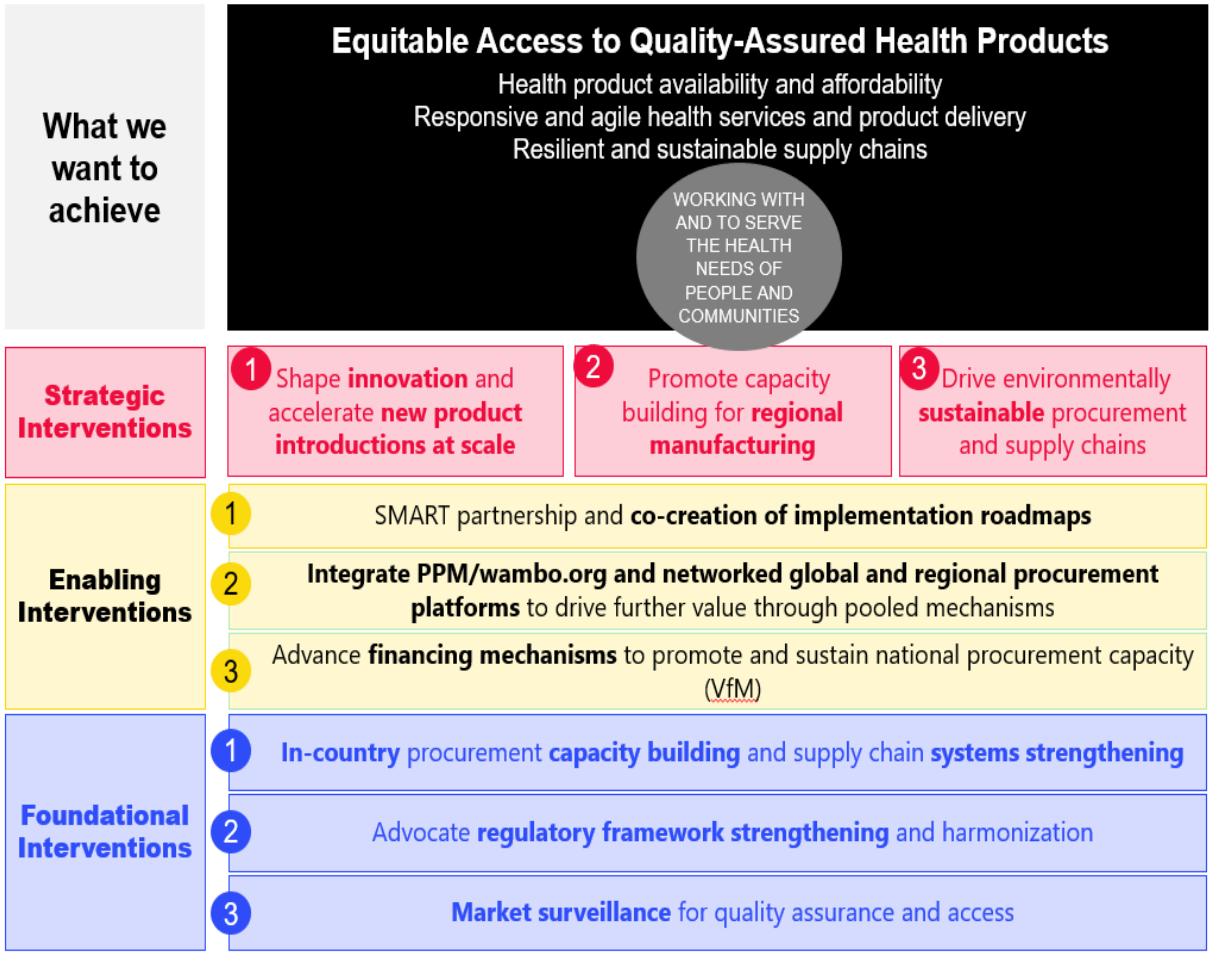
THE GLOBAL FUND

The Global Fund's Procurement System

December 2024

Global Fund's NextGen Market Shaping approach to drive equitable access to quality health products



