



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Revised Global Fund Quality Assurance Policy for Pharmaceutical Products and Price & Quality Reporting

**AIDS Medicines and Diagnostics Services (AMDS)
Partners and Stakeholders Meeting, Geneva, 2-3 April 2009**

Board Decision on QA policy for Pharmaceuticals

18h Board, November 2008 :

The Board **approved** the Quality Assurance Policy for Pharmaceutical Products (“QA Policy”)

The QA Policy shall **come into effect on 1 July 2009** and shall replace the Global Fund’s previous policy for the quality assurance of pharmaceutical products

Revision of the current GF Policy:

Analysis of the Global Fund’s QA Policy took into account:

- **alignment with partner’s QA policies,**
- **concerns** about the **safety, stability and efficacy** of products,
- market dynamics and,
- lessons learned from the implementation of the existing Policy

Key Changes to the QA policy

- Clinical criteria
- Quality criteria
- Selection process of FPPs
- Amendment of the definition of SRAs
- Independent expert review panel
- Monitoring product quality

Clinical criteria

Revised QA Policy

- Medicines listed in WHO or national or institutional Standard Treatment Guidelines (STGs)
- Require grant applicants or PRs to provide technical justification for selection of unlisted products in one of the STGs

Quality Criteria

Same Quality criteria for ARVs, anti-TB and antimalarials

1. Authorized for use by Drug Regulatory Authority (DRA) in recipient country
2. Selection of ARVs, anti-TB and antimalarials FPPs, either
 - WHO prequalified or SRA* authorized or
 - **Recommended for use by an Expert Review Panel (ERP)** for FPPs not yet WHO prequalified nor SRA authorized

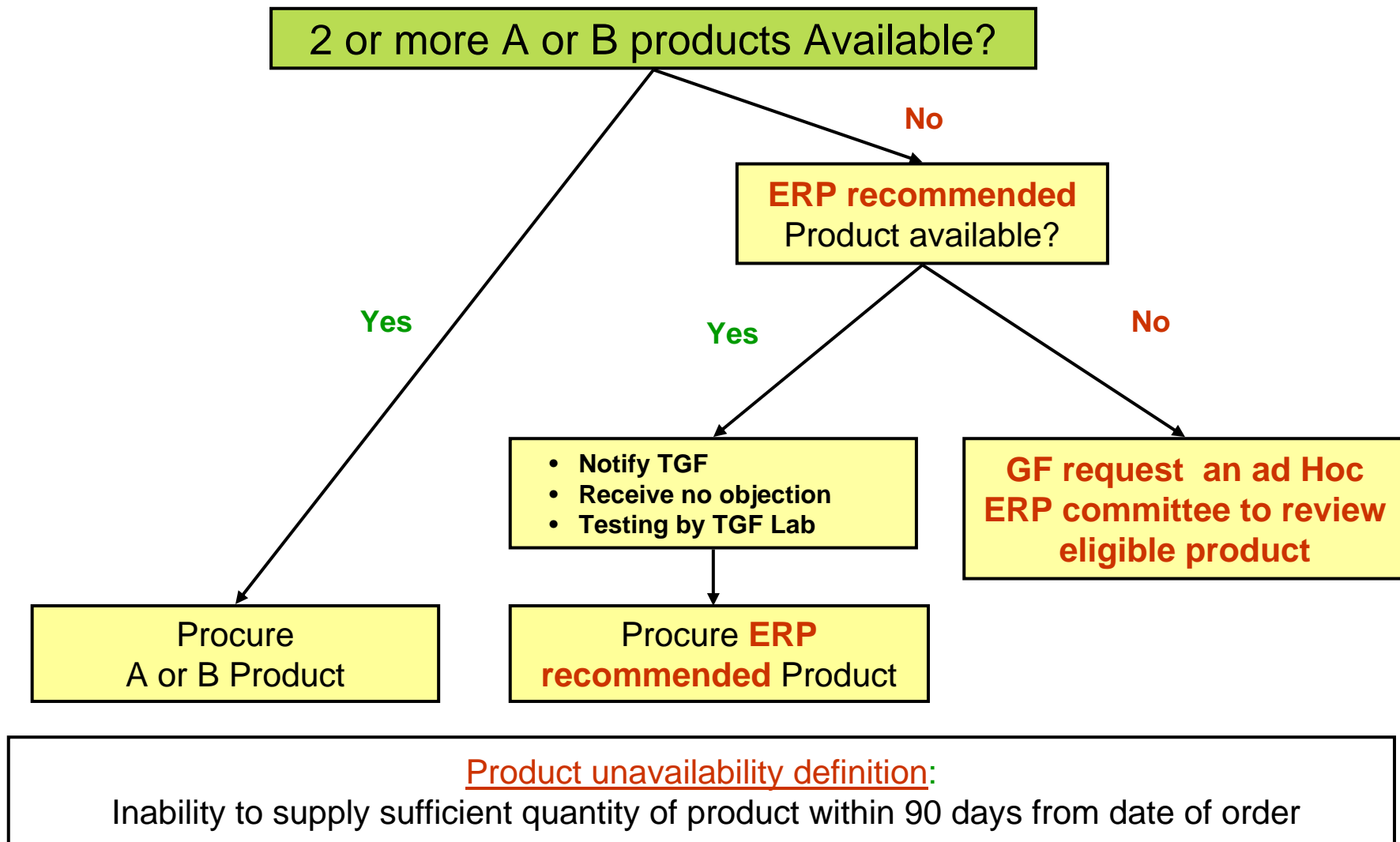
Amended definition of SRA:

