THE GLOBAL FUND

EXTERNAL INFORMATION SESSION

Implementing Global Fund Quality Assurance Requirements for Health Products

16 August 2023

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Overview

Training is tailored for:

- Principal Recipient (PR) representatives
- Procurement Service Agent (PSA) representatives
- Local Fund Agent (LFA) representatives

Objective of the Training

Present the Quality Assurance requirements applicable to health products procured with the Global Fund Funds

Outline of the training

Topic	
1	Background
2	Quality Assurance Ecosystems
3	Overview of Main Requirements
4	Quality Assurance Focal Points
5	Procurement of Health Products
6	Pre-shipment Sampling, Testing and Reporting Results
7	Storage and Distribution
8	Market Surveillance and Quality Control
9	Vigilance and Noncompliance
10	Healthcare Waste Management
11	Price & Quality Reporting
12	Regulatory Systems Strengthening

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1 Background

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Scoping health products

Pharmaceutical Products (FPPs)					Diagnostic Products (DPs)					Medical Devices			PPE	Pesticides	
ARVs	ANTMs	TB Med.	C19	EM	Malaria RDTs	HIV RDTs, VL & EID	TB Diagn.	C19 RDTs and PCR	Other Diagnostics	Medical Supplies, Equipment	Condoms & lubricants	Med. Mask + Oxyg.Th	Core PPE	ITNs	IRS
Pharm. products for Currative treatment & prophylaxie				Opiod Sub Medicines, Oppor Infections & STI			Such as LPA, IGRA,…		Receptacle, DBS Software such as CAD & Instrument such as X-Ray	Syringes & Needles, Blood Lancet,	Male and female condoms	Such as ventilators, PSA	such items as apron protection, gloves, face shields, masks, respirators, gowns and protective goggles.	Such as PBO nets and dual AI Nets	

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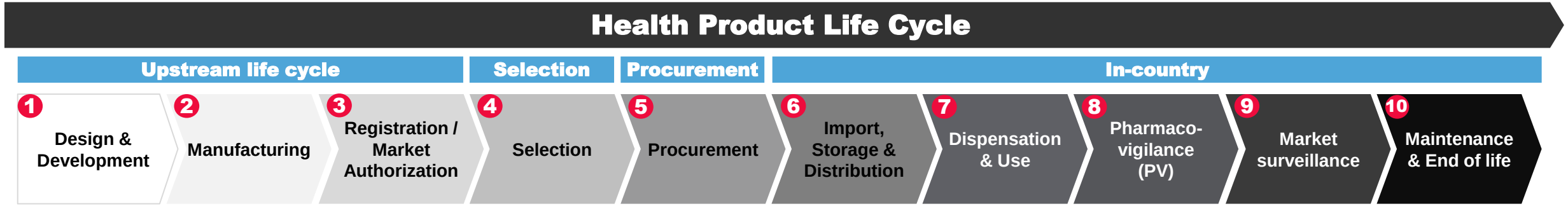
Why quality assurance matters

Quality of health products can be challenged at **every step** of the product life cyle.



Weaknesses in the upstream health product (HP) life cycle (incl. limitations in market authorization mechanisms), leading to **entry of inadequate HPs in the market**

Gaps in procurement mechanisms, resulting in **procurement of substandard HPs**

Weaknesses in **in-country supply chains'** ability to control, monitor & maintain quality of health products

Gaps in **national registration, pharmacovigilance (PV) and post-market surveillance**, can break the necessary feedback that signal issues in quality of health products (e.g. when deploying new medicines for large scale use*)

Varying maturity in national procurement (incl. NPA)

Varying **PR (and NRA) maturity** in terms of **QA awareness and capabilities**

*One risk root cause can be pharmacovigilance (PV), as it affects the assessment of the risks & benefits possible in deploying new medicines for large-scale use. A functional PV system is critical and is expected to be maintained by the NRA and by national programs. Additional support can be provided via Global Fund grant funds.

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Why quality assurance matters

The following risk scenario cases have recently impacted the Global Fund.

- **Donkuk Case:** 31 batches of condoms, stored few months at manufacturer's and country warehouses failed post-shipment testing in Uganda.
- **Intec Case:** Rebranded HIVs RDTs with instructions for use not in line with WHO guidelines, challenging the results of 50,000 tests performed in Ukraine.
- **Tana Netting Case:** Fraudulent manufacturing practices resulting in distribution of millions of bed nets of non-assured quality.
- **Dolutegravir Case:** Safety signals not identified in due time after scale-up of an innovative ARV putting newborns at risk.

Leading to potential public health risks for patients/users

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2 Quality Assurance Ecosystem

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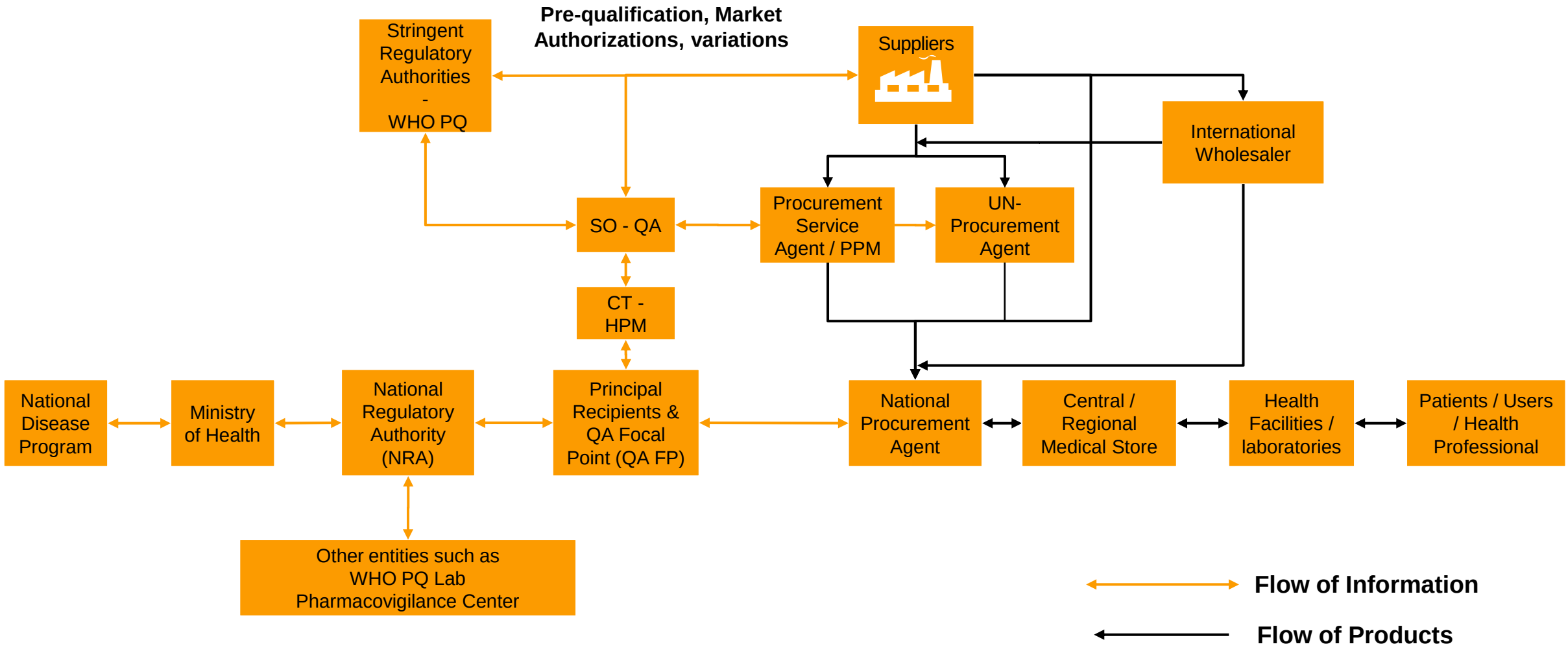
Quality assurance ecosystem



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Health products funded by the Global Fund

Three main procurement channels, with varying level of assurance and Global Fund accountability.

