



Joint WHO & UNAIDS Consultation Meeting with Pharmaceutical Companies

Pharmaceutical Management Unit
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WHO & UNAIDS Consultation,
December, 2010



Presentation Outline

Introduction to Global Fund

Global Fund Quality Assurance Policy

- PSM Policy Principles
- Quality criteria and selection process
- Expert Review Panel (ERP)
- List of ARV, TB and Malaria Products
- Harmonization
- Challenges

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Introduction-The Global Fund



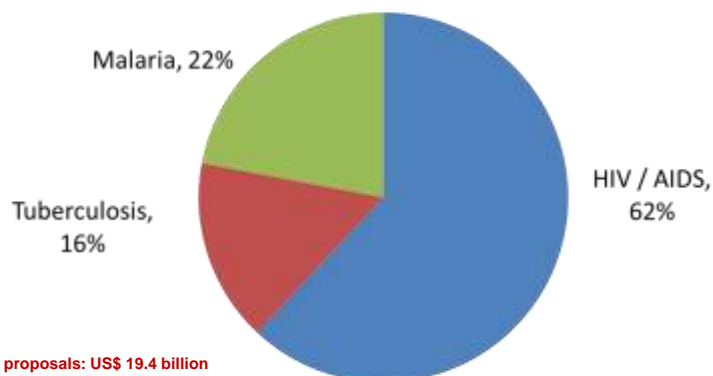
- Financing mechanism but not an implementing or Technical agency;
- **Performance based Funding and Country Ownership;**
- Partnership between governments, civil society, the private sector and affected communities;
- **37% percent funds are used for medicine and health product procurement;**
- Global Fund does not conduct any procurement activities;

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Approved Proposals- by Disease

Expenditure by Disease component



Total approved proposals: US\$ 19.4 billion

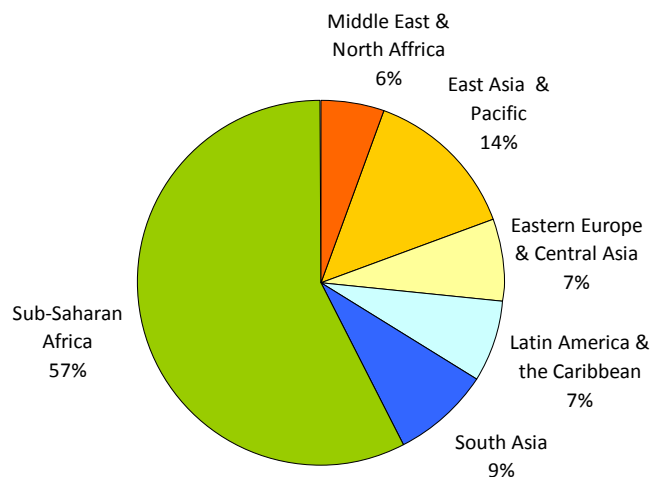
Total disbursed: US\$ 10 billion

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OP140709/2

Approved Proposal- by Regions (Rd 9)



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Rapid Scaling Up of Results

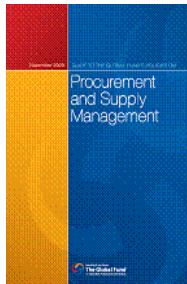
Global Fund Top 3 result indicators (2010)	mid 2007	mid 2008	July 2009	July 2010
HIV: People on ARV treatment	1.1 million	1.75 m	2.3 m	2.8m
TB: People treated under DOTS	2.8 million	3,9 m	5.4 m	7m
Malaria: Insecticide-treated nets distributed	30 million	59 m	88 m	122m

Funding of 825 grants in 145 countries

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The Global Fund PSM Policy Principles



- Quality-assured products;
- Lowest possible price;
- **Transparent, fair and competitive procurement;**
- National laws and international agreements;
- Build on existing systems;

Recipients are responsible for health products management

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QA Policy for Pharmaceutical Products

Clinical Criteria	Quality Criteria	Monitoring Quality
<ul style="list-style-type: none"> • Medicines listed in WHO or National or Institutional Standard Treatment Guidelines; 	<p>For all products: Authorization for use in the recipient countries;</p> <p>For ARVs, anti-TB and anti-malarial products: - WHO Prequalified or authorized by a Stringent Regulatory Authority; Or -Recommended for use by an Expert Review Panel, only if <2 WHO PQed or SRA authorized products available;</p>	<ul style="list-style-type: none"> • Monitoring quality of products all along the supply chain; • Systematic random quality control testing; • Recipients report testing results to the Global Fund;

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Expert Review Panel (ERP)

- A panel of experts (hosted by the WHO);
- **Assesses the potential risks/benefits associated** with the use of FPPs that are not yet WHO-prequalified or SRA-authorized;
- **Eligibility criteria for dossier submission:** product manufactured in GMP site and dossier already submitted to and accepted for review by WHO PQ program or a SRA;
- Assesses abbreviated product dossiers submitted by manufacturers (**questionnaire + annexes**);
- **Makes time limited recommendations:** validity maximum 12 months-contracts can be signed any time up to one year;