- Only ICH members or Associated members are recognized as Stringent Regulatory Authority
- PIC/S members are no longer considered as SRA. However GMP certificate delivered by PIC/S are still acceptable for the GF

Selection of Finished Products: non A, non B

	Until 30 June 2009	From 1 July 2009
If <2 choices of A/B products:	Ci (WHO application+ GMP) Cii (GMP)	Products recommended by the Expert Review Panel (ERP) after review of clinical, safety & quality data
Eligible products:	Ci/Cii: <ul style="list-style-type: none"> •Applied for WHO prequalification (PQ) or to SRA •Manufacturing site GMP-compliant (WHO-PQ, SRA/ PIC/S) 	Eligible for ERP review if: <ul style="list-style-type: none"> • Application to WHO-PQ or an SRA was accepted AND • Manufacturing site GMP-compliant (WHO-PQ, SRA, PIC/S)
How to identify products	PRs must prove that products meet the above criteria and Global Fund list	Interim ERP recommendations (time-limited) are published on the Global Fund's website: Global Fund List

Selection of finished pharmaceutical products for ARVs, Anti-TB or Anti Malaria FPP



The Expert Review Panel

- An independent technical body
- Hosted by WHO Department of Essential Medicines and Pharmaceutical Policies
- Composed of external technical experts.
- Purposes:
 - To **review the potential risks/benefits** associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized.
 - To **make recommendations** to the Global Fund

Expert Review Panel (ERP) mechanism

- Review
 - at the request of the Global Fund, or
 - based on manufacturer's submissions in response to GF invitation for EoI to submit dossiers.
- A **product is eligible for review by the ERP** if:
 - Application to WHO-PQ or an SRA was accepted AND
 - Manufacturing site GMP-compliant (WHO-PQ, SRA, PIC/S)
- **Review of the potential risks/benefits** associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized
 - Manufacturers will be notified of the outcome of the ERP's review.
- ERP recommendations
 - **Time limited recommendations** (maximum 12 months)
 - Possibility of extending the recommendation period, under certain circumstances
- Contracts to supply products based on a recommendation by the ERP may be concluded any time during the validity of the recommendation

Invitation for Expression of Interest (EoI)

- Purpose : to **invite submissions** for ARVS, first-line anti-tuberculosis, Anti Malarial products which are not yet WHO-prequalified or SRA-authorized, for review by the ERP
- Main Goal: **to review in advance** products which could be purchased by PR when only few prequalified products or SRA authorized product are available on the market
- Published on our web site:
<http://www.theglobalfund.org/en/procurement/quality/?lang=en>
- **3rd April 2009**: deadline for submission to the GF of documents for ARVs products ERP review

Technical Areas of ERP review

Product questionnaire dossier :

- product registration information;
- **regulatory (licensing) status of the FPP and manufacturing facility (GMP);**
- finished product specifications and information regarding compliance with international pharmacopoeia standards, if available;
- **stability testing data** (both accelerated and real time studies) as per ICH and/or WHO Guidelines;
- product labelling information;
- **active pharmaceutical ingredient (API) characteristics and certification; and**
- **safety and efficacy data** for innovator products , human **bioequivalence** data for generic products.