CHANNEL	CONTROL	ACCOUNTABILITY	RATIONALE

A **PPM through wambo.org** *~55% Global Fund HP spend*	High	High	• PPM/wambo.org process allowing higher quality assurance control
			  ◦ Direct control of products made available
			  ◦ Direct performance management of PSA (cf. planned improvements allowed by the new PSA tender)
			• Procurement role requires **higher accountability** for the Global Fund

B **International UN Agencies** (incl. GDF, UNICEF, UNDP) *~25% Global Fund HP spend*	Medium	Medium	• Relatively **lower direct control** • Level of assurance driven by level of UN quality assurance standards • Lack of oversight & standardized indicators for partners procuring with Global Fund funds
C **National Procurement Mechanisms** *~20% Global Fund HP spend*	Low	Medium / Low	• **Reliance** on **national assurance providers** (incl. NRA & NPA) and **Global Fund PRs in applying quality assurance requirements** • **Risk profile vary across countries**, depending on country maturity level, with instances of **important capacity gaps in supplier prequalification & adequate storage and transport conditions**

PPM stands for Pooled Procurement Mechanism; simplified version with nuances by product groups; * including non-UN international procurement agent selected by the countries

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Registration authorities and bodies called in the various Global Fund policies – 1/2

National Regulatory Authority (NRA): National regulatory authorities are responsible for ensuring that products released for public distribution (normally pharmaceuticals and biological products, such as vaccines and medical devices including test kits) are evaluated properly and meet international standards of quality, safety and efficacy.

Stringent Regulatory Authority (SRA): National regulatory authorities of certain countries depending on the quality assurance policy being referenced:

- **SRA(*)**:
- For pharmaceuticals: Members or observers or associates of the ICH as before 23 October 2015
  - Members: EU member States including UK, Japan, USA. OBSERVERS: Switzerland and Canada.
  - Associates: Australia, Norway, Iceland and Liechtenstein
- **SRA(**)**:
  - For Diagnostics, Medical Device & PPE: Founding members of the GHTF/IMDRF
  - EU member States including UK (1), Japan, USA, Australia and Canada

WHO Prequalification: The mission of WHO prequalification is to ensure quality, safety and efficacy of key health products for critical diseases. WHO is also working in close cooperation with national regulatory agencies and other partner organizations to make quality priority medical products available for those who urgently need them.

(1) UK is currently transitioning out of CE towards a standalone UKCA model

Registration authorities and bodies called in the various Global Fund policies – 2/2

Expert Review Panel: A group of independent experts who review the potential risks and benefits associated with the use of finished pharmaceutical or diagnostic products and make recommendations to the Global Fund on their use. The Quality and Safety of Medicines department of the World Health Organization hosts the panel.

WHO Emergency Use Listing: The WHO Emergency Use Listing (EUL) Procedure is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the aim of expediting the availability of these products to people affected by a public health emergency.

Stringent Regulatory Authority (SRA) Emergency Use Procedures: An emergency use procedure is a mechanism used by an SRA to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies.

(1) UK is currently transitioning out of CE towards a standalone UKCA model

3 Overview of the Main Global Fund Quality Assurance Requirements

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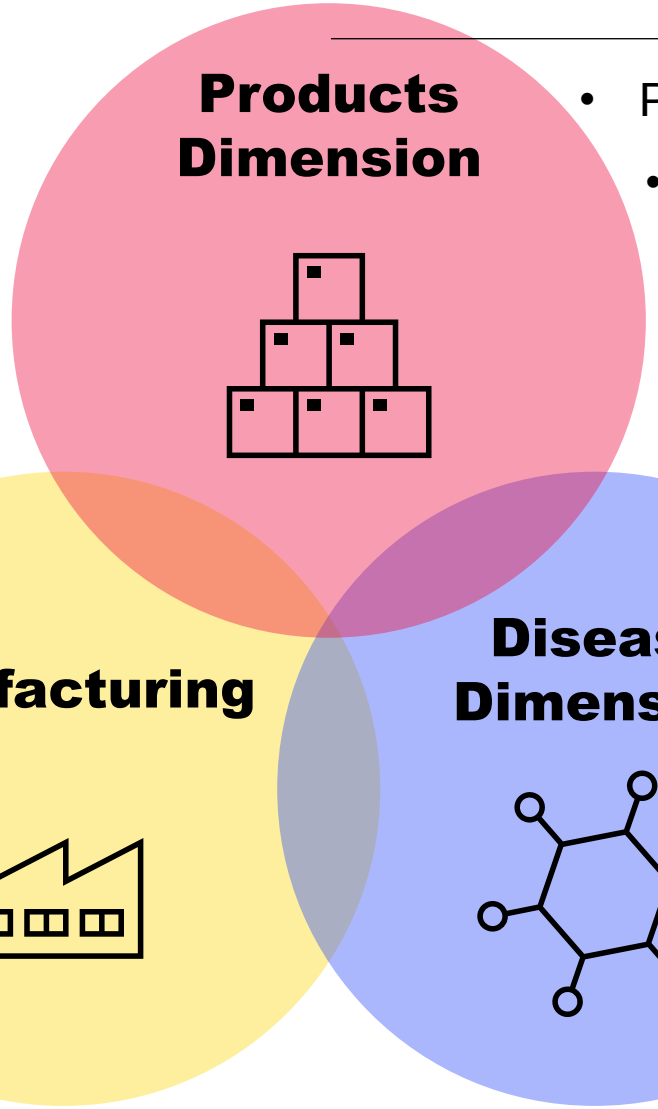
Scope of quality assurance requirements



- Pharmaceuticals
- Medical Devices & Personal Protective Equipment
- In-vitro Diagnostics
- Vector Control Products

- Registration
- Procurement
- Storage & Distribution
- Vigilance
- Market Surveillance
- Waste Management

- HIV
- Tuberculosis
- Malaria
- Co-Infections and Co-Morbidities (COIM)
- COVID-19

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Documentation of quality assurance (QA) requirements

	QA Policy (1) *Global Fund grant funds may only be used to procure products in accordance with the standards prescribed in this QA policy.*	PSM Guide (2) *Outlines the policies and principles that govern the procurement and supply management of health products financed by the Global Fund.*	Interim Requirements *Provides new Quality Assurance Requirements to be applied.*	Briefing Note or Guidance *Guidance to support the implementation of the Global Fund quality assurance requirements.*
Pharmaceuticals	Yes	Yes	COVID-19	Yes
Diagnostics	Yes	Yes	COVID-19	Yes
Condoms		Yes		Yes
Core PPE		Yes		Yes
Medical Devices*	Only Diagnostic Use		COVID-19	Yes
Vector control Products	-	Yes	-	Yes

(1) Approved by Board Committee
(2) Approved by Executive Grant Management Committee

**Classification of a medical device is per IMDRF*
***See the reference documentation slide for links to all documents*

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Types of quality assurance requirements

For the procurement of health products with Global Fund resources

***Applicable quality assurance (QA) requirements are adapted according to the health product being**

Pre-market Phase

Selection	Registration & Authorization	Procurement	Pre-Shipment
Clinical requirements*	**Quality requirements***	**Procurement entities requirements**	**Testing and inspection control requirements***
Target product selection for procurement should be based upon needs and clinical guidelines.	Assure that products have the adequate market authorizations and registrations.	All bodies or agencies that procure health products must comply with the principles in the WHO Model Quality Assurance System for Procurement Agencies (MQAS).	Measures implemented on products prior to shipment .

