INFORMATION SESSION

Implementing Quality Assurance Requirements for Health Products

14 August 2024

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Agenda

Topic	
1	**Overview:** • Quality assurance ecosystem • Main requirements
2	**Grants Recipients Quality Assurance System**
3	**Procurement of Health Products** • Pre-shipment sampling, testing and reporting results • Storage and distribution • Post market surveillance and quality control • Vigilance and non-compliance • Healthcare waste management • Price and Quality Reporting
4	**Regulatory Systems Strengthening**
5	**Q&A**

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Overview

Session is tailored for:

- Principal Recipient (PR) representatives
- Local Fund Agent (LFA) representatives

Objective

Present the current(1) QA requirements applicable to Health Products procured with the Global Fund resources

(1) As updated by the three QA policies on Pharmaceuticals, Medical Devices (including IVDs) and Personal Protective Equipment (PPE) and Vector Controls Products (VCPs) approved by Board

1 Overview

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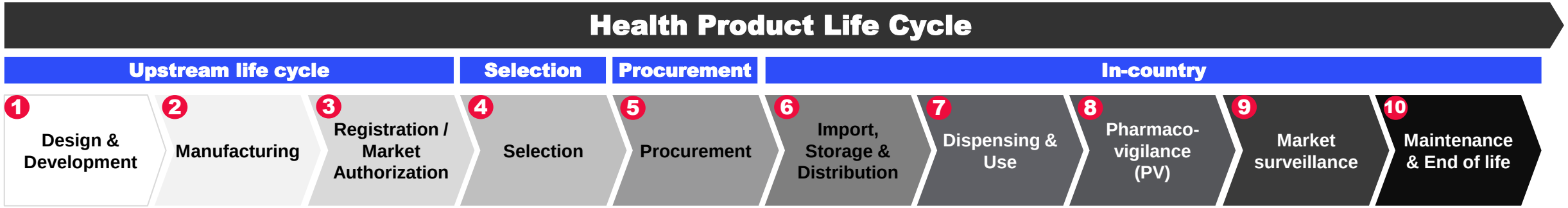
Why quality assurance matters

Quality of health products can be compromised 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 compromised HPs in the market.**

Gaps in procurement mechanisms (e.g. NPA or PPM) and / or maturity of NPA 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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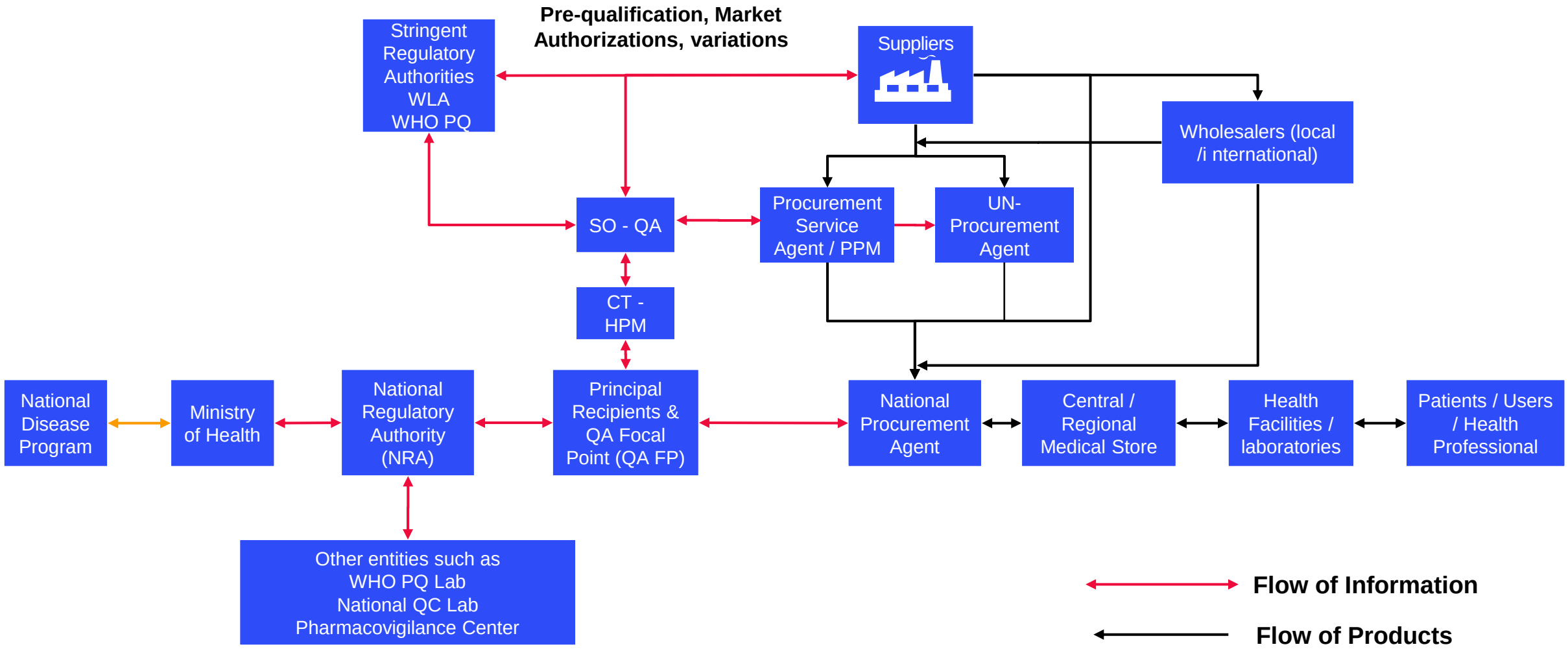
Quality assurance ecosystem



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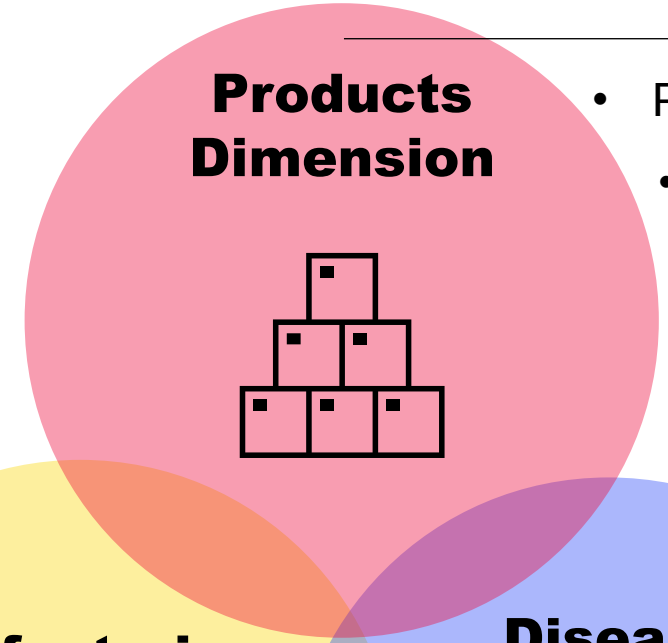
Registration authorities and bodies referenced in the Global Fund QA policies

National Regulatory Authority (NRA)	**Expert Review Panel**
Stringent Regulatory Authority (SRA)	**WHO Prequalification Programme**
WHO Listed Authority (WLA)	**WHO Emergency Use Listing**
Regulatory Authorities of the founding members of the Global Harmonization Task Force	**Stringent Regulatory Authority (SRA) Emergency Use Procedures**

Scope of quality assurance requirements



- Pharmaceuticals
- Medical Devices
  - In-vitro Diagnostics
  - Personal Protective Equipment
- 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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The Global Fund QA Documents and Product Coverage

Quality Assurance Policies
approved by Board provide high level QA requirements for products and practices

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The Health Products Guide*
approved by EGMC recalls high level requirements, along with additional detailed requirements