Global Fund list of ARVs, Anti-Malaria , Anti-TB

Objective

A **procurement tool** providing PRs with information that will assist them in their procurement options

The GF list is an overview of **classified products and manufacturers** based on their compliance with the requirements of the various options (**A, B, ERP recommended products**) according to the Global Fund Quality Assurance Policy

<http://www.theglobalfund.org/en/about/procurement/quality/>

Procurement of All Other FPPs

- All FPPs, other than antiretrovirals, anti-tuberculosis and anti-malarial FPPs, need only to **comply with** the relevant quality standards that are established by the **National Drug Regulatory Authority (NDRA) in the country of use**
- 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)

Quality Control Requirements and Responsibilities

- All pharmaceutical products purchased with Global Fund resources are subject to the monitoring of product quality standards
- **PR responsibilities**
 - To assure systematic random quality control testing
 - To monitor the quality of all products all along the supply chain
 - PR to report testing results to Global Fund
- **GF Secretariat responsibilities**
 - To monitor the quality of products classified as Ci or Cii / **ERP recommended product** before shipment

Conclusion: Uniform stringent standards

- All (single- and multi-source) antiretrovirals, first-line anti-TB medicines and antimalarials must comply with stringent quality requirements
- Second-line TB medicines will continue to be procured through the Green Light Committee
- “Other” medicines (single- and multi-source) need only be authorized in the country of use for the time being

1st July 2009: the revised QA Policy becomes effective

- Ci or Cii products classification is no longer applicable.
- Only A, B or ERP recommended products be purchased
- QA applicable to all ARVs, Anti TB and Anti Malarial products

Revised QA policy-

<http://www.theglobalfund.org/en/procurement/quality/?lang=en>

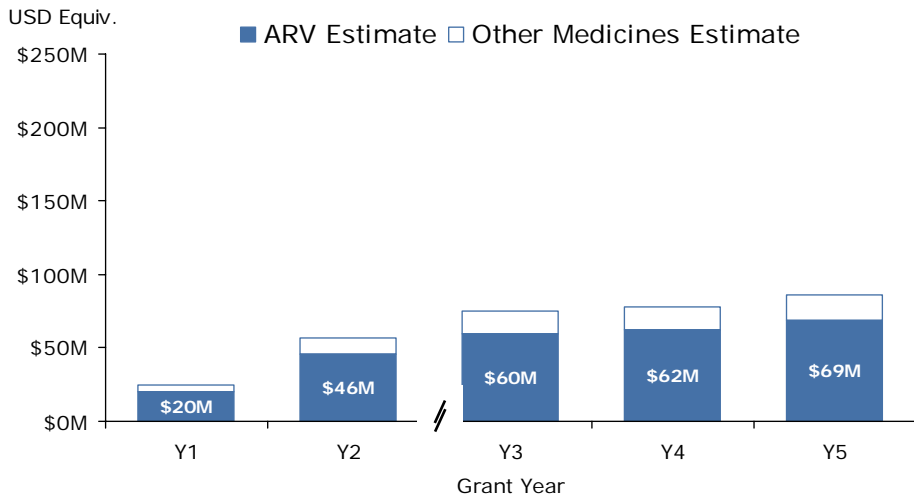
Perspectives for 2009

- **Implementation of the revised QA policy by 1st July 2009**
 - Arrange for the establishment of the ‘Expert Review Panel’
 - Organize the ERP review for a list of recommended products
 - **15 June 2009: GF list of Anti TB, Anti Malarial, ARVs published, including prequalified products, SRA authorized products, ERP recommended products**
 - Develop the procedures and guidance for monitoring quality
 - Develop the reporting tool for quality control testing
 - Prepare guidance and communicate with PRs to implement and adhere to the revised QA policy
- **QA policy for non ARVs, non Anti TB, non anti Malarial FPP:** proposition of study to explore QA criteria for these products
- Review of the current status of **quality assurance for diagnostic** products and make recommendations at the Board’s final meeting in 2009.

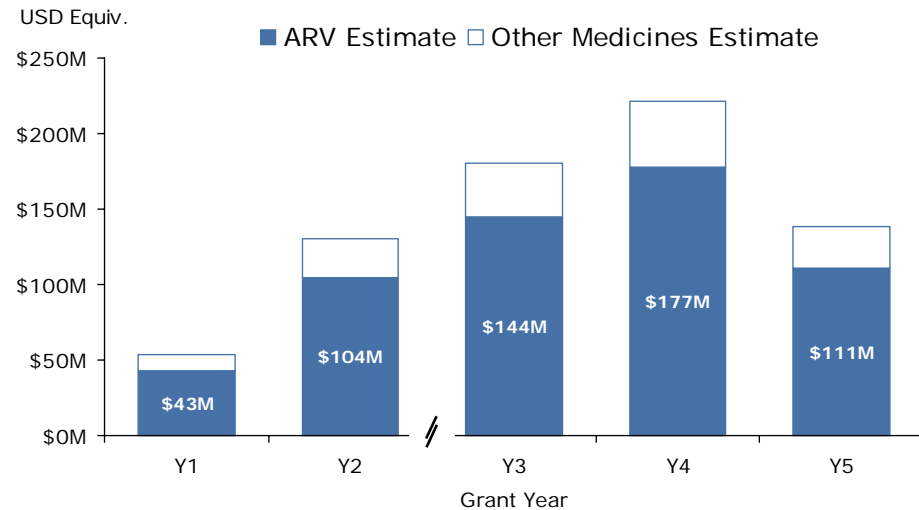
ARV procurement planned in R7 and R8 approved proposals