Post-market Phase

Reporting	Storage & Distribution	Vigilance	Monitoring	Waste Management
Price Quality Reporting (PQR) and reporting Requirements*	**Good Storage and Distribution Practices**	**Pharmacovigilance and Noncompliance***	**Market Surveillance & Quality control requirements***	**Health product waste disposal**
Reporting is required for all testing, vigilance and monitoring activities. Price and Quality Reporting is a requirement for specific products (1).	Contractors, agents, and sub-recipients must comply with the WHO Guide for Good Storage & Distribution Practices (GSDP).	Required on the safety and quality of the products including adverse drug reaction vigilance, noncompliance and out of specification.	Products requiring monitoring at all levels of the supply chain can include planned quality control testing to monitor for noncompliance.	Procedures and strategies for ensure disposal of health products.

(1) See section 11. of the PSM Guide

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Marketing authorization of core* FPPs: ARVs, Anti-TBs & Anti-Malarial Products

Reliance on stringent mechanism in addition to national mechanism

MA Mechanism	Description	Practices	Risk
Stringent Drug Regulatory Authorities (SRA)	• Robust legal/regulatory environment • ICH Requirements • Experienced & Skilled Staff in Quality/Safety/Environment	• Regular GMP inspection as per related regulation • Mutual Recognition Agreement • **Prioritization based on risks**	• Impartiality • Variable robustness
or			
WHO PQ program	• Program managed by WHO which prequalifies medicines considered by Global Fund to be acceptable for procurement • WHO requirements • Experienced & Skilled Staff	• Regular GMP inspection as per WHO PQ Procedure • Consideration of SRA decision • **Prioritization based on risks**	• Accountability • Transparency • Sustainability • Limited Competency • Limited Signal Detection/ Vigilance
or			
Expert Review Panel (ERP)	• Alternative mechanism used upon Global Fund request • Panel of external technical experts • Typically used for accelerated introduction of innovative products where dossier has been submitted to WHO/SRA • Supported by WHO	• Proof of GMP Compliance but no routine inspection • Consideration of SRA & WHO PQ & PIC/S related countries Inspections	• Limited assurance on Quality, Safety & Efficacy • No Signal Detection Mechanism/ Vigilance

**Note for core COVID-19 FPP's, additional authorization mechanism's exist, see section 5.*

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4 Quality Assurance Focal Points

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Principal Recipient quality assurance focal points

The PR should nominate a QA focal point as privilege point of contact on QA related issues with the Global Fund.

The QA focal point should ideally be someone with a good understanding of health products procurement, quality assurance/control and have knowledge of the Global Fund QA requirements.

When necessary and in coordination with rest of the PR Procurement and Supply Management Team, the QA focal point should:

- Liaise with relevant national actors in quality or regulatory field such as national procurement agent, national medicine regulatory authority, quality control laboratory or pharmacovigilance center, if existing.
- Support the Global Fund QA related investigations of noncompliance and out-of-specifications and contribute to management of recall as necessary.
- Ensure adequate reporting mechanism for noncompliance, adverse events and quality control testing reports.

5 Procurement of Health Products

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Procuring “eligible” health products

For procurement with Global Fund funds

What is an “eligible” health product?

Eligible health products are products which meet the criteria set out by the Global Fund QA policies and/or interim guidance and/or PSM guide.

What is a core product?

A core products is a health product which need to satisfy additional QA requirements such as:

- **Pharmaceuticals**: ARVs, anti-TB pharmaceuticals, anti-malarial pharmaceuticals
- **Diagnostics**: HIV RDTs; Malaria RDTs; TB Dx tests, CD4 and viral load tests
- **Vector Control**: ITNs and IRS

How do we know what products are eligible?

For each product category, the list of health products eligible for procurement are on the Global Fund website.

At the end of every quarter, these lists are updated where products may be added or removed.

Product Category	List per Disease (Link)
Diagnostics	HIV
	Malaria
	TB
	Covid-19
Pharmaceuticals	HIV
	Hepatitis
	Malaria
	TB
	COVID-19
Vector Control	IRS
	ITN
Medical Devices	Oxygen Generators
	PPE

Note: If a QA notice is issued it may have an impact on the product eligibility for procurement

In addition, to be procured Health Products should be approved by the NRA.

See the reference documentation slide for other links to related documents

Procurement of pharmaceuticals products

	PHARMACEUTICAL PRODUCTS	COVID-19 PHARMACEUTICAL PRODUCTS
Reference	***QA Pharma Policy***	***QA Pharma Policy + Interim Guidance for COVID-19 Pharma***
Clinical requirements	Medicines listed in current national, institutional and/or WHO Standard Treatment Guidelines (STGs) Require applicants/recipients to provide justification for selection of unlisted products in one of the STGs	Compliant with current national, institutional and/or WHO Standard Treatment Guidelines and/or Essential Medicines Lists
Registration & Authorization Quality Requirements	1. Authorized By NRA And Only for ARVs, anti-TB and anti-malarial pharmaceutical products (Core Products); 2. Approved By SRA (*) Or WHO Prequalification Or Expert Review Panel	1. Authorized By NRA And Only Pharmaceuticals for curative treatment and prevention, 2a or 2b applies; 2a. Approved By SRA (*) Or WHO Prequalification Or Expert Review Panel 2b. Approved under the WHO EUL Or SRA (*) Emergency procedures
Pre-Shipment (training § 6)	For ERP Approved Products: Additional controls may be recommended by ERP	For ERP Approved Products: Additional controls may be recommended by ERP

See the reference documentation slide for links to related documents

SRA (*) Members or observers or associates of the ICH as before 23 October 2015

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Procurement of diagnostic products

	CRITICAL IVD's*	NON-CRITICAL IVD's	NON-IVD DIAGNOSTIC PRODUCTS	COVID-19 DIAGNOSTIC PRODUCTS
Reference	***QA Diagnostics Policy + PSM Guide***	***QA Diagnostics Policy + PSM Guide***	***QA Diagnostics Policy + PSM Guide***	***QA Diagnostics Policy + Interim Guidance COVID-19 Diagnostics***
Clinical requirements	Compliant with national guidelines and/or aligns with WHO guidance Require applicants/recipients to provide justification for selection of unlisted products in one of the STGs			Compliant with national guidelines and/or aligns with WHO guidance
Registration & Authorization Quality Requirements	1. Comply with national laws and regulations And 2. WHO Prequalification Or WHO Global TB Program recommended Or Approved By SRA (**) Or Expert Review Panel	1. Comply with national laws and regulations And 2. Manufacturer compliant with ISO 13485 requirements Or QMS recognized by SRA (**)	1. Comply with national laws and regulations And 2. ISO 13485 for in-vitro diagnostic products and imaging equipment; or ISO 9000 series for any other diagnostic product (such as microscopes) Or QMS recognized by SRA (**)	1. Comply with national laws and regulations And 2. Manufacturer compliant with ISO 13485 requirements Or QMS recognized by SRA (**) And 3. Approved under the WHO EUL Or SRA (**) Emergency procedures
Pre-Shipment (training § 6)	For ERP Approved Products: Additional controls may be recommended by ERP			For ERP Approved Products: Additional controls may be recommended by ERP