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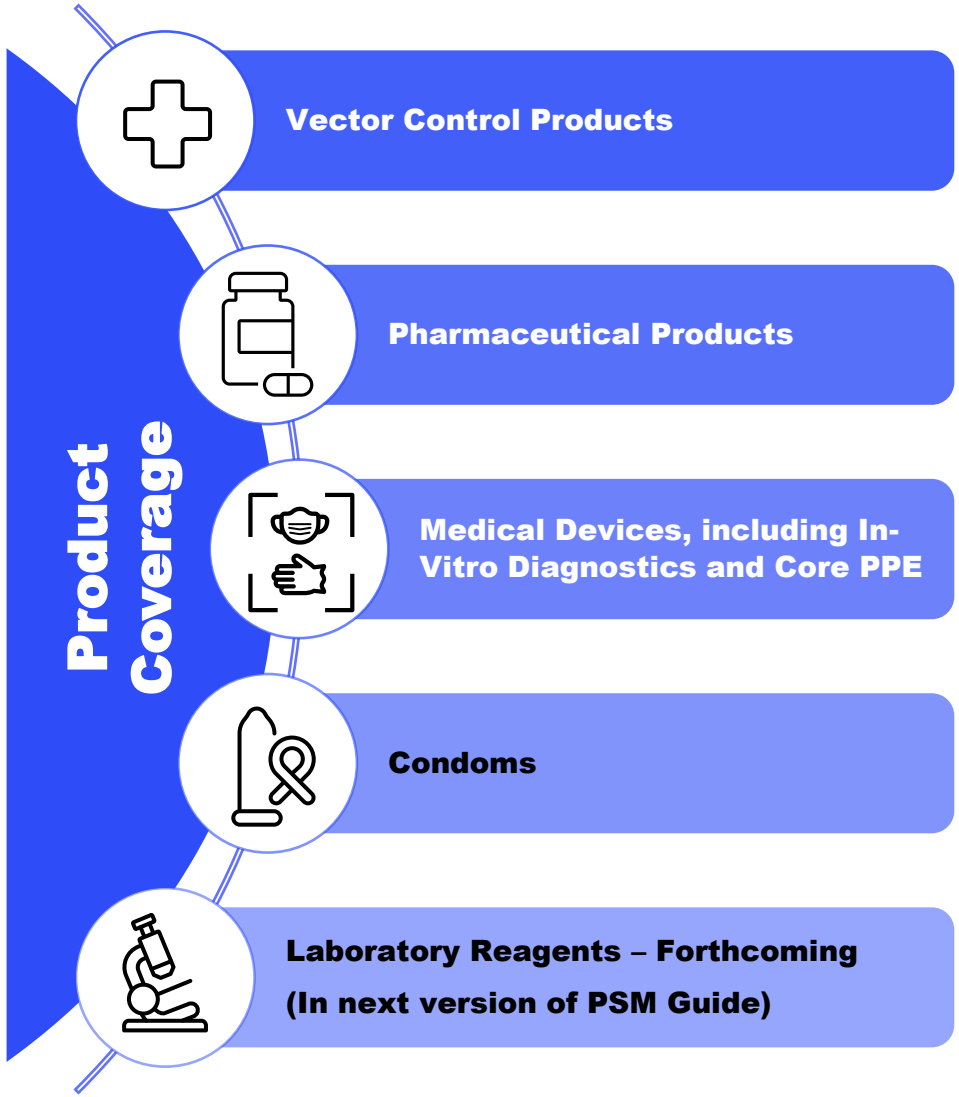
Additional QA Documents

- QA Briefing Notes
- Other internationally recognized guidance, norms and standards
- QA Information Notice
- Other QA Documents



*The Guide to Global Fund Policies on Procurement and Supply Management of Health Products is sometimes referred to as the "PSM Guide" or, in Global Fund Grant Regulations, as the "Health Products Guide".

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 procured.**

Upstream

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	Measures implemented on products prior to shipment .

Downstream / in-country

Reporting	Storage & Distribution	Vigilance	Monitoring	Waste Management
Price Quality Reporting (PQR) and other reporting Requirements*	**Good Storage and Distribution Practices**	**Pharmacovigilance and Non-compliance***	**Market Surveillance & Quality control requirements***	**Health product waste disposal**
Price and Quality Reporting is a requirement for specific products (1). Also reporting is required for all testing, vigilance and monitoring activities	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, non-compliance and out of specification.	Products requiring monitoring at all levels of the supply chain can include planned quality control testing to monitor for non-compliance.	Procedures and strategies to ensure disposal of health products.

(1) See section 11. of the PSM Guide

3

Grants Recipients
Quality Assurance System

Grants Recipients Quality Assurance System

The Vision

The PR shall develop, implement and continuously update a Quality Assurance System for the procurement and supply management of health products procured.

The Tools

A QA Focal Point to support PR

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

A Plan for adherence to QA requirements

The QA plan should describe the processes, resources, tools and partnership to ensure adherence to QA requirements.

Standard Operating Procedures for robustness

Limited number of SOPs for main QA processes are requested but up to PRs or SRs to decide to develop more.

A Principle to make best use of funds

To implement risk-based approach to identify and assess risk factors, mitigate these risk by applying relevant controls, monitoring and reviewing.

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 non-compliance and out-of-specifications and contribute to management of recall as necessary.
- Ensure adequate reporting mechanism for non-compliance, adverse events and quality control testing reports.

Quality Assurance (QA) Communication to Principal Recipient (PR) QA Focal Points

The Global Fund Quality Assurance team communicates using a no reply email address (noreply-healthproductqualityassurance@theglobalfund.org) for the following purposes:

- Updates in Global Fund List of Health Products Eligible for Procurement (Quarterly)
- Revisions in Global Fund Policy for Health Products
- Publication of new Briefing Note, QA Information Note or Guidance for Health Products

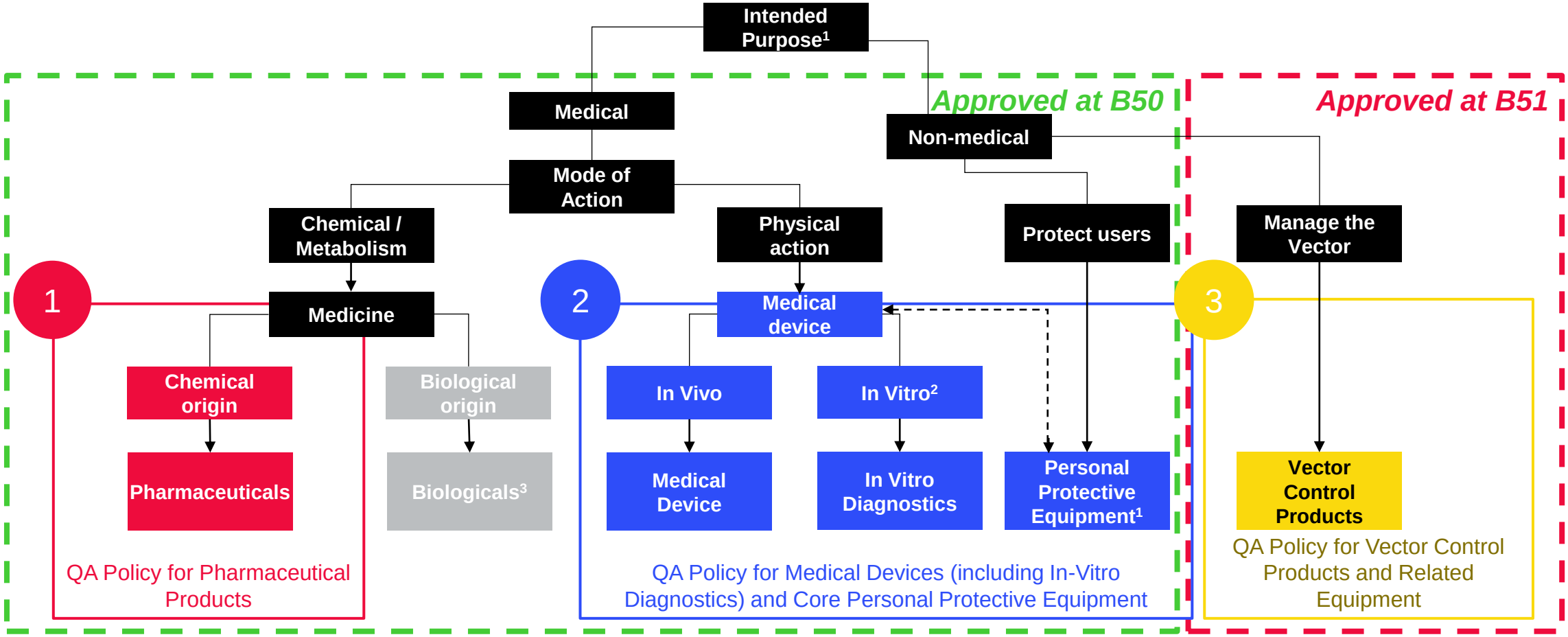
Note: Publication of new policies or guidance documents shall be accompanied by additional focused information sessions to assist PRs in the implementation of the related QA requirements.