ESTIMATE

Estimated ARVs in Round 7 Approved Proposals



Estimated ARVs in Round 8 Approved Proposals



Source: Proposal budgets for TRP recommended applications with assumption on portion of medicines category to ARV's based on sampling of detailed budgets and proposed procurement.

Round 8's \$116M average annual ARV spend over five year grant lifetime is more than double the \$51M average proposed in Round 7

QA Compliance

- It is **mandatory** for PRs to **notify** the GF Secretariat before procuring **ERP recommended products**
- It is a requirement that purchases are reported in the **Price Quality Reporting (PQR)**:
 - **ARVs**, TB medicines, ACTs, Bed nets, Condoms, Rapid diagnostics.
- The GF Secretariat assess policy compliance on the PQR data,
 - monthly report to Country Programs for follow up (notify FPM of potential non compliance),
 - compliance analysis for phase 2 grants review.

In case of non compliance, corrective measures applicable



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PQR

PRICE &
QUALITY
REPORTING

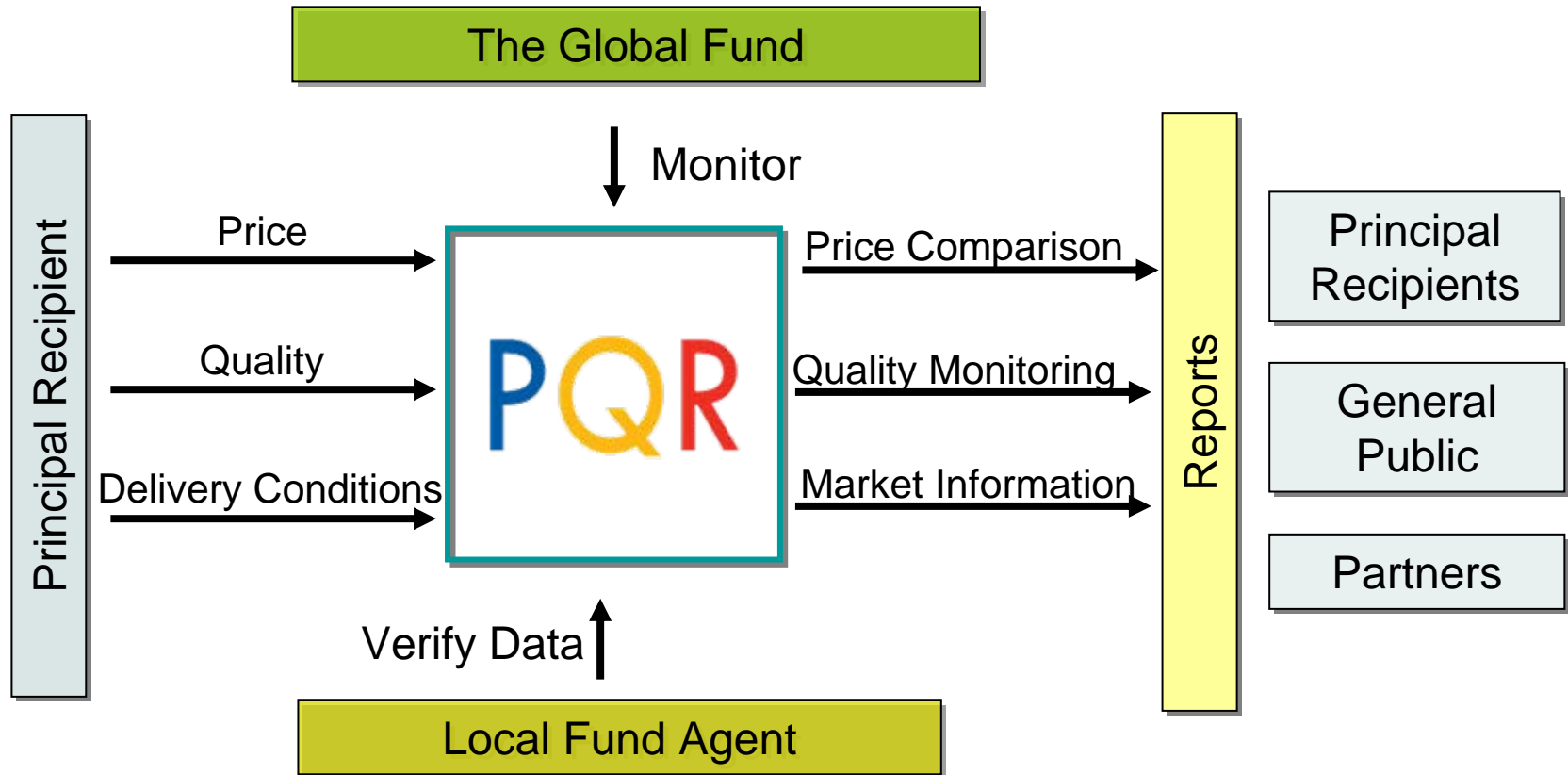
(Formerly known as PRM)

