



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Global Fund Quality Assurance Policy for Pharmaceutical Products

**Pharmaceutical Management Unit
Quality Assurance and Data Management Team**

Overview of the Global Fund's QA policy

(issued 1 July 2009, last amended 14 December 2010):

Strict selection process

1. Clinical Criteria

- Medicines listed in WHO or national or institutional Standard Treatment Guidelines
- Require applicants/recipients to provide justification for selection of unlisted products in one of the STGs

2. Quality Criteria

For all products
Authorization for use in the recipient countries

For ARVs, anti-TB and anti-malarial products

WHO-prequalified (PQ) or authorized by a Stringent Regulatory Authority (SRA); ---or---

Found eligible for use by the **Expert Review Panel**, (only if <2 WHO PQ or SRA authorized products available

GMP assessment and dossier review

3. Monitoring Quality

- Monitoring quality of products all along the supply chain
- Systematic random quality control testing
- Recipients report testing results to Global Fund

Outline

Global Fund Quality Assurance Policy for Pharmaceutical Products (“QA Policy”):

	Slides
1. Clinical criteria	4
2. Quality criteria and selection process	5-12
3. Monitoring product quality	13-14
▶ Pre-shipment quality control	15
▶ Quality monitoring at country level	16-25
4. Compliance with the Quality Assurance Policy	25
5. Conclusion and links to further information	26-29

1. Clinical criteria

- Medicines procured with Global Fund resources must be listed in WHO or national or institutional Standard Treatment Guidelines (STGs)
- If grant applicants or PRs select products not listed in at least one set of STGs, they must provide a technical justification

2. Quality Criteria

All medicines must be

- Authorized for use by drug regulatory authority in recipient country

In addition, ARVs, anti-TB and antimalarial medicines (“ATM medicines”) must be

- Prequalified by WHO (**Option A**) or authorized for use by a stringent regulatory authority (SRA) (**Option B**)
- OR
(if fewer than two A/B products are available):
Permitted for use based on the advice of the Expert Review Panel (**ERP**)

Stringent requirements for ATM Products

- Option A: WHO prequalification
 - <http://apps.who.int/prequal/>
- Option B: SRA (Stringent Regulatory Authority)
 - SRAs are defined as countries participating in ICH (International Conference on Harmonization) as members, observers or associates
 - Approval under EMEA Art. 58, Canada Bill C9 and FDA tentative approval are also recognized

Expert Review Panel (ERP)

- A panel of experts (hosted by WHO)
- Assesses the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized
- Assesses abbreviated product dossiers submitted by manufacturers (questionnaire + annexes)
- Conclusion: Product is classified into one of 4 categories
- Makes time limited recommendations: validity maximum 12 months
 - Contracts can start any time during the validity, duration may not exceed 12 months

http://www.theglobalfund.org/documents/psm/communication/2010_QAPresentation_ERP.PPT

Before procuring ERP-reviewed products

Notification and QC process

1. PR has to notify* the GF Secretariat
2. No Objection/Objection - GF letter
3. QC testing initiated by GF initiate -SGS lab
4. QC result and shipment - GF issue final letter with QC result for shipment of the product