*High Risk IVD's for HIV, TB, Malaria, Hep B, Hep C, Syphilis and others such as I*VDs providing information that is critical for patient treatment of these diseases, such as testing for G6PD deficiency*

SRA(**) Founding members of the GHTF i.e., EU member States including UK, Japan, USA, Australia and Canada

See the reference documentation slide for links to related documents

Procurement of other health products

	VECTOR CONTROL PRODUCTS	MALE AND FEMALE CONDOMS	MEDICAL DEVICES FOR COVID-19	CORE PPE
Reference	***PSM Guide***	***PSM Guide***	***Interim Guidance for COVID-19 Medical Device***	***PSM Guide (See also Information Note for masks and respirators)***
Clinical requirements	Complies national policy and guidelines and/or aligns with WHO guidance for management of public health pesticides	Compliant with specifications indicated in WHO UNFPA Guidelines for Male Condoms Procurement	Compliant with national guidelines and/or aligns with WHO guidance	Compliant with national guidelines on infection prevention and control and/or WHO guidelines
Registration & Authorization Quality Requirements	1. Comply with national laws and regulations And 2. WHO Prequalification Or Expert Review Panel	1. Comply with national laws and regulations And 2. UNFPA Prequalification Or All of the following: i. Manufacturer compliant with ISO 13485 ii. The condoms meet Directive 93/42/ CEE or other equivalent requirements for SRA(**) iii. The pre-shipment QC testing was performed in an ISO 17025- accredited lab for condoms iv. The testing was done as per ISO 4074 (latest edition) as recommended by WHO v. The test reports are reviewed by a competent expert acting under supervision of the recipient for compliance with the above specifications	1. Comply with national laws and regulations for all Classes (A, B, C and D) And Only for Class C or Class D devices; 2a or 2b applies; 2a. Approved By SRA(**) Or WHO Prequalification Or Expert Review Panel Or 2b. Approved under the WHO EUL Or SRA(**) Emergency procedures	1. Comply with national laws and regulations And 2. Approved By SRA(**) Or WHO Prequalification Or Expert Review Panel
Pre-Shipment (training § 6)	IRS and ITN's testing and inspection controls	Randomized sampling and testing	No	Randomized sampling and testing

SRA(**) Founding members of the GHTF i.e., EU member States including UK, Japan, USA, Australia and Canada

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The Expert Review Panel (ERP)

Call for Expression of Interest (EOI) following extensive consultation.

A panel of experts hosted by WHO assesses the potential risks/benefits associated with the use of products that are not yet WHO-prequalified or Stringent Regulatory Authority (SRA)-authorized.

Eligibility criteria for dossier submission:

- Product manufactured in line with best site practices.
- Dossier already submitted to and accepted for review by WHO PQ program or by an SRA.

Assesses abbreviated product dossiers submitted by manufacturers (questionnaire and annexes).

Makes time limited recommendations to the Global Fund: validity maximum 12 months.

Provides a risk categorization for the product which may be linked to specific mitigation or control measures.

ERP approved products are listed within the Health Product Eligible Products lists.

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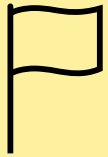
Procuring ERP products



Principal Recipient has to notify the Country Team/HPM

Non-objection/ Objection

➔ Global Fund letter

If Non-objection

➔ Quality Control testing initiated by **the Global Fund**

QC result*:

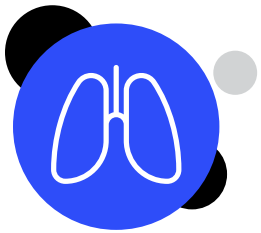
➔ Global Fund approval letter to PR/Manufacturer

➔ Shipment of the product

- The non-objection Letter valid for 12 months.
- Purchase orders (PO) may be issued during full validity of the non-objection Letter.
- There is a possibility to organize for a shipment under quarantine status to allow the transport and the testing of the goods to be done in parallel.

*QC testing is required for all Pharma ERP assessed products and only applicable to Diagnostic ERP assessed products depending on the associated risk mitigations.

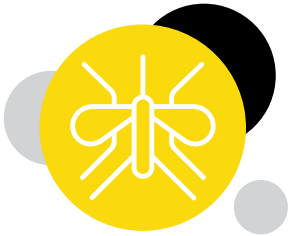
Examples of ERP outcomes of importance



Tuberculosis

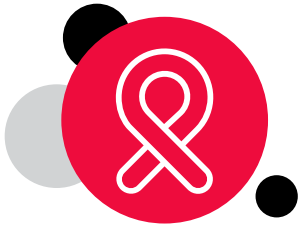
Rifampicin 75mg and Isoniazid 50mg, Dispersible tablets

3HP Rifapentine/Isoniazid



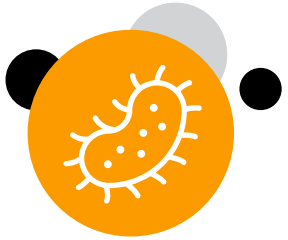
Malaria

Malaria RDTs HRP2 deletion



HIV

HIV Self-test



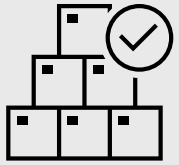
Opportunistic infections

Syphilis test

Quality assurance requirements for procurement entities

For All Products: Procurement must comply with the principles set forth in the WHO **Model Quality Assurance System for Procurement Agencies (MQAS)**.

The MQAS is describing the quality management system which should be implemented by procurement entities. The scope of the MQAS is covering four critical functions such as:



1. Prequalification of products and manufacturers
2. Purchasing
3. Storage
4. Distribution

Principal Recipients should ensure that the relevant norms and standards which are necessary for the adequate implementation of the MQAS are established and implemented.

Procurement entities will have to implement partially or totally the principles of the MQAS covering the different functions depending on their mandate.

Example of Procurement Entities:

- National procurement agency for direct procurement
- UN procurement agency
- PSA for PPM procurement

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6 Pre-shipment Sampling and Testing

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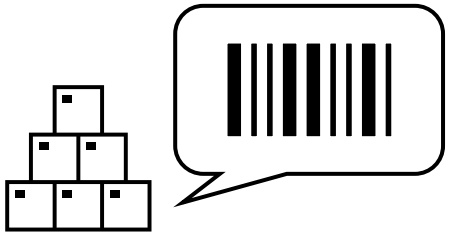
Pre-shipment inspection and controls



Principal Recipients should ensure that all products conform to their procurement specification.