The Country Team HPM Specialist is the primary point of contact and communication for PR QA focal points and should be contacted for any questions or issues related to the quality of health products financed by Global Fund grants.

5 Procurement of Health Products

The QA Policy Framework covers the range of Global Fund-financed health products

Schematic Representation of Health Product Categories*



* Simplified overview. For more detail, please refer to the standardized definition of each health product category.

1. Some products may meet the conditions for more than one product category. In such cases, quality assurance requirements for both categories apply. Examples include: medical cement, surgical masks and injectable insulin device with online testing for glucose. See dotted line above.
2. On samples taken from the human body.
3. Current Global Fund spend on Biologicals is negligible and thus does not warrant development of a QA policy to date.

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Updates to procurement of Pharmaceutical Products -1/3

Eligible products include those that are authorized for use:

- By a WHO Listed Authority (WLA) within their scope of listing for HIV, TB and malaria.
- Through emergency use procedures WHO/SRA/WLA during a health emergency, if the Global Fund Board approves use of funds.

Submissions for External Review Panel (ERP) review eligible if WLA meet the following regulatory functions:

- Registration and Marketing Authorization
- Regulatory Inspection
- Vigilance
- Market Surveillance and Control

Transitional measures from SRA to WLA defined

New approach for addressing QA issues:

- Global Fund's Strategy Committee (SC) overseeing implementation of policy
- The Global Fund secretariat addressing quality related issues on an order-by-order basis eg non-conformities or non-compliance

Procurement of Pharmaceutical Products – 2/3

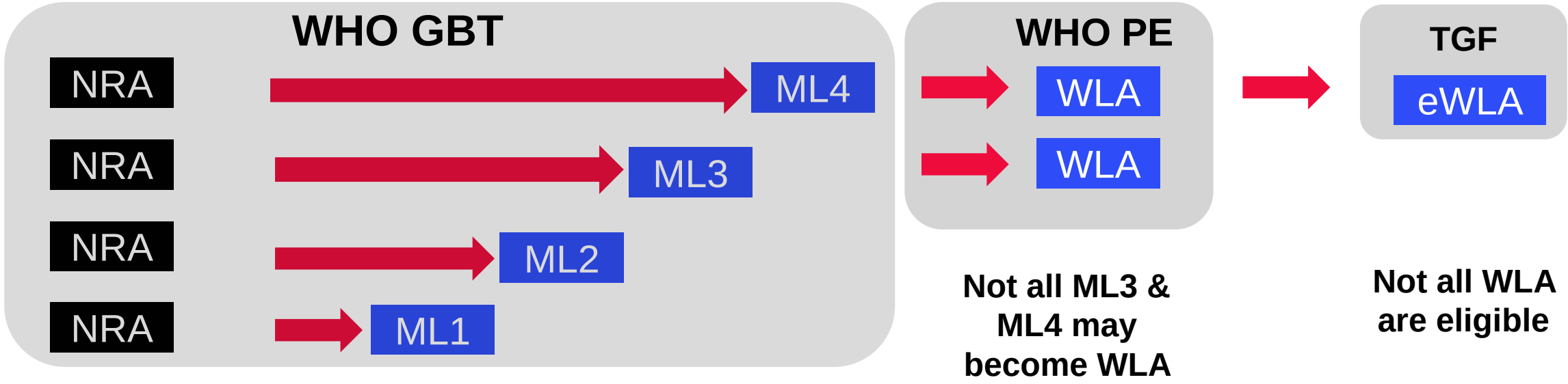
QA requirements for Procurement of Pharmaceutical products

Reference	QA Pharma Policy
Product applicability	For all pharmaceutical products
Clinical requirements	Medicines listed in current National STGs/EML or WHO STG//EML or WHO rapid communication
Registration & Authorization Quality Requirements	1. Authorized by NRA And only for ARVs, anti-TB and antimalarial pharmaceutical products 2. Prequalified by the WHO Prequalification Programme OR Authorized for use by SRA OR Authorized for use by WLA OR Recommended for use by Expert Review Panel For Emergencies (PHEIC); Approved under the WHO Emergency Use Listing OR Under SRA/WLA Emergency procedures

Procurement of Pharmaceutical Products – 3/3

WHO Listed Authorities (WLAs) for Pharmaceutical Products

- National Regulatory Authority who has been benchmarked towards the Global Benchmarking Tool (GBT) as Maturity Level (ML) 3/4 AND satisfied the Performance Evaluation (PE) as performed by WHO
- It can be :
  1. A standalone National Regulatory Authority **OR**
  2. A System of (more than one) National Regulatory Authorities

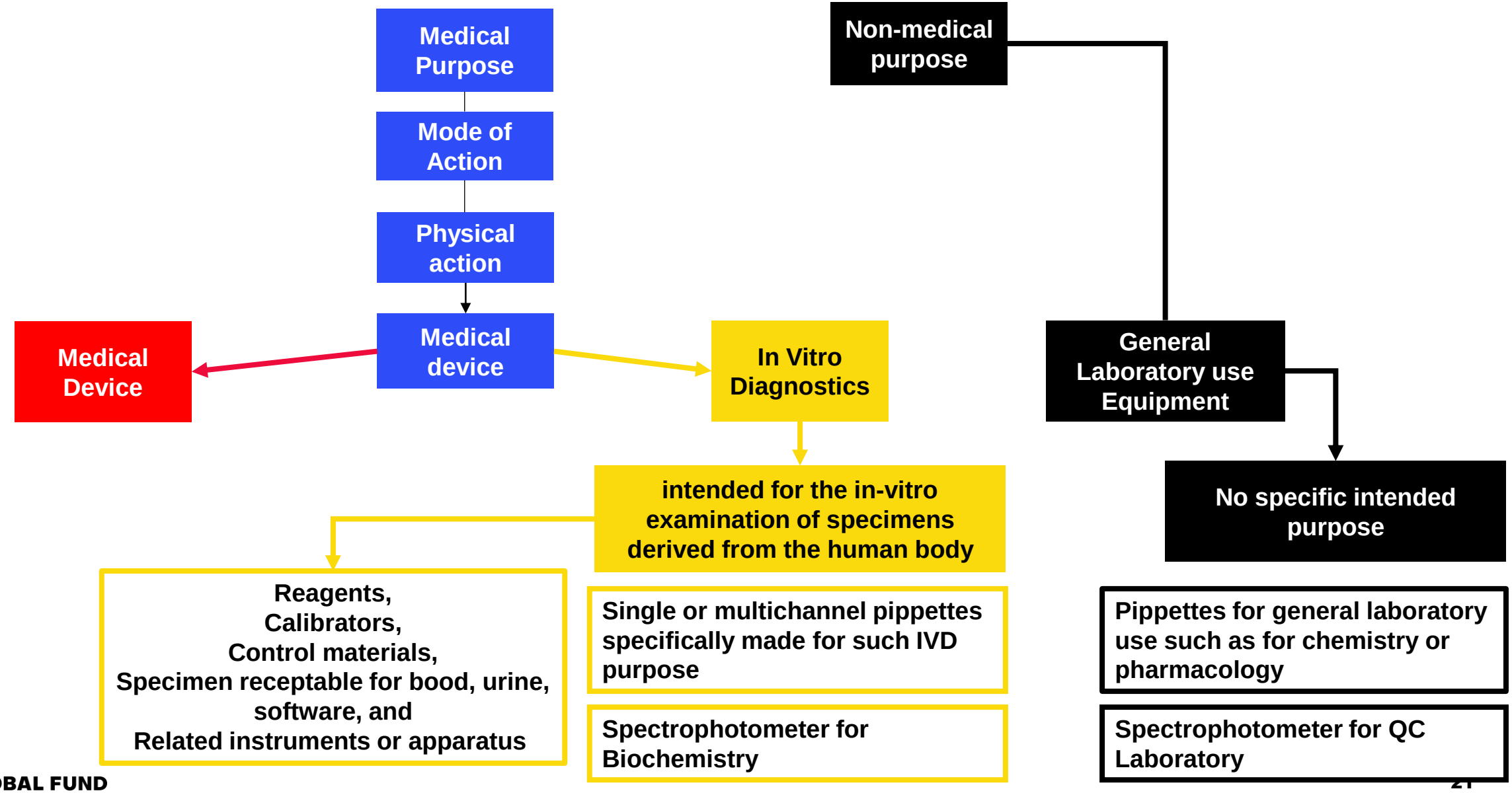


WHO Q&A on WLA https://www.who.int/news-room/questions-and-answers/item/who-listed-authorities