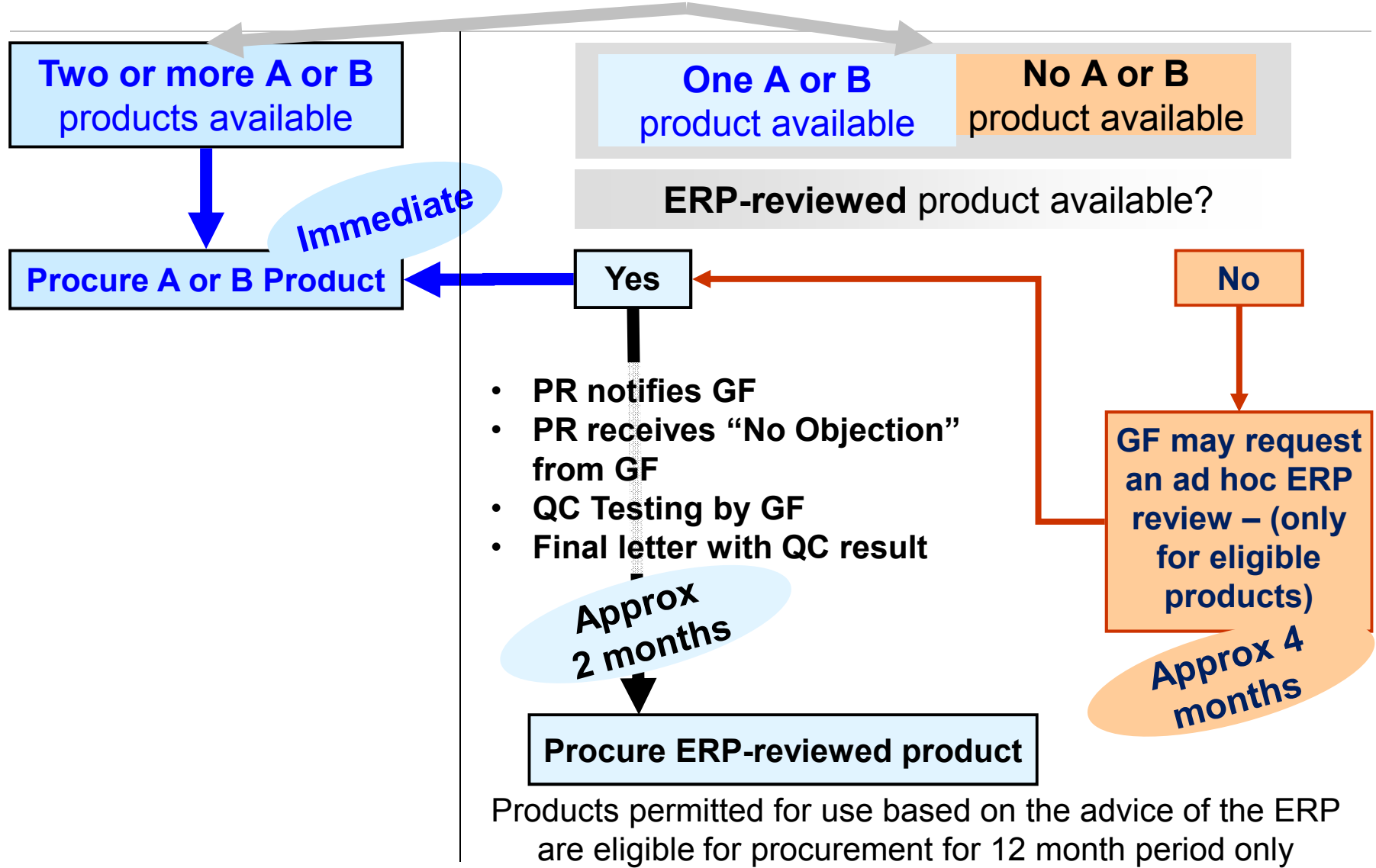
* http://www.theglobalfund.org/documents/psm/Notification_Form.doc

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

Selection of ATM products



Global Fund List

- An overview of products and manufacturers classified according to the Global Fund QA Policy criteria
- Tool to assist countries:
 - to identify Global Fund QA-compliant products
 - to make decisions for procurement selection
- Not an exhaustive list - based on the information available to the Global Fund submitted by manufacturers

PRs must verify that products meet criteria,
even if purchased through a procurement agent
(local, international, UN, NGO...)

Global Fund List (continued)

Documentation used for Global Fund List:

- **A classified product:** WHO prequalification letter;
- **B classified product:** SRA approval letter or market authorization/registration;
- **ERP-reviewed product-** Cat 1 and 2 products are published based on the ERP report;

List is updated regularly, usually at the end of the each month

Published on the Global Fund webpage:

<http://www.theglobalfund.org/en/procurement/pharmaceutical/?lang=en#Lists>

Basic principles in procurement

When procuring **any pharmaceutical products**, PRs must ensure that

- All FPPs are procured in accordance with principles set forth in the Interagency Guidelines:

“A Model Quality Assurance System for Procurement Agencies “ (WHO, 2006)

<http://www.who.int/medicines/publications/ModelQualityAssurance.pdf>

- All FPPs are authorized for use by Drug Regulatory Authority (DRA) in recipient country

A policy will be defined for products other than ARVs, anti-TB and antimalarials (“Non-ATMs”)

3. Monitoring product quality

QA Policy:

“The quality of FPPs procured with Global Fund grant funds must be monitored.”