	Pre-shipment control requirements
Pharmaceutical Products	All ERP Products
Diagnostic Products	Some ERP Products
Condoms & PPE	Condoms and Core PPE
Medical Devices	No
Vector control Products	ITNs and IRS

Pre-shipment inspection and controls

	ERP Products (1)	Insecticide Treated Nets (ITNs) & Indoor Residual Spray (IRS)		Condoms (non UNFPA procurement)	Core PPE
What	Testing	Inspection	Testing	Testing	Testing
Responsibility	Global Fund Secretariat	Principal Recipients Or PSA	Principal Recipients Or PSA	Principal Recipients Or PSA	Principal Recipients Or PSA
When	Pre-shipment	Pre-shipment	Pre-shipment	Pre-shipment	Pre-shipment
Frequency	Batch randomization decided by Global Fund	Randomly (as per the Global Fund Briefing Note)	Randomly (as per the Global Fund Briefing Note)	Randomized pre-shipment sampling and testing	Randomized pre-shipment sampling and testing
Laboratory	WHO PQ lab ISO 17025 lab	No but inspection agent needed	GLP or ISO 17025	Compliant with ISO 17025	Compliant with ISO 17025
Methods	Approved Methods	ISO 2859 series	CIPAC, ISO	ISO 4074	As per Information Note
References	ERP website page	Briefing Note Visual Inspection of ITNs	Briefing Note Pre-Shipment Sampling, Testing and Reporting Results for ITNs	PSM Guide	Information Note on PPE masks

(1) ERP-Reviewed Products may have other risk mitigations to be implemented as recommended by ERP Panel

See the reference documentation slide for links to related documents

7 Storage and Distribution

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Importation, storage and distribution

Best Practice: Perform an independant audit of GSDP regularly.

For all health products and not only pharmaceuticals:

Recipients shall comply with the WHO Guide for Good Storage & Distribution Practices (GSDP) to ensure that:

- Products in the supply chain are authorized in accordance with country legislation.
- Products are always stored in the right conditions, including during transportation.
- Contamination by or of other products is avoided.
- An adequate turnover of stored products takes place.
- The right products reach the right addressee within a satisfactory time period.

In addition, all storage and distribution facilities should be authorized by the national regulatory Authorities as per national legislation

Important: As per PSM Guide Principal Recipients should ensure that each of its contractors, agents, and sub-recipients comply with such GSDP requirements.

See the reference documentation slide for links to related documents

8 Market Surveillance and Quality Control

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Summary: Products with monitoring requirements

The PR is expected to monitor quality of the procured health products throughout the supply chain in collaboration with NRA and report the results of quality control inspection or testing activities.

	Monitoring	Responsible & Report Results
Pharmaceuticals Products	All*	PR
Diagnostics Products	All*	PR
Condoms & Core PPE	All	PR
Medical Devices	COVID-19	PR
Vector Control Products	ITNs and IRS	PR

* Some ERP-Reviewed Products may have monitoring risk mitigations to be implemented as recommended by ERP Panel

Market surveillance and quality control

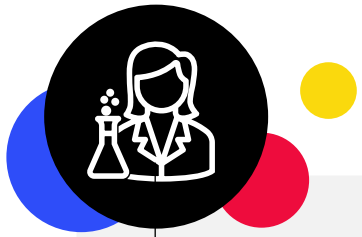
For more information, review Briefing Note on In-country Quality Monitoring

The quality of the **health products** procured with Global Fund grant funds is **required to be monitored following mostly same principles independent of products category.**

1. Design a plan on how the PR will satisfy such post-market surveillance requirements, regularly update and evaluate its efficacy.
2. Collaborate with the NRA and other relevant actors and investigate synergies.
3. Implement risk-based approach for products selection as well as verification activities.
4. Strategize the verification activities (visual inspection, partial or full testing) in order to ensure that the high costly activities have the best chances to provide meaningful results.
5. Report the findings and follow-up as necessary with the NRA.
6. The cost of conducting quality control activities may be budgeted in the Global Fund grant.
7. Technical assistance can be provided via the Global Fund resources to improve the competencies of the NRA on this matter.

Important: Quality control is a tool to identify noncompliance but not to provide assurance on quality.

Planning for quality control monitoring activities



For more information, review the Global Fund In-country Quality Monitoring Guidance.

1. Designing a sampling and testing program in close collaboration with the NRA using risk-based approach; the risk criteria can be issued based on information gathered.
2. Selection and contracting sampling agent.
3. Selection and contracting of quality control laboratory.
4. Sampling products during the in-country warehousing and distribution.
5. Transporting of samples to the laboratory.
6. Conducting method transfer and quality control testing.
7. Managing the results and follow up in case of out-of-specifications or noncompliance, in collaboration with the NRA preferably. It may be needed to put in place immediate protective measures in case of serious noncompliance.
8. Reporting results to the Global Fund.
9. Records and documentation.
10. Reporting any noncompliance to the NRA and to the Global Fund QA through the Country Team.

9 Vigilance and Noncompliance

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Quality assurance requirements for vigilance

Best Practice: Quality Assurance Focal Point may facilitate.

1. PRs are strongly encouraged to support NRA and the Global Fund Secretariat to monitor **adverse drug reactions (ADRs)** with products procured with the Global Fund funds.
2. ADRs to be reported by the PR within 5 working days, preferably using the standardized format* to the QA team via your country team representative; **All ADRs related to ERP products should be reported to Global Fund Secretariat.**
3. Reported to national authority in charge (please inform the Global Fund QA of the same).
4. Support the Global Fund QA Investigations and implement decision/advice from the Global Fund in line with NRA decision.
5. Regular updates by the PR or PSA on the NRA's investigations to be provided to the Global Fund QA.

**Forms to be made available on the Global Fund QA webpage (notification will be sent upon publication)*

Global Fund minimum requirements for vigilance

For more information, review the Technical Brief on Reg. Strengthening.

1. A **national pharmacovigilance (PV) center** with:
   - Designated staff (at least one full time).
   - Stable basic funding.
   - Clear mandates.
   - Well defined structures and roles.
   - Collaborating with the WHO Program for International Drug Monitoring.

2. The existence of a **national spontaneous reporting system** with a national individual case safety report (ICSR) form i.e. ADR reporting form.

3. A **national database or system** for collating and managing ADR reports.

4. A **national ADR or pharmacovigilance advisory committee** able to provide technical assistance on
   - Causality assessment.
   - Risk assessment.
   - Risk management case investigation and where necessary crisis management including crisis communication.

5. A **clear communication strategy** for routine communication and crises communication to healthcare workers and the public.

Important: Global Fund financing can also support the strengthening of PV in countries, linking with one, or all of our HIV, TB, malaria and RSSH grant activities (e.g. TB aDSM).
(*See section on Regulatory System Strengthening*)

Noncompliance and out-of-specifications

Best Practice: The Health Product Risk Committee can be involved in case of risk of shortage.

1. PRs are encouraged to support the Global Fund Secretariat to deal with noncompliance and out-of-specifications of health products procured with the Global Fund Funds and in particular to:
   a. Provide the most adequate information.
   b. Support the investigations in case further information needed.
   c. Report on activities performed at country level.
   d. Report on internal/external partners engaged.
2. Noncompliances and out-of-specifications to be reported by the PR or PSA within 5 working days preferably using the standardized format* to the QA team via your country team representative.
3. Reported to national authority in charge (please inform the Global Fund QA of the same) and implement their recommendations.
4. Support Global Fund investigations and implement Global Fund advice in line with NRA decision.
5. Regular updates by the PR or PSA on the investigations to be provided to the Global Fund QA.