Updates to procurement of Medical Devices (Including IVDs) and core PPE - 1/6

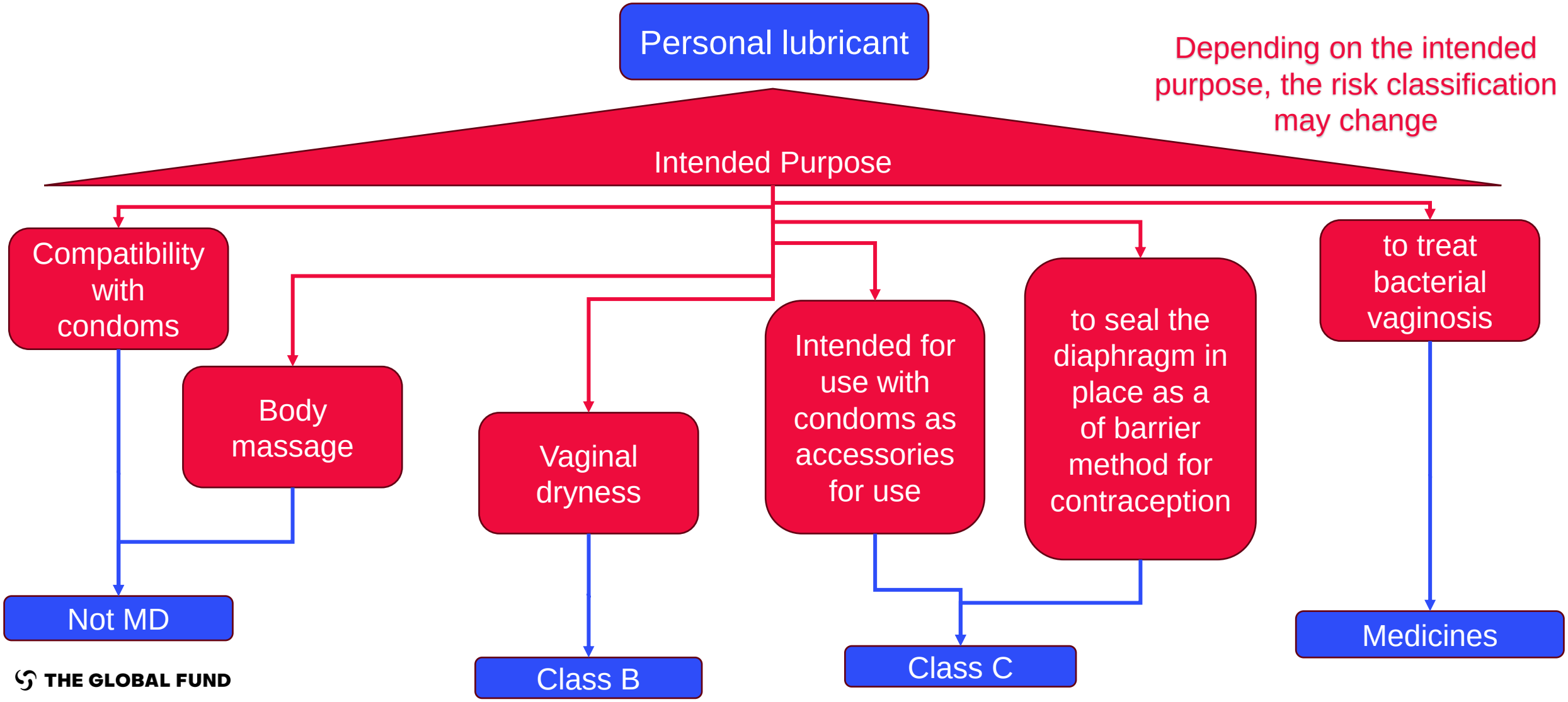
- QA Policy for Diagnostics expanded to become QA Policy for **ALL** Medical Devices including in-vitro diagnostics and core personal protective equipment.
- Eligibility includes products authorized for use by a WLA within their scope of listing
- Eligibility includes MDs (IVDs) and PPE authorized through emergency use procedures during a PHEIC
- Post marketing surveillance and obligations expanded to cover all Medical Devices (including IVDs) and core PPE
- The Global Fund's Strategy Committee (SC) overseeing Policy implementation
- Provisions for WLA transitioning defined

The QA Policy Framework covers a broad range of Health Products - 2/6



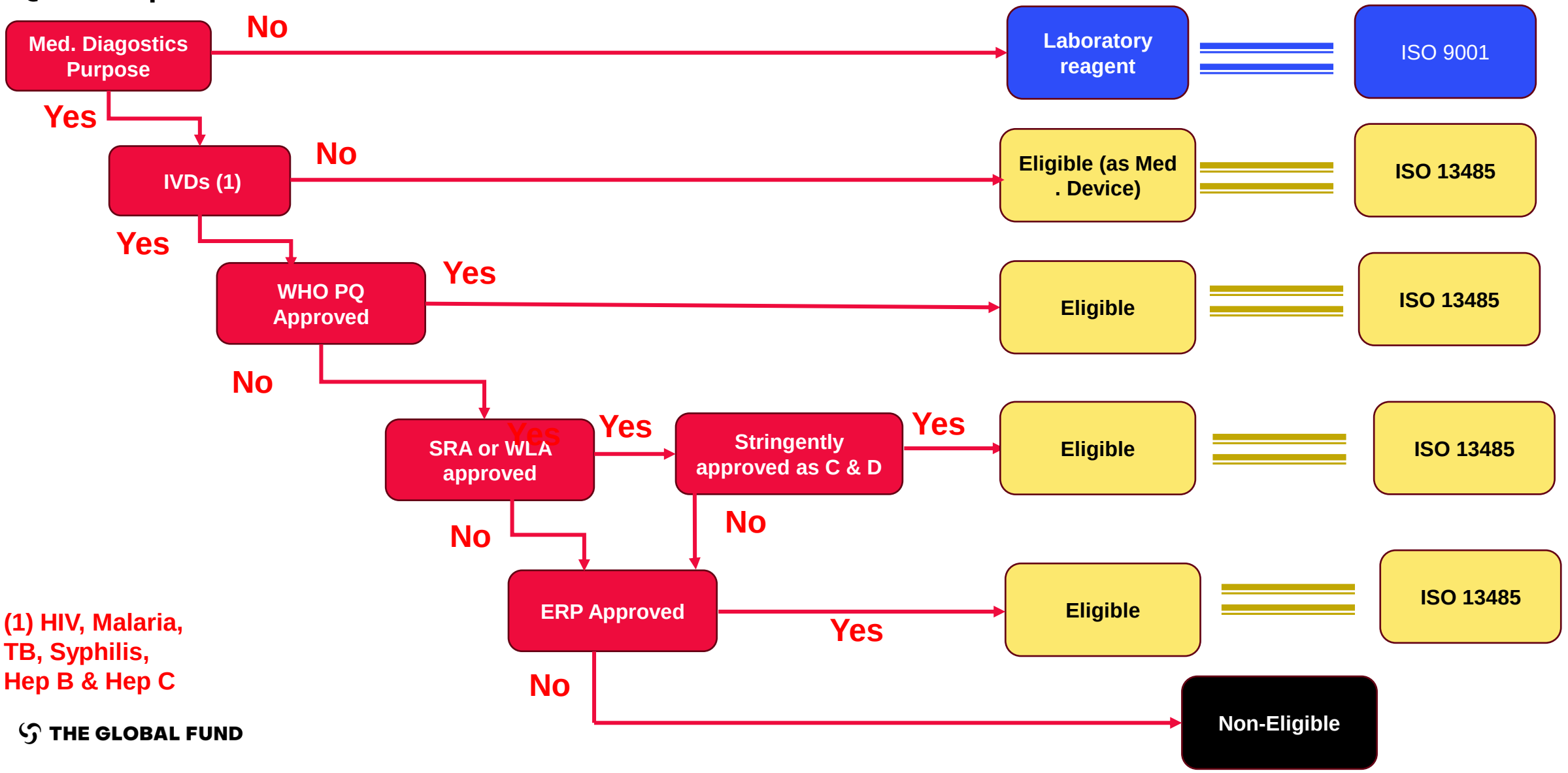
Procurement of Medical Devices (Including IVDs) and core PPE – 3/6