Global

1. Work with industry and partners to **drive innovation that is accessible** to LMICs
2. Secure supply that is **affordable, available, quality and responsiveness**
3. Foster **South-to-South collaboration**

Regional

1. Leverage PPM / wambo.org procurement mechanism to collaborate with partners to build regional procurement capacities
2. Stimulate and sustain regional manufacturing capacity building

National

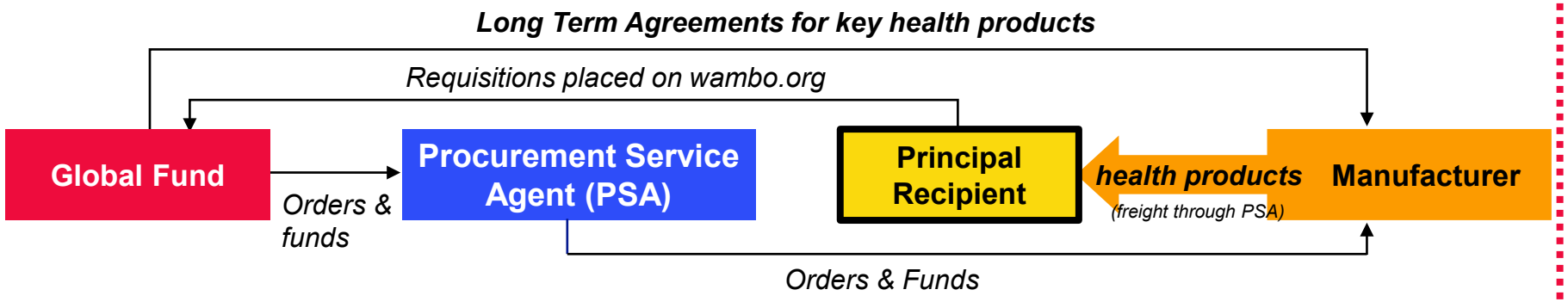
1. Use grant investments and country partners to strengthen in-country supply chain systems
2. Ensure quality assured health products will be distributed effectively and efficiently to communities and people we serve

Procurement Channels and Routes to Market

Every year about $ 2-3 billion or more of the Global Fund's grant financing is used for procurement of health products with the Global Funds Pooled Procurement Mechanism (PPM) being the largest channel, representing around 50-60% health product spend depending on the category.

Three types of channel that implementing countries use for the procurement of health products

1. Pooled Procurement Mechanism (PPM/wambo)
Managed by Supply Operations Department in the Global Fund Secretariat
(50-60% by value)



2. National Procurement Mechanisms

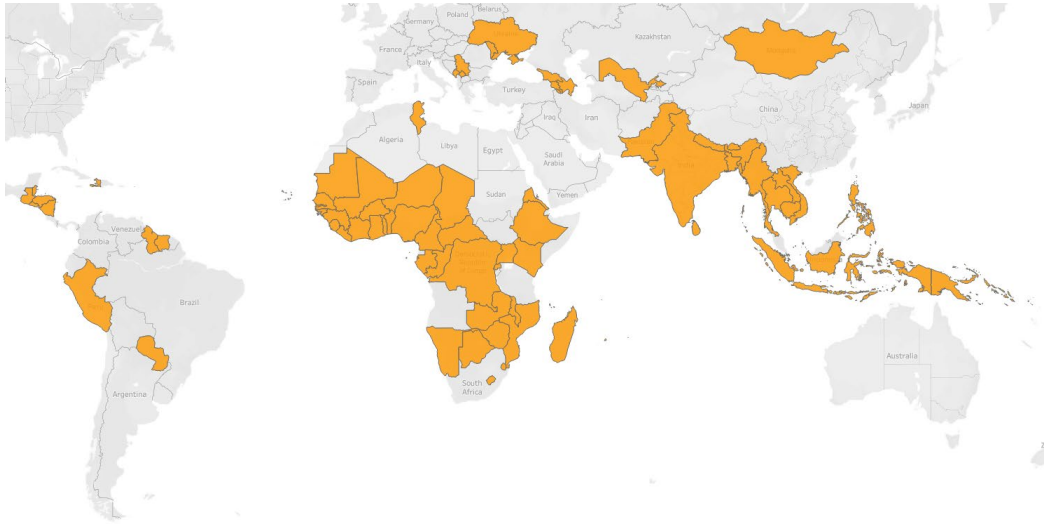
3. Other Procurement Agents
(e.g., UN agencies when they are PR); Stop TB's Global Drug Facility*

