of **key regulatory outputs** over time

Just to remind…

Maturity Level of NRAs worldwide as of March 2023

70% «non-functional» NRAs

Supplier document Management system

Supplier Dossier Library:

- The Suppliers Dossier Library has been in existence since 2020. It is a collection of product dossiers submitted by suppliers as part of their participation in various UNICEF/MNC tenders.

- Each supplier folder in the supplier dossier library has two main folders:
  - ✓ folders for specific products and
  - ✓ folder for site documents.

- As of 2022, the Supplier Dossier Library will now be used in all UNICEF/MNC tenders for the submission of technical proposals.

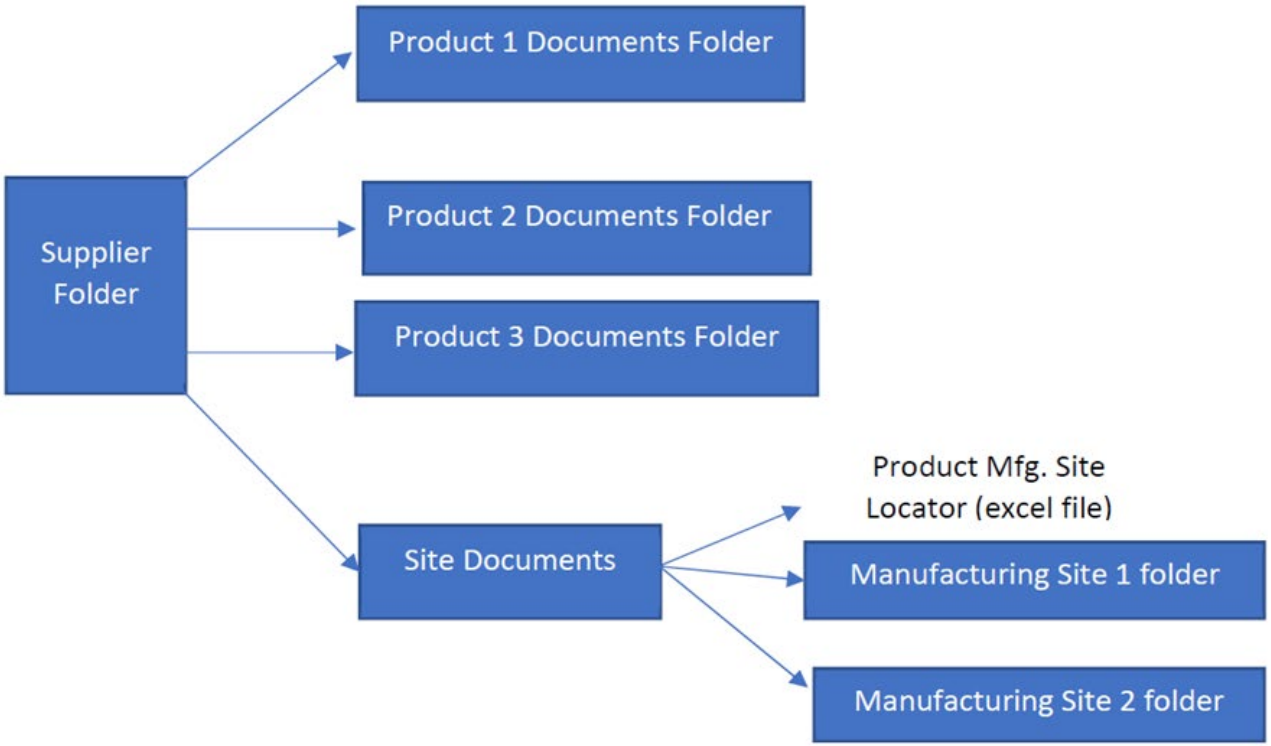
Supplier document Management system

Supplier Dossier Library:

- Each supplier will be given their own link to access their own folder only if they have expressed an interest in participating in a specific tender.
- The information in the library is confidential and only accessible to the supplier, the technical unit and the QAC inspectors.
- The advantage of the library is that it facilitates the re-evaluation of future tenders, as suppliers only need to update the information that is already in their folder.

Supplier document Management system

Supplier Folder Structure:



Important Links

	Link	Description
1	https://www.unicef.org/supply/medicines	UNICEF Supply Division Medicines Page - includes areas of focus, catalogue, Medicines tender calendar and market notes on strategic products
2	https://www.ungm.org	United Nations Global Marketplace website where suppliers to the UN register and UN (including UNICEF) tenders are advertised.
3	https://www.unicef.org/supply/suppliers-and-service-providers	How UNICEF engages with suppliers
4	https://www.unicef.org/supply/documents/general-terms-and-conditions-contract	UNICEF standard texts for general terms and conditions for contracts for goods and services
5	https://www.unicef.org/supply/questionnaires-and-requirements-pharmaceutical-and-nutrition-products	Technical requirements for pharmaceuticals and questionnaires to be filled by suppliers
6	https://www.unicef.org/supply/resources/annual-reports	UNICEF Supply Division annual reports
7	https://www.unicef.org/supply/media/17276/file/Medicines-Tender-Calendar-2023.pdf	Calendar of the medicines tenders planned for 2023
8	https://supply.unicef.org/	List of products including pharmaceuticals that UNICEF procures and their specifications

Q&A