Medical Devices classification – Concrete example for Personal Lubricant



Procurement of Medical Devices (Including IVDs) and core PPE – 4/6

QA requirements



(1) HIV, Malaria, TB, Syphilis, Hep B & Hep C

Procurement of Medical Devices (including IVDs) and PPE - 5/6

Reference	QA Policy for Medical Devices (incl.IVDs) and core PPE
Product applicability	For Medical Devices (including IVDs) of class A,B,C and D
Clinical Standards	Comply with national guidelines Or consistent with WHO guidelines including WHO rapid communication
General quality standards (section 7 & 8)	1.Quality Management System requirements (ISO 13485 or equivalent)
Additional Quality Requirements (sec. 9)	AND 2.For class C & D MDs excluding IVDs: • WHO Prequalified OR • Authorized for use by RA of GHTF founding member OR • Authorized for use by WLA OR • Recommended for use by ERP
Additional Quality Requirements (sec.10)	AND 3. For IVDs for HTM, Hep B, Hep C, syphilis co-infection: • Prequalified by the WHO Prequalification Programme OR • WHO Global TB programme rec/Rapid Communications OR • Authorized for use by RA of GHTF Founding Members if Class C & D OR • Authorized for use by WHO Listed Authority (WLA) OR • After assessment by Expert Review Panel
Emergencies (section 25)	In case of PHEIC for MDs (incl IVDs) and core PPE • Approved under the WHO Emergency Use Listing (EUL) OR • Under GHTF/WLA Emergency procedures

Procurement of Medical Devices (including IVDs) and PPE - 6/6

Requirements of Core PPE and condoms elevated to QA policy level from PSM Guide

Reference	QA policy for MDs (incl.IVDs) and core PPE
Product applicability	• Core PPE And • condoms (male and female) & lubricants
Clinical standards	Comply with national guidelines Or consistent with WHO guidelines including WHO rapid communication
Additional Quality requirements	For PPE: • WHO prequalification OR • GHTF requirements and standards OR • Authorized for use by WLA For Condoms (male and female) & lubricants: • UNFPA prequalification OR • Authorized for use by RA of founding members of GHTF if Class C or D OR • Authorized for use by WLA OR • Recommended by ERP

Updates to procurement of Vector Control Products -1/4

- NRA authorization in country of use requirement added
- Revision of QA standards
  - *Removal of WHOPES*
  - *Addition of selection process*
- ERP process explained
- Quality monitoring and handling non - compliance requirements
- New requirement on monitoring of insecticide resistance
- Requirement on waste management introduced
- Strategic Committee role in overseeing policy implementation
- Transitional measures to new policy

Procurement of Vector Control Products -2/4

QA requirements

	Current QA requirements
Reference	***QA policy for VCP and related equipment***
Product applicability	**For all VCP products and related equipment**
Clinical requirements	• **National or regional malaria vector control guideline / strategy OR** • **WHO guidelines for malaria OR WHO rapid communication on Malaria**
Registration & Authorization Quality Requirements	**1. Compliance with** • **Applicable laws and regulations AND** • **Authorized by NRA in country of use** **AND** **2. (i) Prequalified by the WHO Prequalification Programme; or** **(ii) Recommended for use by the ERP.** **3. (i) Related equipment comply with WHO specifications** **(ii) Related PPE comply with QA policy for MDs (including IVDs) and core PPE**

Procurement of Vector Control Products -3/4

QA requirements: key changes

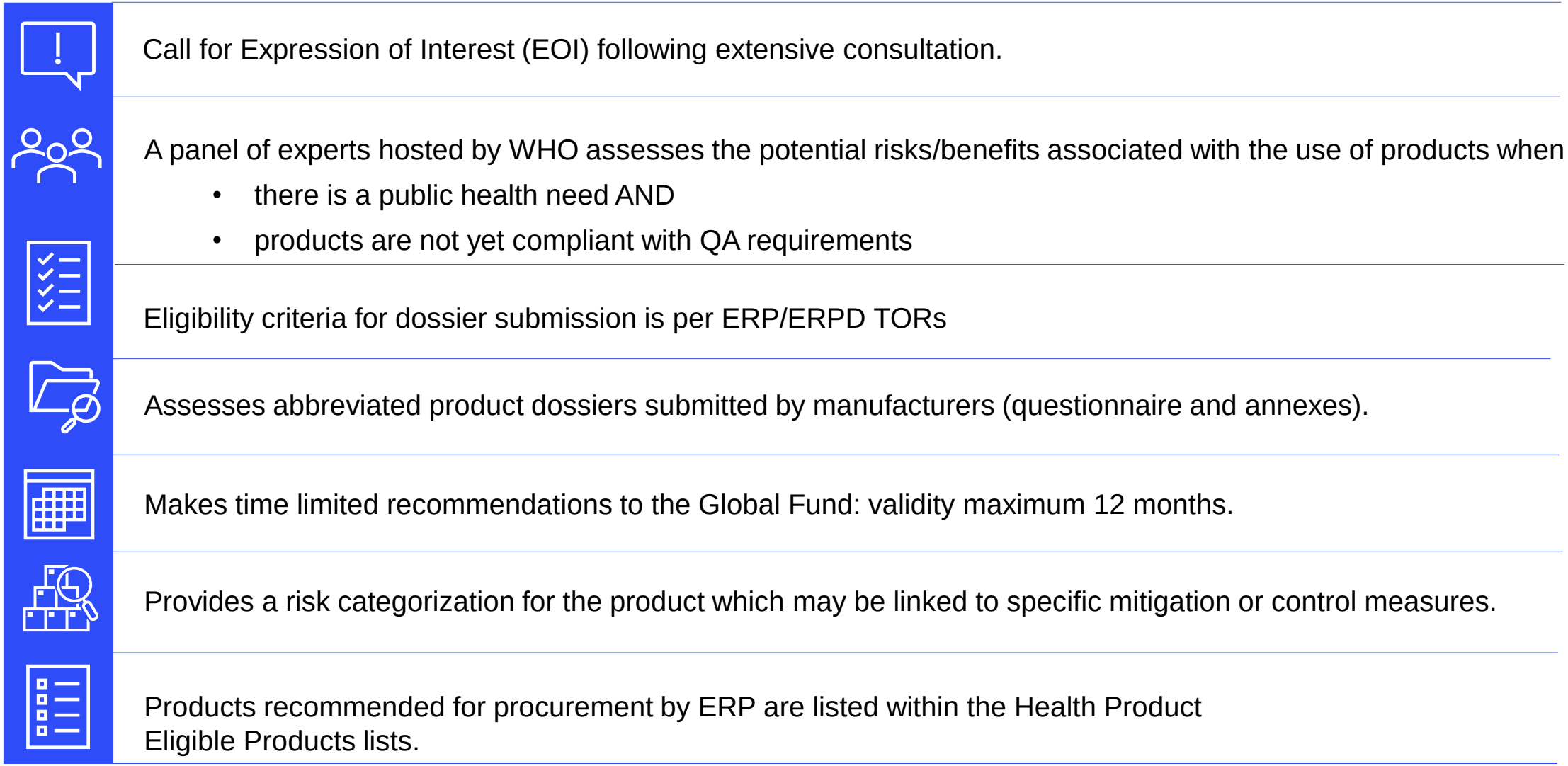
	Current QA requirements
Reference	***QA policy for VCP and related equipment***
Selection	• **If 2 or more WHO PQ'ed VCPs available → select product** • **If none or only 1 WHO PQ'ed VCP available → consider selection of ERP VCPs** • **Approval of procurement of ERP products required**
Transportation, storage and distribution	• **WHO or internationally recognized guidance for good transportation, storage and distribution practices** • **Traceability mechanisms encouraged**
Pre-shipment inspection, sampling and testing	**Inspection and Sampling** • **Risk based** • **Independent sampling agent** • **Per WHO / internationally recognized standards** **Testing** • **Independent laboratory with testing methods in the scope of accreditation** • **Lab accredited in accordance with ISO 17025 OR** • **Good Laboratory Practices certified** • **Testing conducted in accordance to methods and specifications approved by WHO PQ or ERP**