* Recipients of Global Fund funding for TB often procure medicines & may procure other health products for TB through the Stop TB Partnership's Global Drug Facility (GDF).

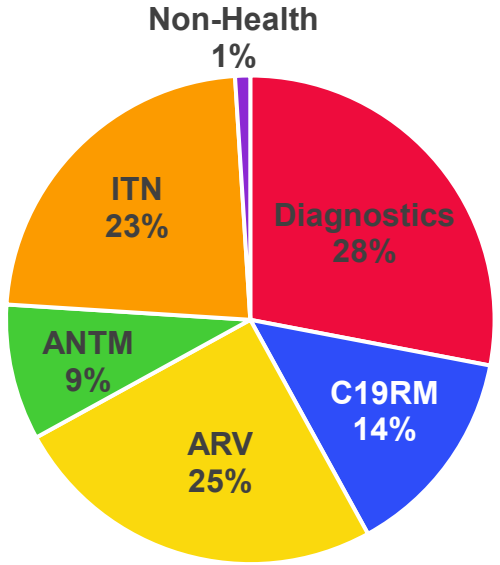
US$1.34 billion orders placed in 2023 through PPM

Nearly 5,000 shipments of needed health products reliably delivered despite global supply chain disruptions

PPM through its wambo.org platform connected **452 PR users** from **108 organizations** in **81 countries**



Processed 1,367 Purchase Orders for a total value of US$1.34 billion



Product category spend (US$)

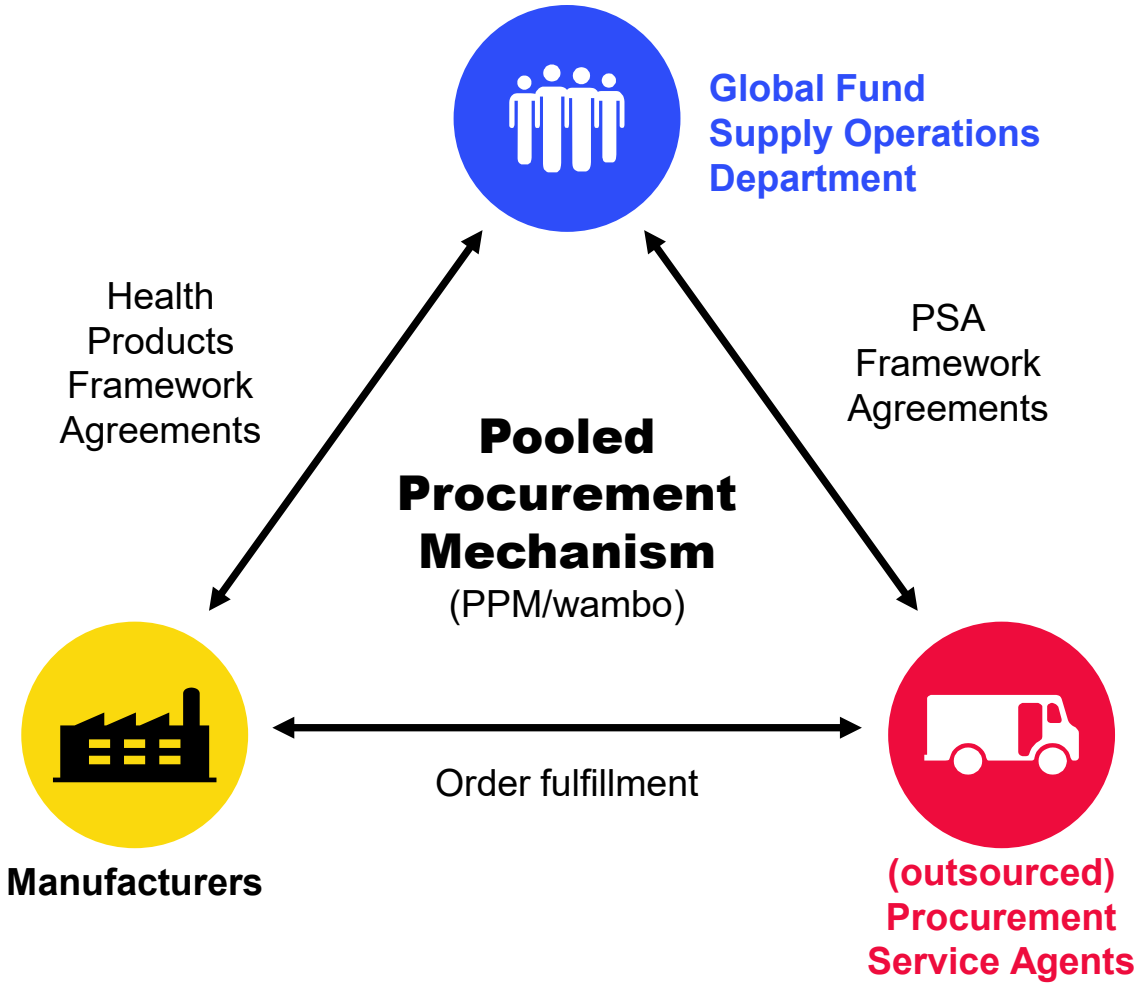
Diagnostics: diagnostic and lab consumables and equipment
C19RM: pandemic preparedness through the Global Fund's C19RM financing
ARV: antiretrovirals
ANTM: antimalarials
ITN: Insecticide-treated nets