ERP status does not replace WHO PQ/SRA approval but should be seen as a step towards WHO PQ/SRA approval;

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Products reviewed by the ERP since 2009

- **3 round** of ERP reviews of product dossiers based on the EOI were already completed;
- **4th round** ERP review is currently being finalized;
- **100 product** dossiers were submitted and reviewed by ERP;
- **51 products** were permitted for use for a one year period;

ERP reviewed product	Total	ARV
Permitted for use by ERP	51	28
– pre qualified by WHO	18	11
– approved by SRA (USFDA)	7	7

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Procurement of ERP Products

All ERP products are subject to Notification Request, even if these are procured through procurement agency;

1. PR has to notify the GF Secretariat;
2. No Objection/Objection letter issued by GF;
3. QC testing initiated by GF –SGS/NIDQC lab;
4. QC result and shipment - GF issue final letter with QC result for shipment of the product;
5. Publication of QC Results on the web page;

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List of ARV, TB and Malaria

- An overview of products and manufacturers classified according to the Global Fund QA Policy criteria;
- Tools to assist countries:
 - to identify GF QA Complaint products;
 - In making decision for procurement selection;
- Not an exhaustive list-based on the information available to the Secretariat and submitted by manufacturers;

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Documentations- List of ARV products

- **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;
- Published regularly, **usually at the end of the each month** on the Global Fund webpage;

Manufacturers needs to proactively provide the SRA approval information to the GF Secretariat;

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QA Harmonization with Partners

- **Global Drug Facility (GDF):**
 - The quality and selection criteria of the GF and GDF QA policies are now fully aligned;
 - Same ERP process (joint EOI) and also harmonization of pre-shipment QC process;
- **UNITAID:**
 - working on toward the same ERP process- joint EOI, product dossier submission, and ERP validity;
- **WHO PQ Programme:** Continued close collaboration;

**One Common Process!
One Standard!
One Outcome!**

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Importance for Manufacturers

- To Submit product dossier to either WHO PQ or SRA and produce products in GMP (WHO/ICH/PICH) compliant site;
- **Quality submission and respond to query for quicker approval time from WHO or SRA;**
- **All product variations must be submitted to WHO PQP / SRA for review and can not be implemented until fully accepted;**
- No variations accepted for review by ERP. Full dossier is needed;
- Review regularly the EOI for products eligible for ERP Review;
- Register products in resource limited countries;
- **Inform the Global Fund right the way to include in the product in the List of ARV, TB and Malaria;**

To send all the information requested by the SGS/NIDQC in due time -documentation, SOPs, list of lots to be shipped to the specific country;

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Challenges ...and Update

Challenges:

- Increasing demand of Quality Control Laboratories compliant with Global Fund requirements;
- **Lack of sources for some product formulations (such as heat stable formulations for Lop/r, Ata/r; or pediatrics, etc.);**
- Strengthening the capacity of National Drug Regulatory Authority;

Update:

- New Diagnostic QA Policy for Board approval in Dec. 2010;
- Amendment of the QA policy for the non ATM to be proposed to the Global Fund Board by end 2011;

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Application Process Explained

Apply Now

Funding Decisions

New Grant Architecture

Phase 2

Procurement and Supply Management

Guide to Writing IFM Plans

Quality Assurance Information

Quality Assurance of Pharmaceutical Products

Price & Quality Reporting (PQR)

Procurement Support Services (PSP, CSO/SCSA)

Information for suppliers

Affordable Medicine Facility - malaria (AMFM)

Monitoring and Evaluation

Regional Meetings

Policies and Guidelines

Quality Assurance of Pharmaceutical Products

- [Quality Assurance Policy for Pharmaceutical Products](#)
- [Marketing authorization in countries of use](#)
- [Criteria for AIDS, anti-TB products and antimalarials](#)
 - [A, B and ESC-registered products](#)
 - [Global Fund lists of products \(AIDS, Anti-TB, Antimalarials\)](#)
 - [Interim suspension](#) (Re-stated, valid until 31st December 2010)
- [Before assessing FFP-reviewed products or those falling under the interim suspension](#)
- [Pre-shipment QC testing and results](#)
- [Monitoring product quality](#)
- [Contact us](#)

QA Policy requirement	Links
For any pharmaceutical products to be eligible for purchase with the Global Fund resources, its compliance with quality standards must be assured. (Back to top)	<ul style="list-style-type: none"> • 18th Global Fund Board Decision Point, November 2008: Quality Assurance Policy for Pharmaceuticals (English) • QA Policy for Pharmaceutical Products (as amended on 10th November 2009) ("QA policy") (English English Español Français العربية PDF - 90 KB)
All finished pharmaceutical products (FFPs), must comply with the relevant quality standards established by the National Drug	<ul style="list-style-type: none"> • See QA Policy, Sections 19 – 21

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THANK YOU!