Price & Quality Reporting

Objectives

- Track procurement **price and quality** information on key health products procured with Global Fund funds:
 - Inform implementers on market conditions
 - Monitoring Pricing and supplier / vendor performance
 - Monitoring QA Policy compliance
- Analyze procurement information for various policy and decision-making purposes
- Make publicly available price and quality information
 - Inform procurement decisions by countries
 - Basis for stakeholders to develop long-term demand forecasts

How PQR Works?



Progress update

- PQR Launched in first week February 2009
- 150 users (PR & LFA) from 71 countries registered
- More features and reports are being developed:
 - Price analysis report
 - Price trend
 - Purchase price report
 - PQR usage & data audit status
 - QA Compliance regional comparison
- Help?
 - Contact us at pqr@theglobalfund.org
- No online connectivity/Offline?
 - Off-line templates are available in MS Excel

WEBSITE information

<http://www.theglobalfund.org/en/procurement/>

Procurement and Supply Management - Applicants and Implementers - The Global Fund to fight AIDS - Windows Internet Explorer pro

http://www.theglobalfund.org/en/procurement/

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Applicants and Implementers

- Applying for Grants
- Procurement and Supply Management**
 - Guide to Writing Procurement and Supply Management (PSM) Plans
 - Quality Assurance Information
 - Price & Quality Reporting (PQR)
 - Voluntary Pooled Procurement and Capacity Building
 - Information to Suppliers
- Monitoring and Evaluation
- Regional Meetings
- Policies and Guidelines

Procurement and Supply Management

An estimated 47% of Global Fund grants has been used on procurement. The Global Fund's role in procurement and supply management is **primarily focused on policy approach and assistance to countries with policy requirements** when procuring products with Global Fund resources for the prevention, the treatment and care of HIV/AIDS, Tuberculosis and Malaria. The Global Fund is not engaged in direct procurement activities, which are managed and conducted under the full responsibility of grant recipients. The Global Fund is establishing voluntary pooled procurement and capacity building services for Principal Recipients beginning in January 2009.

This section provides information, guides and template forms related to **procurement and supply management of health products**, including medicines and related health products and equipment, conducted with Global Fund resources. In addition, background information and updates are available on the Voluntary Pooled Procurement and Capacity Building Services / Supply Chain Management Assistance programs.

For general enquiries or comment about information on the procurement and supply management Web pages, you may contact the Procurement team at: procurement@theglobalfund.org, or call us at: +41-22-791-1700

List of FAQs

- FAQs related to policy on QA of single and limited source pharmaceutical products
[English](#) [Français](#) [Español](#)
- FAQs about Quality - Control Testing of Pharmaceutical Products
[English](#) [Français](#) [Español](#)

Guide to the Global Fund's Policies on Procurement and Supply Management

English PDF - 151 KB
Français PDF - 179 KB
Español PDF - 411 KB
Русский PDF - 169 KB

View [Procurement and Supply Management Plan Template](#)

[Voluntary Pooled Procurement and Capacity Building Services](#)
Background, project updates, and contact information

The Global Fund's **Quality Assurance policy** related to procurement of Pharmaceutical Products
[WHO's Prequalification Programme](#)

[Lists of ARVs, TB and Malaria products classified according to Global Fund Quality](#)

Thank you