Environmental sustainability: Increased shipment by sea to mitigate carbon footprint associated with delivery.

79% by value

95% by volume

GF's PPM holds Framework Agreements with manufacturers for key product categories: medicines for HIV Malaria, bednets, diagnostic testing



The Global Fund Secretariat aggregates order volumes to leverage our spending power and achieve value-for-money:

- Competitive tenders to select manufacturers: links from category pages found at https://www.theglobalfund.org/en/sourcing-management/health-products/
- Require adherence to GF quality assurance policies https://www.theglobalfund.org/en/sourcing-management/quality-assurance/
- Stringent performance management through contract implementation

Business opportunities & requirements for manufacturers

Characteristics

- Long term contracts with volume allocation and potentially commitment (2 - 5 years)
- Annual volume allocations and regular updates
- A focus on total cost of ownership
- Seek Value-added services

Impact for Manufacturers

- Ability to make plans
- Optimize plant loading
- Risk mitigation
- Viability of inward investment
- Opportunity for innovation and investment

Key requirements

- Product need to be compliant with relevant Global Fund Quality Policy
- National registration also required

The Global Fund/Jiro Ose

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

Procurement strategies and implementation to ensure quality delivery to the country programs

We are finalizing the following Request for Proposals (RFPs) to maximize GC 7 value delivery in line with the NextGen Market Shaping.

- Rapid dynastic tests (RDTs)
- Molecular diagnostics
- Procurement Services Agencies (PSAs)

We plan to launch the following Request for proposals (RFPs) in 2025 to optimize GC 7 value delivery and support the new grant-making

- Pharmaceuticals (ARV, ANTM and other pharmaceuticals)
- Insecticide-treated nets (ITN)

Getting Started

The Global Fund does not maintain a list of preselected suppliers with whom implementing partners may work. Suppliers that wish to provide goods and supplies to countries supported by the Global Fund should:

- Review the Policies and Principles section of the Global Fund Sourcing & Management of Health Products page.
- Familiarize themselves with the quality assurance requirements applicable to specific products.
- Look at the Transaction Summary in the Price & Quality Reporting page to see examples of what grants have already purchased
- Read about wambo.org, our online procurement marketplace, on our Procurement Tools page. At this time, all products available on wambo.org are ordered through Procurement Service Agents
- Read our Code of Conduct for Suppliers as well as our Procurement Policy