Procurement of Vector Control Products - 4/4

QA requirements

	Current QA requirements
Reference	***QA policy for VCP***
Supply chain monitoring	• **Monitoring plan and implementation done in collaboration with NRA** • **Per WHO / internationally recognized guidelines** • **Results submitted to stakeholders including the Global Fund**
Monitoring Insecticide resistance	• **PRs Implement insecticide resistance surveillance plan** • **Use of insecticide susceptibility test kits and impregnated papers per WHO recommendations**
Incidents and product non-compliance	• **PRs develop and maintain a reporting system** • **Reporting per NRA requirements** • **Communication with stakeholders**
Waste management	• **Done in line with National / regional guidelines OR** • **Global Fund, WHO or FAO issued guidance**

The Expert Review Panel (ERP) – 1/2



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 when

- there is a public health need AND
- products are not yet compliant with QA requirements

Eligibility criteria for dossier submission is per ERP/ERPD TORs

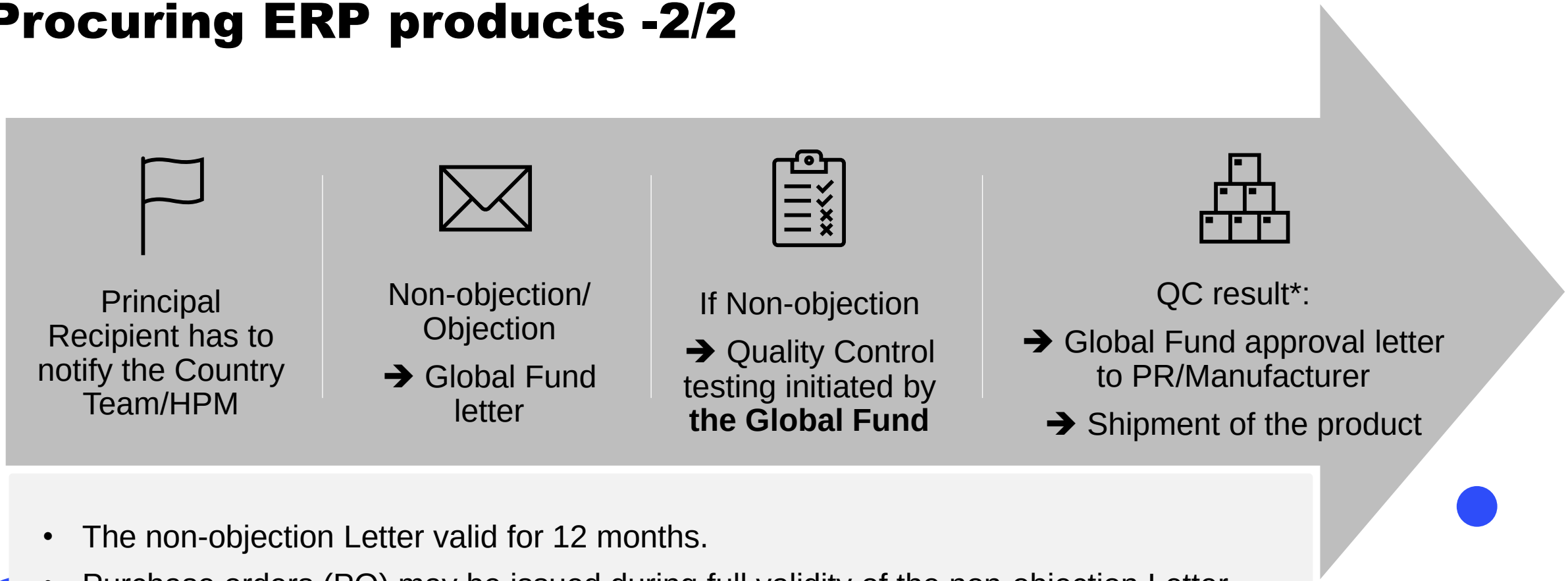
Assesses abbreviated product dossiers submitted by manufacturers (questionnaire and annexes).

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.

Products recommended for procurement by ERP are listed within the Health Product Eligible Products lists.

Procuring ERP products -2/2



- 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.

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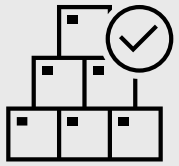
Quality assurance requirements for procurement entities

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

The MQAS describe the quality management system which should be implemented by procurement entities. The scope of the MQAS cover 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.

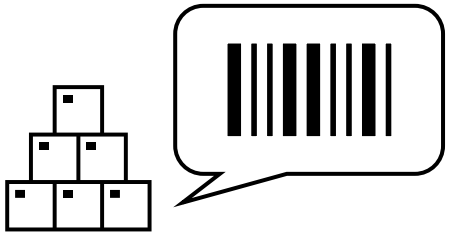
Procurement entities will have to implement partially or totally the principles of the MQAS covering the different functions depending on their mandate.

Example of Procurement Entities:

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

6 Pre-shipment Sampling and Testing

Pre-shipment inspection and controls



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

	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 PSM guide

(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

Importation, storage and distribution

Best Practice: Perform an independent audit of GSDP regularly.

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 Post Market Surveillance and Quality Control

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	All	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

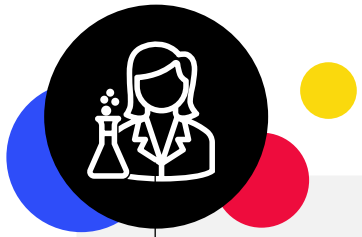
Post Market surveillance and quality control

Principles of monitoring the quality of health products procured using Global Fund grant funds are similar regardless of product 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 non-compliance but not to provide assurance on quality.

Planning for quality control monitoring activities



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 non-compliance, in collaboration with the NRA preferably. It may be needed to put in place immediate protective measures in case of serious non-compliance.
8. Reporting results to the Global Fund.
9. Records and documentation.
10. Reporting any non-compliance to the NRA and to the Global Fund QA through the Country Team.

9 Vigilance and non-compliance

Quality assurance requirements for vigilance

Best Practice: PR Quality Assurance Focal Point may facilitate.

1. PRs are strongly encouraged to support NRA and the Global Fund Secretariat to monitor **adverse reactions** and **defects** with products procured with the Global Fund funds.
2. Report to national authority in charge (please inform the Global Fund QA of the same*).
3. Support the Global Fund QA Investigations and implement decision/advice from the Global Fund in line with NRA decision.
4. 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 pharmacovigilance

For more information, review the Technical Brief on Regulatory 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*)

Non-compliance and out-of-specifications

The secretariat can be involved in case of risk of shortage.

1. PRs are encouraged to support the Global Fund Secretariat to deal with non-compliance 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. Reported to national authority in charge (please inform the Global Fund QA of the same) and implement their recommendations.
3. Support Global Fund investigations and implement Global Fund advice in line with NRA decision.
4. 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)*

Reporting form for non-compliance & 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

Quality assurance requirements for healthcare waste management

Several documents are available 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

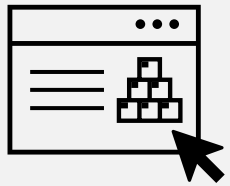
Quality assurance requirements for reporting

For more information, review the PQR Quick Guide.