Based on this information or from other sources, the Global Fund may issue a QA Information Notice which would be published on the QA website: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/information-notice

**Forms to be made available on the Global Fund QA webpage (notification will be sent upon publication)*

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Reporting form for noncompliance & out-of-specifications

The Reporting Form has the same structure independently of the product categories such as:

Main Section	Comments
TITLE	Each product category has its own form which is aligned to product specificity; the QA contact within the Global Fund is also recalled.
ORIGIN OF REPORT	Contact details of the reporting entity but also need to clarify if different from the entity which has observed the signal to adequality reconnect for further investigations.
PRODUCT DETAILS / EXTENT OF THE PROBLEM	Details of the products and batch(es), including information on potential quantity used/on stock.
NATURE OF DEFECT(S)	Description of the events or the signals with additional information on background or circumstances including potential risk identified.
ACTION TAKEN AND PROPOSED	Preliminary actions taken to protect patient such as quarantine, detailed of investigations already engaged or partners internal/external involved
ANNEXES	Any supportive information is welcomed to substantiate the signal such as certificate of analysis, photos…
PRIVACY STATEMENT	Recalling the Global Fund obligations on data collected.

**Forms to be made available on the Global Fund QA webpage (notification will be sent upon publication)*

10 Healthcare Waste Management

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Quality assurance requirements for healthcare waste management

Numerous documents have been published for specific product categories (i.e. Pharmaceuticals) or activities such as medical laboratories. See list of reference documentation for further information.

1. **General Requirements:**

   Recipients shall ensure the safe disposal of unusable pharmaceuticals products and other health products such as diagnostics, condoms or vector control products using methods that involve minimal risks to public health and the environment.

2. **Specific for Medical Laboratories:**

   Recipients shall ensure that laboratories undertake to comply with applicable laws and relevant WHO guidance for the management of health care waste, including laboratory waste.

11 Price and Quality Reporting

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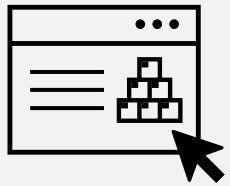
Quality assurance requirements for reporting

For more information, review the PQR Quick Guide.

	PQR Reporting	Responsible non-PPM	Responsible PPM
Pharmaceuticals Products	Yes – Core Products* & Hep C Pharmaceuticals No - Essential medicines	PR	PSA
Diagnostics Products	Yes – Specific IVD's**	PR	PSA
Laboratory Equipment for Diagnostic Purpose	Yes***	PR	PSA
Condoms & PPE	Yes – Condoms, Surgical & non-surgical masks and respirators	PR	PSA
Medical Devices	Yes - Class C and D (for COVID-19 use)	PR	PSA
Vector Control Products	Yes – All ITN's and IRS	PR	PSA

** ARVs, Anti-Malaria & Anti-Tuberculosis Products*
** High Risk IVD's for HIV, TB, Malaria, Hep B, Hep C, Syphilis and others such as I*VDs providing information that is critical for patient treatment of these diseases, such as testing for G6PD deficiency*
**** Laboratory equipment : for HIV, Hepatitis, TB and Malaria testing. Polymerase chain reaction (PCR) equipment for HIV Viral Load and HIV early infant diagnostics (EID), Hepatitis and Malaria. TB Liquid culture equipment, TB molecular and Cartridge based molecular testing, CD4 and Enzyme-linked Immunosorbent Assay (ELISA) Test equipment.*

Quality assurance requirements for reporting



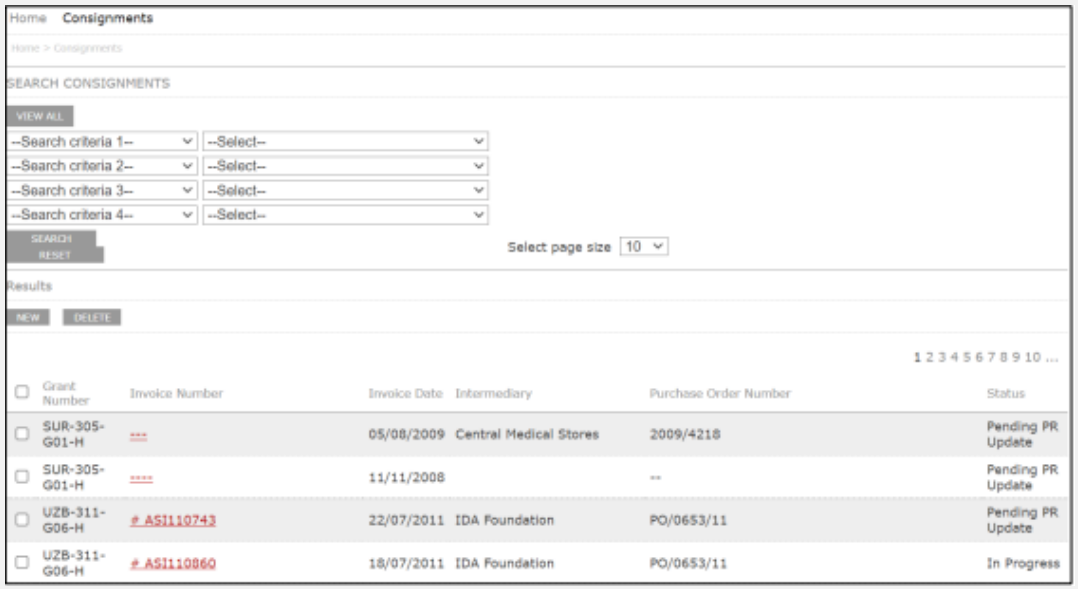
The Global Fund has set a specific online-platform to collect information on:

Products

Supplier

Procurement transactions

Certificate of analysis & test reports



http://pqr.theglobalfund.org/

How does the Global Fund use this information?

- Verify compliance to the eligibility requirements.
- Verify the manufacturing sites.
- Traceability for management of noncompliance issues.

For more information, review the PQR Quick Guide.

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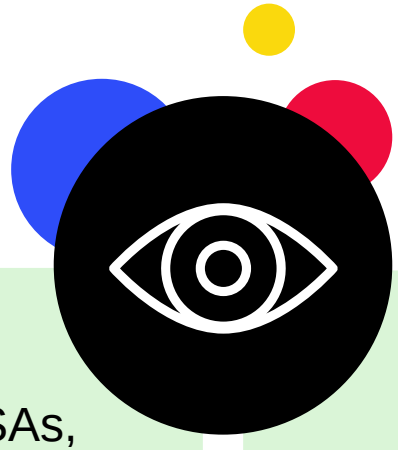
Role of the Local Fund Agent (LFA)

Verify PQR Data



- To ensure the accuracy and completeness of reporting by PRs/PSAs, the Global Fund requires that LFAs verify PQR data entries, including entries made by PPM procurement agents.
- LFA verification of data is a key step to ensure high data quality.

Compliance verification services

The LFA may be commissioned by the Global Fund to check compliance to various other QA requirements during grant implementation.

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12 Regulatory System Strengthening

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National regulatory system strengthening

Supporting capacity of national regulators **provide additional value**.

It is recommended for CCM/PRs to plan for national regulatory system strengthening support, if applicable in the GC7 funding requests.