THE GLOBAL FUND

QA Policy Framework & Operationalization

4th December 2024

Content

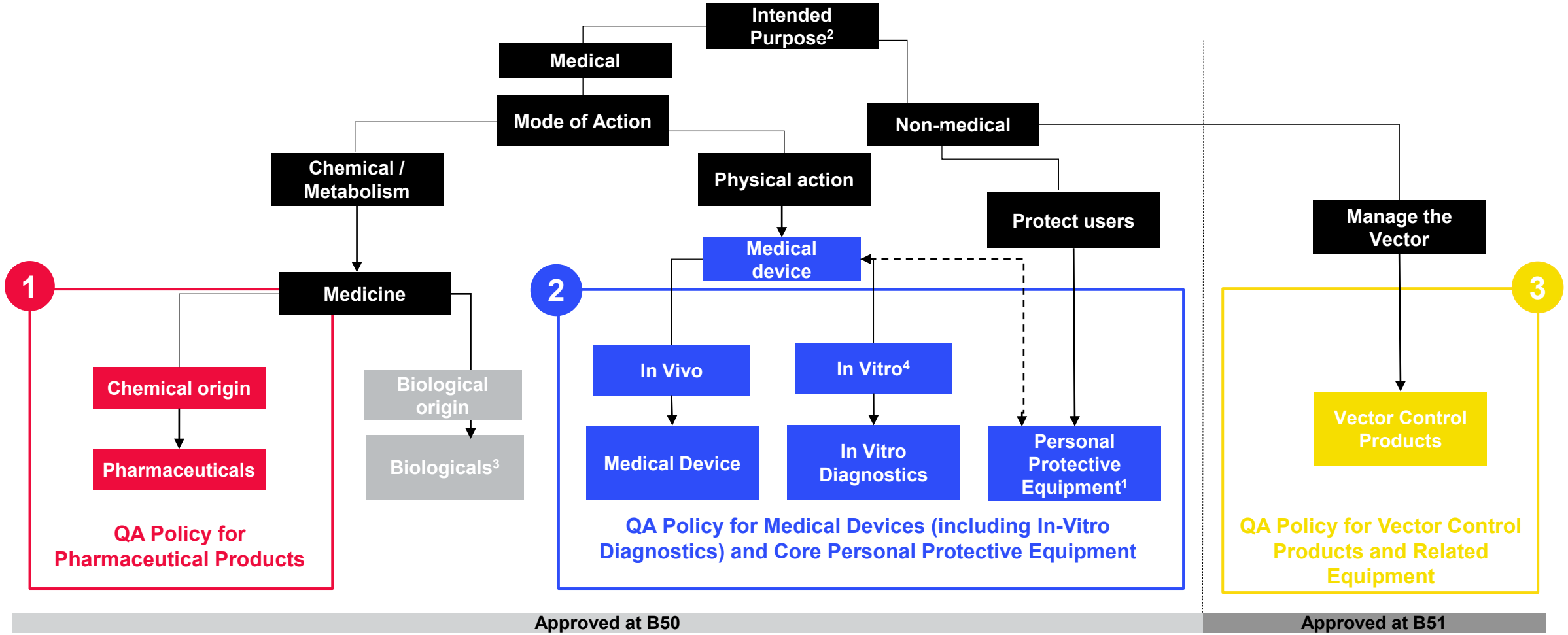
1 Overview

2 QA Policies - Requirements

3 Operationalization of the QA Policies

The QA Policy Framework Covers the Range of Global Fund-Financed Health Products

Schematic Representation of Health Product Categories[1]



[1] Simplified overview. For more detail, please refer to the standardized definition of each health product category
[2] Some products may meet the conditions for more than one product category. In such cases, quality assurance requirements for both categories apply
[3] Current TGF spend on Biologicals is negligible and thus does not warrant development of a QA policy to date
[4] On samples taken from the human body