	PQR Reporting	Responsible non-PPM	Responsible PPM
Pharmaceuticals Products	ARVs, antimalarials, Anti-TBs & Hep C Pharmaceuticals	PR	PSA
Diagnostics Products	Yes* – (HIV/TB/MAL, and co-infections; syphilis, Hep B and Hep C)	PR	PSA
Laboratory Equipment for Diagnostic Purpose	Yes**	PR	PSA
Condoms & PPE	Condoms, Surgical & non-surgical masks and respirators	PR	PSA
Medical Devices	Class C and D	PR	PSA
Vector Control Products	All ITN's and IRS	PR	PSA

* and others such as IVDs 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



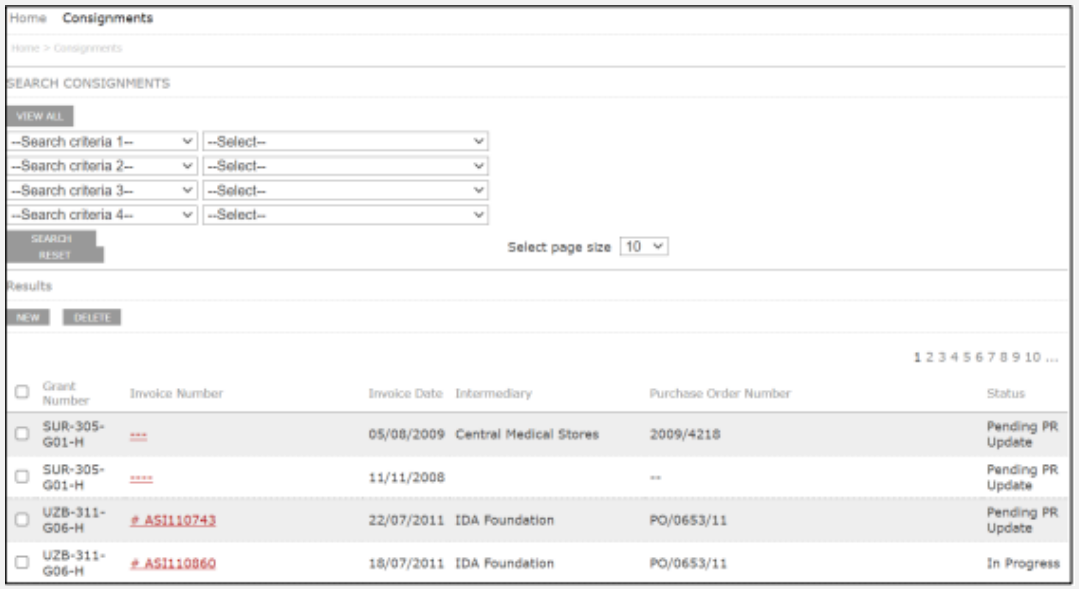
The Global Fund has set a specific online-platform to collect information on:

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 non-compliance issues.

For more information, review the PQR Quick Guide.

Thank you

THE GLOBAL FUND

The Global Fund to Fight
AIDS, Tuberculosis and Malaria

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theglobalfund.org

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Useful References

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

Quality assurance is ensuring health products – everything from medication to X-ray machines – 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

References

Global Fund Quality and Procurement Policies and guidance

QA Policies

- QA policy for pharmaceutical products https://www.theglobalfund.org/media/5894/psm_qapharm_policy_en.pdf
- QA policy for Medical Devices (including IVDs) and PPE https://www.theglobalfund.org/media/13577/psm_qa-medical-devices_policy_en.pdf
- QA policy for Vector Control Products https://www.theglobalfund.org/media/13767/psm_qa-vector-control-products-equipment_policy_en.pdf
- Procurement and Supply Management (PSM) guide https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf
- Q&A on revised QA policy for pharmaceutical products and QA policy for MDs (including IVDs) and core PPE https://www.theglobalfund.org/media/13592/psm_qa-medical-devices_faq_en.pdf

WHO Listed Authority (WLA)

- Evaluating and publicly designating regulatory authorities as WHO listed authorities Policy document https://iris.who.int/bitstream/handle/10665/341749/9789240023444-eng.pdf?sequence=1
- WHO Questions & Answers on WLAs https://www.who.int/news-room/questions-and-answers/item/who-listed-authorities
- Operational guidance for evaluating and publicly designating regulatory authorities as WHO-listed authorities https://iris.who.int/bitstream/handle/10665/374054/9789240074767-eng.pdf?sequence=1
- List of WHO Listed Authorities as of May 2024 https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/list_of_wla_may24.pdf?sfvrsn=1f6c2140_34&download=true

References

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

Pharmaceuticals

- 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
- WHO prequalification for medicines https://extranet.who.int/pqweb/medicines
- List of Antihepatitis Pharmaceutical Products Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/11150/psm_productshepatitis_list_en.pdf
- List of ARV Pharmaceutical Products Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/4758/psm_productshivaids_list_en.pdf
- List of COVID-19 Pharmaceutical Products Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/11881/psm_productscovid19_list_en.pdf
- List of Malaria Pharmaceutical Products Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/11151/psm_productsmalaria_list_en.pdf
- List of Tuberculosis Pharmaceutical Products Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/4757/psm_productstb_list_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
- FAO Guidelines on retail distribution of esticides with particular reference to storage and handling at the point of supply to users in developing countries https://www.fao.org/fileadmin/user_upload/obsolete_pesticides/docs/retail_es.pdf
- WHO Manual for monitoring insecticide resistance in mosquito vectors and selecting appropriate interventions https://www.who.int/publications/i/item/9789240051089
- WHO's Framework for a national plan for monitoring and management of insecticide resistance in malaria vectors https://www.who.int/publications/i/item/9789241512138
- The Global Fund Information Note on Malaria https://www.theglobalfund.org/media/4768/core_malaria_infonote_en.pdf
- List of Indoor Residual Sprays (IRS) that Meet Global Fund Quality Assurance Requirements for use Against Malaria Vector https://www.theglobalfund.org/media/5857/psm_indoorresidualsprayirsgf_list_en.pdf
- List of Insecticide Treated Nets (ITNs) that meet Global Fund Quality Assurance Requirements for use Against Malaria Vector https://www.theglobalfund.org/media/11805/psm_insecticidetreatednets_list_en.pdf

References

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

Medical Devices (Including IVDs) And Core PPE

- Chest Radiography and CAD Solutions for Tuberculosis Programs https://www.theglobalfund.org/media/11374/operational_chest-radiography-cad-solutions-tb-programs_briefingnote_en.pdf
- 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
- List of HIV Diagnostic Test Kits and Equipments Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf
- List of Rapid Diagnostic Test Kits for Malaria Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/5891/psm_qadiagnosticsmalaria_list_en.pdf
- List of SARS-CoV-2 Diagnostic Test Kits and Equipment Eligible for Procurement: COVID-19 https://www.theglobalfund.org/media/9629/covid19_diagnosticproducts_list_en.pdf
- List of TB Diagnostic Tests Classified According to the Quality Assurance Policy https://www.theglobalfund.org/media/9461/psm_productsdiagnosticstb_list_en.pdf
- List of Medical Oxygen Generators Classified According to the Quality Assurance Requirements https://www.theglobalfund.org/media/12026/covid19_medical-oxygen-generators_list_en.pdf
- List of Surgical and Non-surgical Masks and Respirators Classified According to the Quality Assurance Requirements https://www.theglobalfund.org/media/12057/covid19_masks-respirators_list_en.pdf

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

Useful Acronyms

- ACTs: Artemisinin-based combination therapy
- ADR: Adverse Drug Reaction
- ARVs: Anti-retrovirals
- COIM: Co-Infections & Co-morbidities
- CT: Country Team
- Dx: Diagnostic
- EFTA: European Free Trade Association
- 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
- ICH: The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
- IRS: Indoor Residual Spray
- ITNS: Insecticide Treated Nets
- IMDRF: International Medical Device Regulators Forum
- MA: Marketing Authorization
- NC: Non-compliance
- 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)
- SOP: Standard Operating Procedure
- SRA: Stringent Regulatory Authority
- STG: Standard Treatment Guidelines
- VCP: Vector Control Products
- WHO PQ: World Health Organization Prequalification
- WLA: WHO Listed Authority

ANNEXES

Why quality assurance matters

The following risk scenarios 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 HIV 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 on potential serious adverse events to the foetus in pregnant women not captured by the vigilance system and reported to by NRA in due time after scale-up

Leading to potential public health risks for patients/users

Registration authorities and bodies referenced in the Global Fund QA policies -1/2

National Regulatory Authority (NRA): Official authority of a country responsible for regulatory activities including evaluating the quality, safety and efficacy of health products released to the public for distribution

Stringent Regulatory Authority (SRA): A Regulatory Authority which was prior to 23 October 2015 either a member of ICH or an ICH observer being the EFTA as represented by Swiss Medic, Health Canada and WHO or a regulatory authority associated with an ICH member through a legally binding recognition agreement including Australia, Norway, Iceland and Liechtenstein

WHO Listed Authority (WLA): A Regulatory Authority or a Regional Regulatory System which has been documented by WHO to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.