A good proposal for national NRA capacity building should have the following elements:

Evidence based	Refer to a clear description of existing situation analysis, gaps and weaknesses as identified preferably by independent party.
Country buy-in	Refer to consultative process to demonstrate country buy-in in the activities supported.
Partnership engagement	Consider engagement with other partners involved in supporting the country and participate in any country initiative to bring coherency in country support.
Strategic alignment	Demonstrate that the proposed activities are supportive of country strategic vision expressed via national medicines policy and/or strategic plan established following such policy directions.
Logic of Global Fund intervention	Provide integrated approach with other Global Fund investments (incl. past investments) to close the financial gaps or plan for increased future investments from other areas of work (RSSH, Disease program) and from domestic financing.

Regulatory system strengthening

It is recommended that intervention proposals are designed based on the following structure:

Assessment of National Regulatory System

- Support assessment of the NRA and the regulatory system to identify gaps and weaknesses

Leadership and governance

1. National policy development with focus on quality assurance and regulatory system.
2. Develop of national Strategic plan on quality assurance and regulatory systems; monitoring & KPI design development supported.
3. Leadership development and management training.

Structure of the regulatory system

1. Gap analysis of national regulatory systems and identification of focus areas.
2. Re-engineering institutions and institutional arrangements.
3. Operating model refinement including areas such as authority distribution and reporting lines.
4. Institutional capacity-building.

Methods and processes

1. Developement of quality and risk management system.
2. Support implementation of good regulatory practices.
3. Review and streamlining regulatory processes and services provided.
4. Develop good governance practices.

Workforce Development

1. HRH workforce assessment.
2. Human resources development plan.
3. Support development of training curricula for NRA staff.
4. Collaboration with academia for delivery of training.
5. Development of online training platform.

Regulatory information systems

1. Regulatory information system implementation and stabilization.
2. Procurement of the IT tool and adaptation to country-specific needs.
3. Training/software validation.
4. Data standards, data use, data quality interventions.

Partnership & Coalition

- Support strong partnership and support coalition and harmonization activities
- Facilitate continental and regional convergence initiative

Review the Technical Briefing Note on Support to Effective Regulatory Systems for Procurement and Supply Management of Health Products.

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Useful References

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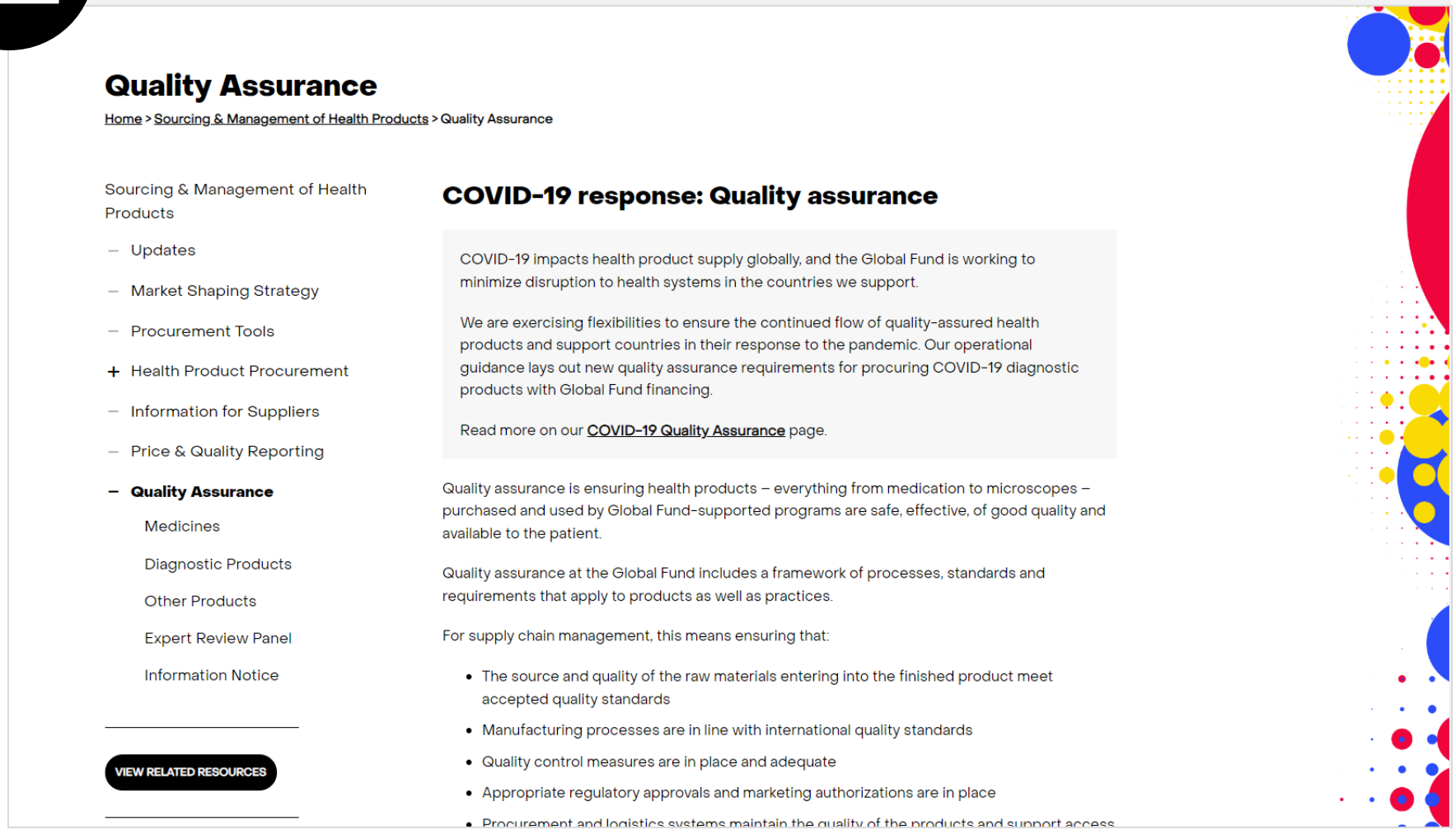
Quality Assurance website reference

https://www.theglobalfund.org/en/sourcing-management/quality-assurance/



Quality Assurance

Home > Sourcing & Management of Health Products > Quality Assurance

Sourcing & Management of Health Products

- Updates
- Market Shaping Strategy
- Procurement Tools
- \+ Health Product Procurement
- Information for Suppliers
- Price & Quality Reporting
- **Quality Assurance**
  - Medicines
  - Diagnostic Products
  - Other Products
  - Expert Review Panel
  - Information Notice

VIEW RELATED RESOURCES

COVID-19 response: Quality assurance

COVID-19 impacts health product supply globally, and the Global Fund is working to minimize disruption to health systems in the countries we support.

We are exercising flexibilities to ensure the continued flow of quality-assured health products and support countries in their response to the pandemic. Our operational guidance lays out new quality assurance requirements for procuring COVID-19 diagnostic products with Global Fund financing.

Read more on our COVID-19 Quality Assurance page.

Quality assurance is ensuring health products – everything from medication to microscopes – purchased and used by Global Fund-supported programs are safe, effective, of good quality and available to the patient.

Quality assurance at the Global Fund includes a framework of processes, standards and requirements that apply to products as well as practices.