Quality Assurance Requirements

Upstream

Eligibility

Clinical standard requirements

Quality standard requirements
(*selection process*)

Registration & Authorization

Clearance for the country of use

Market authorizations/ registrations

Procurement

Procurement entities requirements

Compliance with WHO Model Quality Assurance System for Procurement Agencies

Monitoring Product Quality (Pre-Shipment)

Inspection, Sampling & Testing requirements

Downstream / In-Country

Reporting

Reporting requirements

Price & Quality Reporting (PQR) for specific products

Incidents & Product Non-Compliance

Vigilance and Non-compliance

Waste Management

Storage and disposal

Monitoring IR

Insecticide Resistance

Monitoring Product Quality (Throughout SC)

Market Surveillance & Quality control requirements

Transportation, Storage & Distribution

Good Transportation, Storage and Distribution Practices

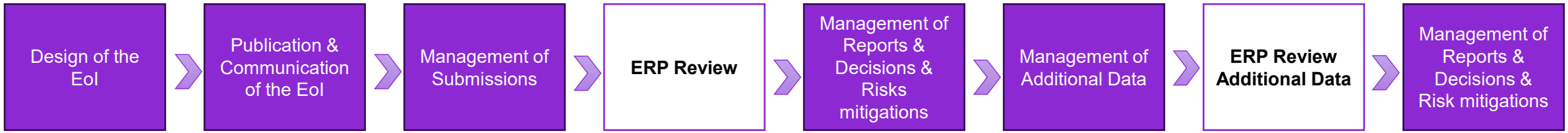
QA Policies - Overview

Product Category	Clinical Standards	Quality Standards
Pharmaceutical Product	• WHO standard treatment guidelines (including WHO Rapid Communication); OR • WHO Essential Medicines List; OR • National standard treatment guidelines; OR • National Essential medicines list	• For HIV, TB and Malaria pharmaceutical products: - WHO PQ; OR - Authorized by SRA or WLA; OR - Recommended for use by ERP • For other pharmaceutical products: quality standards established by the NRA in the country of use
Medical Devices[1] (incl. In-Vitro Diagnostic[2]) & Core Personal Protective Equipment[3]	• WHO guidance (including a WHO Rapid Communication); OR • Applicable national guidelines	• For all MD (incl. IVD): Manufactured at a site compliant with ISO 13485 or an equivalent recognized QMS; AND • For all IVDs for HIV, TB, malaria, as well as Hepatitis B & C, and Syphilis co-infections, MD (class C or D), and core PPE: - WHO PQ[5] or UNFPA PQ[6]; OR - Authorized by a RA of the GHTF Founding Members[7] or WLA; OR - Recommended for use by ERP; OR - Recommended by WHO Global TB Programme (including WHO Rapid Communication)[8] • For al MD (inc. IVD) compliance with applicable law and regulation including putting on the market
Vector Control Product4	• WHO Guidelines for Malaria (including WHO Rapid Communication); OR • National or Regional Malaria Vector Control Guideline or Strategy	• WHO PQ; OR • Recommended for use by ERP[9] AND • Authorized by the NRA in the country where used

[1] "MD"
[2] "IVD"
[3] "PPE"
[4] "VCP" used for malaria prevention
[5] Except for condoms (male and female) and lubricants
[6] Only for condoms (male and female) and lubricants
[7] Only for IVDs for HIV, TB, malaria, as well as Hepatitis B & C, and Syphilis co-infections
[8] Only for TB IVDs
[9] To be developed

Expert Review Panel (ERP)

Steps of the ERP process



KEY DELIVERABLES

Stakeholders' consultations Finalized scope of product categories to accept EoI	"Invitation for EoI" published on TGF website Manufacturer submit an EoI (questionnaire & supporting documentation)	Manufacturer are informed about the screening outcome of the Product Questionnaire	ERP Meetings/ Review TGF receives the outcome of the ERP Review	Inform manufacturer on the ERP Review outcome and decision Update TGF List of products Request Additional Data / Not all Implement Risk mitigations if applicable	Transfer of additional data from manufacturer for ERP Review	ERP Review of additional data TGF receives ERP Reports	Inform manufacturer on the ERP Review outcome and decision Update of TGF List of products Implement Risk mitigations if applicable