Regulatory Authorities of the founding members of the Global Harmonization Task Force: Regulatory Authorities of the United States, EU including UK, Japan, Canada and Australia

Registration authorities and bodies referenced in the Global Fund QA 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 WHO hosts the panel.

WHO Prequalification Programme: Managed by WHO for prequalifying a) Health Products acceptable for procurement by UN and specialized agencies and b) quality control laboratories

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, during public health emergencies.

The Global Fund QA Documentation-facing Recipients

Updates to the QA Policies are summarized into other change management documents (such as will have to be translated into the lower levels of Global Fund owned documentation

but this may take time

Quality Assurance Policies
approved by Board provide high level QA requirements for products and practices

The Health Products Guide*
approved by EGMC recalls high level requirements, along with additional detailed requirements

Signals, ADR, OOS,…

QA Briefing Notes
issued by QA Team in consultation with HPM provide operational guidance to facilitate implementation of above QA requirements

Other internationally recognized guidance, norms and standards
issued by WHO, ISO or Others

QA Information Notice
issued by QA Team as risk mitigations measures

Other QA Documents:
issued by QA Team in consultation with HPM provide operational guidance to facilitate implementation of above

***The Guide to Global Fund Policies on Procurement and Supply Management of Health Products is sometimes referred to as the "PSM Guide" or, in Global Fund Grant Regulations, as the "Health Products Guide".**

Operationalizing Quality Assurance Policies

Overview

Topic	Activity	2023 Q4	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025
QA Policy	QA Policies on Pharma, MD, IVD and PPE issued and published								
	QA Policies on VCPs Issued and published								
	BN on summary of changes on QA policies for Pharma, MD IVDs and PPEs developed and published								
	BN on summary of changes on QA policies for VCPs developed and published								
	Trainings for PRs/LFAs and PSA on QA policies								
Policy Guidance	Update PSM Guide content in line with new policies including procurement								
	Training for PRs/LFAs on PSM Guide update								
	Briefing notes e.g. PMS, WLA								
Policy Implementation	Set Up ERP mechanism for VCPs								
Policy Compliance	Compliance verification activities								

Stringent Mechanisms for Procurement of Core Health Products

Reliance on stringent mechanism in addition to national mechanism

MA Mechanism	Description	Practices
Stringent Regulatory Authorities (SRA)	• Robust legal/regulatory environment • ICH Requirements • Experienced & Skilled Staff in Quality/Safety/Environment • Applicable in the procurement of core FPP	• Regular GMP inspection as per related regulation • Mutual Recognition Agreement • Prioritization based on risks
WHO Listed Authority (WLA)	• Performance evaluation process conducted by WHO to designate a RA or RRS as a WLA • RA or RRSs must have attained ML 3 to be eligible for consideration as a WLA • Applicable in procurement of core FPP and MDs	• Meets WHO standards and other internationally recognized standards • Listing includes scope of designation, products and / or regulatory function • Risk-based approach used to renew listing
WHO PQ program	• Program managed by WHO • WHO requirements • Experienced & Skilled Staff • Applicable to core FPP, IVD, VCP	• Regular inspection as per WHO PQ Procedure • Consideration of stringent assessment decisions for FPP and IVDs • Dossier review

Stringent Mechanisms of Core Health Products

Reliance on stringent mechanism in addition to national mechanism

MA Mechanism	Description	Practices
GHTF RA	• RA of founding members of GHTF i.e USA, Canada, Japan, Australia and EU including UK • Robust legal/regulatory environment • Applicable in procurement of MDs (including IVDs) and core PPE • Experienced & Skilled Staff in Quality/Safety/Environment	• Regular GMP inspection as per related regulation • Prioritization based on risks
Expert Review Panel (ERP/ERPD)	• Alternative Mechanism used upon Global Fund request • Panel of external technical experts • Used for accelerated introduction of innovative products • Supported by WHO • Applicable for core FPP, MDs (including IVDs), VCPs	• Assesses abbreviated product dossiers • Clear analysis of benefits and potential risks • Product categorization with specified risk mitigation measures

Procurement of Pharmaceutical Products

Examples of The Globa Fund eligible WLAs (1)

ML3 - Medicines	ML4 -Medicines	WLA- Medicines (2)	Eligible WLA (3)
Ghana-Food and Drugs Authority Nigeria-National Agency for Food and Drug Administration and Control Tanzania-Tanzania Medicines and Medical Devices Authority Türkiye-Turkish Medicines and Medical Devices Agency (TİTCK)	Singapore-Health Sciences Authority Rep. Korea-Ministry of Food and Drug Safety Saudi Arabia-Saudi Food and Drug Authority	Singapore-Health Sciences Authority Rep. Korea-Ministry of Food and Drug Safety Switzerland-Swissmedic European Medicines Regulatory Network - EU DG SANTE, EMA, NRAs USA - USFDA	Singapore-Health Sciences Authority Switzerland-Swissmedic European Medicines Regulatory Network - EU DG SANTE, EMA, NRAs USA - USFDA

(1): No WLA for MD and IVDs at present

(2): WLA for vaccines should not be considered as eligible

(3): Only NRAs having the regulatory function of marketing authorization in their scope of listing are eligible

Eligible Global Fund WHO Listed Authorities[1] (WLAs): Illustration

List of WHO-Listed Authorities (WLA) (in alphabetical order) as of May 2024

Country	Regulatory Authority (RA)	Link to the RA and contact point	Listed product stream(s)	Listed function(s)	Date of first listing	Date of renewal	Link to the listing summary
Austria[1]	Austrian Federal Office for Safety in Health Care (BASG)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: basg_anfragen@basg.gv.at	Medicines (including multisource [generics], and new medicines [new chemical entities], biotherapeutics and similar biotherapeutic products)	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP) 6. Laboratory testing 7. Clinical trials oversight	13 May 2024	June 2029	TBC
Austria[1]	Austrian Federal Office for Safety in Health Care (BASG)	▪ Please click HERE to access the site of the regulatory authority ▪ Contact point: basg_anfragen@basg.gv.at	~~Vaccines~~	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection (GMP, GSDP and GCP)	13 May 2024	June 2029	TBC

[1] List of WHO Listed authorities as of May 2024

Procurement of Medical Devices (Including IVDs) and core PPE

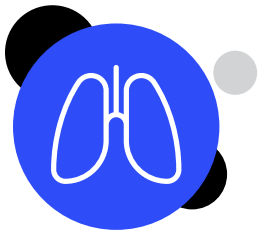
Medical Devices classification

- Medical Devices are classified per the globally harmonized principles[1] of the Medical Devices classification consisting of 4 classes; A,B,C and D where A represents the lowest risk and D the highest
- Depending on the intended purpose, the risk classification can change
- When Class C or D, stringent requirements must be complied with

Class	Risk level	MDs examples
A	Low	Laryngoscope
		Oxygen mask
		Endotracheal tube
B	Low - moderate	Electrocardiogram
		Oxygen cylinder
		Patient monitor
C	Moderate - high	PSA oxygen plants
		X-rays
		Mechanical ventilator
D	High	Absorbable sutures

[1] https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

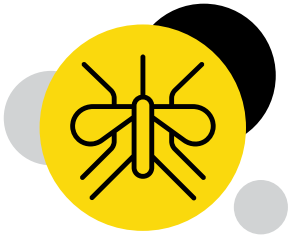
Examples of ERP outcomes of importance



Tuberculosis

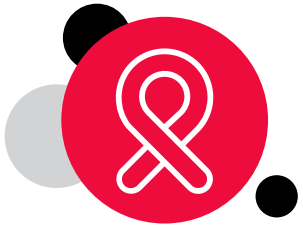
Rifampicin 75mg and Isoniazid 50mg, Dispersible tablets

3HP Rifapentine/Isoniazid



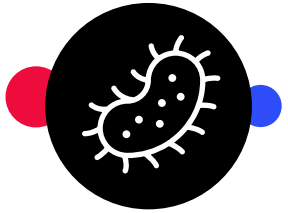
Malaria

Malaria RDTs HRP2 deletion



HIV

HIV Self-test



Opportunistic infections

Syphilis test

Role of the Local Fund Agent (LFA)

Verify Price and Quality Reporting (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 at various stages of health product life cycle during grant implementation.

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 and / or reinvestment of savings.

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.