“PRs to conduct systematic random testing, and report testing results to Global Fund”

Principles of quality monitoring:

- Concerns all products (including WHO-prequalified and SRA-authorized products)
- Monitoring done all along the supply chain
- Systematic random quality control testing (following a plan - not all products / lots will be tested)
- Recipients report testing results to Global Fund

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

Overview

QC	All FPPs: Post-Shipment	ERP-reviewed FPPs: Pre-Shipment
Responsibility	PR or Sub-Recipient (cost may be included in the grant budget)	Global Fund Secretariat, (arranges and pays for QC testing)
Condition	Good Procurement Practices are followed	Notification to Global Fund has been submitted by PR No Objection by Global Fund
When	After receipt in country	Before shipment to country
Frequency	Systematic random	Mandatory for all Purchase Orders (PO)

Pre-shipment Quality Control (QC)

- Two QC Laboratories have been contracted by the Global Fund:
 - SGS Netherland
 - NIDQC in Vietnam (WHO-prequalified laboratory)
- **Sampling:** by SGS shipment agent at manufacturing site
- **Methods used and parameters tested:**
 - Int Ph, British or USP Pharmacopoeia methods when exist
 - Manufacturers methods
- **Interpretation**
 - A batch is acceptable if the results of the testing are within the pharmacopoeia or manufacturer's specifications
 - If the batch passes QC tests, the batch is shipped
 - If the batch fails QC tests, it is replaced by a new lot to be tested
 - Results published on Global Fund website:
http://www.theglobalfund.org/documents/psm/communication/Preshipment_QC_testing_result.htm

Quality monitoring at country level

Quality Assurance before arrival of products in country

➤ Procurement:

Product selection according to Global Fund QA Policy

Pre-shipment quality control testing for ERP-reviewed products (organized by Global Fund Secretariat as per

➤ Receipt in country, storage, distribution

➤ Quality control in countries:

Step 1: Selection of quality control laboratory

Step 2: Designing a sampling and testing programme

Step 3: Sampling

Step 4: Transport of samples to the laboratory

Step 5: Quality control testing results and reports

Step 6: Records and documentation

➤ Monitoring storage and distribution sites

➤ Safe disposal of pharmaceutical products

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

Guidance document

at country level

“Guidance for Reinforcing and /or Establishing
Pharmaceutical Quality Control Systems and Related Stock
Management Activities in Countries Supported by the Global
Fund “

Global Fund document tool developed:

- in close collaboration with the WHO PQ program for Quality Control Laboratory
- to support the implementation of the revised Global Fund’s Quality Assurance Policy.
- to provide technical guidance to Global Fund grant recipients on quality control testing activities (see document outline on notes page below)
- Published on Global Fund website:

http://www.theglobalfund.org/documents/psm/PSM_QCMonitoringGFPRsVP_Guide_en.pdf

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

at country level

Receipt, storage

See [Guidance document for details](#)

- Receipt of consignment
 - Check consignment received into the country with shipping document/packing list/purchase order for condition of packing, product detail, quantity received.
- Storage
 - Store only in appropriate locations for pharmaceutical products.
 - Ensure appropriate storage conditions in all locations as required and indicated on labels.
 - Daily monitoring and registering of room temperature of storage.
 - Ensure storage are always free from pest, water logging, rain water leakage, etc.
 - Perform routine stock inventory in all locations.

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

at country level

Quality control, distribution, disposal

See [Guidance document](#)
for details

- Post-shipment Quality Control (six steps)
- Distribution
 - Prepare distribution schedule and follow plan as laid down.
 - Monitor stock level in all locations for excess or shortage during each distribution.
- Securing and disposal of expired medicines
 - Ensure expired medicines are located in secured places away from stock in all locations.
 - Dispose expired medicines according National Drug Regulatory guidelines.

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

at country level

Laboratory selection

See [Guidance document](#)
for details

QA Policy:

“The selected Quality Control laboratory should be:

- WHO prequalified and listed on WHO website, **OR**
- ISO/IEC 17025 certified for the required scope of drug testing”

- List of well-established ISO 17025-certified QC Laboratories meeting Global Fund requirements for quality monitoring by PRs posted on Global Fund’s website:

http://www.theglobalfund.org/documents/psm/communication/QCLab_List_v1.pdf



1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

Laboratory selection (continued)

at country level

See [Guidance document](#)
for details

- Role of National Laboratories
- Minimum requirements for laboratory (Global Fund)
- List of qualified laboratories
- Competitive tendering
- Technical capacity
- Cost evaluation
- Selecting more than one laboratory
- Contracting