Acronyms: ERP : Expert Review Panel, EoI: Expression of Interest, TGF: The Global Fund

QA Policy for Pharmaceutical Products

Major Changes

- Eligibility includes products authorized by a **WLA within their scope of listing** (HIV, TB & Malaria) or recommended for use by ERP
- Eligibility includes products authorized through **emergency use procedures WHO/SRA/WLA during a health emergency** – if Board allows use of funds
- **Explicit approach for addressing QA issues**
- Role of the **Global Fund's Strategy Committee** (SC) in **overseeing the QA Policy implementation** (dedicated section)
- **Transitional Measures: SRA-WLA**

Alignment of changes

- Grant funds & Resources
- Definitions revised for NRA, WLA, PHEIC, Regulatory Systems
- Intervention of TRP deleted in clinical section
- Expanded scope of WHO clinical tools
- Outdated reference to Green Light Committee deleted
- Terms of the ERP revised, WLA Added + additional risk mitigations
- GSDP included

QA Policy for Medical Devices (Including IVDs) and core PPE

Major changes

- **QA Policy scope**: replacing the original QA Policy for Diagnostics, expanding its scope to cover **all medical devices including in-vitro diagnostics and condoms**, as well as **core personal protective equipment**
- Eligibility includes products authorized by a **WLA within their scope of listing or recommended for use by ERP** (excl. Core PPE)
- Eligibility considers medical devices (including IVDs) and PPE authorized through **emergency use procedures during a PHEIC**
- **Monitoring Policy Implementation** Section:
  - ✓ Guidance and training
  - ✓ Management of QA issues
  - ✓ Monitoring and Oversight
- Role of the **Global Fund's Strategy Committee** (SC) in **overseeing the QA Policy implementation** (dedicated section)
- Provision for **WLA transitioning** although this will be on a different timeline than for Pharmaceutical Products

Alignment Changes

- Grant funds & Resources
- New Definitions: IVD, NRA, WLA, PHEIC, RRS
- Clinical requirement includes WHO Rapid Communication
- All MD suppliers to be ISO 13485, or eq.
- Stringent QA requirements for Class C & D
- Terms of the ERP revised, WLA added + additional risk mitigations
- GSDP requirement expended to all MDs

QA Policy for VCPs and Related Equipment

QA requirements elevated to new QA policy for VCP from PSM guide

Major Changes

- NRA **authorization in country of use**
- Revision of the **QA standards**
  - *Removal of WHOPES*
  - *Addition of selection process for procurement*
- **ERP process** (elevated)
- **Quality monitoring and handling noncompliance** requirements
- Requirement on **monitoring of insecticide resistance**
- Requirement on **waste management** (elevated)

Alignment of changes

- Grant funds & Resources
- Expanded scope of WHO clinical tools i.e. inclusion of WHO rapid communications and regional malaria vector control guideline or strategy
- Good Transportation, Storage & Distribution Practices requirements
- Model of Quality Assurance for procurement agencies

TGF QA Documentation

By design changes initiated by the QA Policies are to be translated into the lower levels of TGF documentation

QA Policy
approved by TGF Board provides high level QA requirements for products and practices

Health Products Guide*
approved by TGF EGMC recalls highlevel requirements along with additional detailed requirements

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

QA Briefing Notes
issued by TGF QA & Compliance Team (in consultation with internal/external stakeholders) provide operational guidance to facilitate the implementation of the quality requirements from the QA Policy

Signals, accidents, OOS…

QA Information Notices issued by TGF QA & Compliance Team as risk mitigations measures

Other Quality Assurance Documents:
Issued by TGF QA & Compliance Team (in consultation with internal/external stakeholders) provide operational guidance to facilitate the implementation of the quality requirements

***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"**

THANK YOU FOR YOUR ATTENTION