For supply chain management, this means ensuring that:

- The source and quality of the raw materials entering into the finished product meet accepted quality standards
- Manufacturing processes are in line with international quality standards
- Quality control measures are in place and adequate
- Appropriate regulatory approvals and marketing authorizations are in place
- Procurement and logistics systems maintain the quality of the products and support access

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Useful Acronyms

- ACTs: Artemisinin-based combination therapy
- ADR: Adverse Drug Reaction
- ARVs: Anti-retrovirals
- COIM: Co-Infections & Co-morbidities
- CT: County Team
- Dx: Diagnostic
- EGMC: Executive Grants Management Committee
- ERP: Expert Review Panel
- FPP: Finished Pharmaceutical Product
- GHTF: Global Harmonization Task Force
- HP: Health Product
- HPM: Health Product Management Specialist
- HPRC: Heath Product Review Committee
- ICH: The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
- IMDRF: International Medical Device Regulators Forum
- ITNs: Insecticide treated nets
- NC: Noncompliance
- NPA: National Procurement Agency
- NRA: National Regulatory Authority
- OOS: Out of Specification
- PIC/S: Pharmaceutical Inspection Co-operation Scheme
- PPM: Pooled Procurement Mechanism
- PQR: Price Quality Reporting
- PR: Principal Recipient
- PSA: Procurement Service Agent
- PV: Pharmacovigilance
- QA: Quality Assurance
- QA FP: Quality Assurance Focal Point
- RDTs: Rapid diagnostic tests
- SO: Supply Operations Department (of Global Fund)
- SRA: Stringent Regulatory Authority
- STG: Standard Treatment Guidelines
- WHO PQ: World Health Organization Prequalification

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References

Global Fund Quality and Procurement Policies

- QA policy for pharmaceutical products https://www.theglobalfund.org/media/5894/psm_qapharm_policy_en.pdf
- QA policy for diagnostics https://www.theglobalfund.org/media/5885/psm_qadiagnostics_policy_en.pdf
- Procurement and Supply Management (PSM) guide https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf

COVID-19 INTERIM REQUIREMENTS

- Interim QA requirements for the procurement of COVID-19 diagnostic products https://www.theglobalfund.org/media/9628/covid19_interimqualityassurancerequirementsdiagnosticproducts_guidance_en.pdf
- Interim QA requirements for the procurement of COVID-19 pharmaceutical products https://www.theglobalfund.org/media/11061/covid19_interimqualityassurancerequirements-pharmaceuticalproducts_guidance_en.pdf
- Interim QA requirements for the procurement of COVID-19 Medical Devices https://www.theglobalfund.org/media/11060/covid19_interimqualityassurancerequirements-medicaldevice_guidance_en.pdf

References

Global Fund Information Notes, Briefing Notes, and other external references

PHARMACEUTICALS

- FAQs on QA policy for pharmaceutical products https://www.theglobalfund.org/media/5882/psm_qaandqc_faq_en.pdf
- Guidance on In country quality monitoring of pharmaceutical products https://www.theglobalfund.org/media/5901/psm_qcmonitoringgfprsvp_guide_en.pdf
- Management of limited exceptions to QA requirements of pre-shipment inspection and testing https://www.theglobalfund.org/media/9609/covid19_qualityassurancepreshipmentinspectionexceptions_guidance_en.pdf
- Therapeutics and COVID-19: WHO living guideline 13 Jan 2023 https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.1
- WHO prequalification for medicines https://extranet.who.int/pqweb/medicines
- The WHO Programme for International Drug Monitoring https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/health-professionals-info/pidm

DIAGNOSTICS

- WHO prequalification for diagnostics https://extranet.who.int/pqweb/in-vitro-diagnostics
- Chest Radiography and CAD Solutions for Tuberculosis Programs https://www.theglobalfund.org/media/11374/operational_chest-radiography-cad-solutions-tb-programs_briefingnote_en.pdf

VECTOR CONTROL PRODUCTS

- Briefing Note Visual Inspection of ITNs https://www.theglobalfund.org/media/12436/psm_visual-inspection-itn_briefingnote_en.pdf
- Briefing Note Pre-Shipment Sampling, Testing and Reporting Results for ITNs https://www.theglobalfund.org/media/12437/psm_pre-shipment-sampling-testing-reporting-itn_briefingnote_en.pdf
- WHO guidelines for procuring Public Health pesticides https://apps.who.int/iris/bitstream/10665/44856/1/9789241503426_eng.pdf
- List of QC Labs compliant with the Global Fund QA requirements for testing public health pesticides https://www.theglobalfund.org/media/11598/psm_qclaboratoriespesticides_list_en-pdf.pdf
- WHO vector products prequalification https://extranet.who.int/pqweb/vector-control-products

MEDICAL DEVICE AND PPE

- Information Note on the QA requirements for the procurement of Masks and Respirators https://www.theglobalfund.org/media/12125/covid19_qa-requirements-procurement-masks-respirators_informationnote_en.pdf
- Briefing Note on QA Requirements for the Procurement of Oxygen Therapy Medical Devices https://www.theglobalfund.org/media/13113/covid19_qa-requirements-procurement-oxygen-therapy-devices_briefingnote_en.pdf

CONDOMS

- Female condoms prequalification and guidelines for procurement https://www.theglobalfund.org/media/5846/psm_femalecondomspecification_guidelines_en.pdf
- WHO/UNFPA prequalification for male latex condoms https://www.unfpa.org/suppliers#prequalification

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References

Global Fund Information Notes, Briefing Notes, and other external references

REGULATORY STRENGTHENING and COUNTRY CAPACITY BUILDING

- Information Note: Resilient and Sustainable Systems for Health (RSSH) https://www.theglobalfund.org/media/4759/core_resilientsustainablesystemsforhealth_infonote_en.pdf
- Technical Briefing Note: Support to Effective Regulatory Systems for Procurement and Supply Management of Health products https://www.theglobalfund.org/media/8894/core_regulatorysystemsprocurementsupplymanagementhealthproducts_technicalbrief_en.pdf
- Model for establishing risk-based post market surveillance - https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based-post-marketing-surveillance-feb-2018.pdf

PQR REPORTING

- A quick Guide to the Global Fund's Price and Quality Reporting System (PQR) https://www.theglobalfund.org/media/5870/psm_pqr_quickguide_en.pdf
- A LFA Guide to the PQR https://www.theglobalfund.org/media/5872/psm_pqrforlfas_guide_en.pdf
- Price and Quality Reporting Data Caveats https://www.theglobalfund.org/media/5871/psm_pqrdatacaveats_note_en.pdf

EXPERT REVIEW PANEL

- Expert Review panel webpage https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/

STORAGE AND DISTRIBUTION

- WHO Good Storage and Distribution Practices for Medical Products https://www.gmp-compliance.org/files/guidemgr/TRS1025_Annex7.pdf
- Annex 9 Model guidance for the storage and transport of time and temperature sensitive pharmaceutical products https://www.who.int/publications/m/item/trs961-annex9-modelguidanceforstoragetransport

MQAS

- Annex 3 Model quality assurance system for procurement agencies https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs986-annex3-who-model-quality-assurance-system-for-procurement-agencies.pdf?sfvrsn=275b3abc_2

WASTE MANAGEMENT

- Condoms https://www.unfpa.org/resources/safe-disposal-and-management-unused-unwanted-contraceptives
- Technical Brief Avoidance, Reduction and Safe Management of Health Care Waste https://www.theglobalfund.org/media/9356/core_healthcarewastemanagement_technicalbrief_en.pdf
- Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies https://apps.who.int/iris/bitstream/handle/10665/42238/WHO_EDM_PAR_99.2.pdf

Thank you

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