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

Planning for QC testing; sampling

at country level

See [Guidance document](#)
for details

- PR with the QC laboratory need to define:
 - Plan of testing: **not all products/ batches should be tested**
 - Prioritize products associated with risk factors
 - Adopt advice of contracted QC lab to identify such products
 - Documentation to be collected
 - Sampling procedure
 - Tests to be done and timeline with defined procedures
 - Reporting process
- Sampling:
 - by trained staff
 - according to appropriate standard operating procedure
 - Respecting storage conditions at different distribution sites

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

Design a sampling & testing programme

at country level

See [Guidance document](#)
for details

- Definition of a sample
- Which products should be sampled and tested?
- What should be considered when planning an annual testing programme?
- Examples of products to be prioritized for testing
- Duplicate testing of batches
- Methods and standards for testing
- Size of samples to collect

1. Clinical Criteria

2. Quality Criteria

3. Monitoring Quality

at country level

Testing results and reports

See [Guidance document](#)
for details

- Testing: methods and process
- Handling out-of-specification results
- Reporting of results to the Global Fund

4. Compliance monitoring

- It is mandatory that procurement of ARVs, anti-TB, antimalarial products, bed nets, condoms, rapid diagnostic tests are reported in the Price Quality Reporting system (PQR)
- The QADM Team monitors compliance with QA Policy based on PQR data:
 - Monthly report: notify FPMs of potential non-compliance
 - Compliance analysis for Phase 2 Review.

In case of non-compliance, corrective measures apply

5. Conclusion and links to further information

- All ARVs, anti-TB and antimalarial medicines (“ATM medicines”) must comply with stringent quality requirements
- “Non-ATM” medicines need only be authorized in the country of use for the time being
 - A QA Policy for non-ATM medicines will be proposed to the Global Fund Board in May 2011
- Quality monitoring at country level for all FPPs funded with Global Fund resources should be strengthened
- Review of the current status of **quality assurance for diagnostic** products and recommendations presented at the Board’s final meeting in 2010

PRs must verify that products meet criteria,
even if purchased through a procurement agent
(local, international, UN, NGO...)

Further questions ...?

- How to select a pharmaceutical product?
- How to notify the Global Fund? When?
- If no labs are available in the recipient country, where can testing be done?
- Which products should be tested?
- What is risk-based selection of products for QC testing ?
- Do we test each and every batch?
- What are the cost implications of drug testing?

Answers to these questions, and to many others, are found in

- the [Guidance document on quality monitoring](#) and in
- the [Frequently Asked Questions](#)

posted on the Global Fund website



Application Process Explained

Apply Now

Funding Decisions

New Grant Architecture

Phase 2

Quality Assurance Information

Quality assurance refers to the management activities required to ensure that the medicines (and/or other health products) that reach patients are safe, effective and acceptable to the patient. These activities may include, but are not limited to, (pharmaceutical products) registration, pre-qualification and quality control.

We strongly encourage you to visit this site frequently and make sure to use the most recent considering the procurement options.

→ **Procurement and Supply Management**

Best Practices to Assure Quality

→ **Quality Assurance Information**

the Fund's existing policies for procurement practices, Principal Recipients' procurement practices and pharmaceutical products are procured in accordance with the principles and best practices outlined in the agency guidelines "A Model Quality Assurance System for Procurement of Pharmaceuticals".

→ **Quality Assurance of Pharmaceutical Products**

Procurement Support Services (VPP, CBS/SCMA)

Information for suppliers

Affordable Medicines Facility - malaria (AMFm)

Monitoring and Evaluation

Regional Meetings

Policies and Guidelines

Compliance with National Regulations

Pharmaceuticals and other health products procured with Global Fund resources must at all times comply with national regulations and, where applicable, be authorized by the national drug regulatory authority in the country in which they are used, following its standard practices for registration (or other forms of authorization, such as authorizations for special use).

Quality Assurance of Pharmaceutical Products

- [Quality Assurance Policy for Pharmaceutical Products](#)
- [Frequently Asked Questions](#)
- [Marketing authorization in country of use](#)
- [Criteria for ARVs, anti-TB products and antimalarials:](#)
 - [A, B and ERP-reviewed products](#)
 - [Global Fund lists of products \(ARVs, Anti-TB, Antimalarials\)](#)
 - [Interim exception](#) (Re-stated, valid until 31st December 2010)
Reminder: The interim exception ends on 31st December 2010.
Click here for further information: [English](#) – [Français](#) - [Español](#)
- [Before procuring ERP-reviewed products or those falling under the interim exception](#)
- [Pre-shipment QC testing and results](#)
- [Monitoring product quality](#)
New [Guidance on quality monitoring](#)
- [Contact us](#)