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
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;

Approved Proposals- by Disease

Total approved proposals: US$ 19.4 billion
Total disbursed: US$ 10 billion
Approved Proposal- by Regions (Rd 9)

Rapid Scaling Up of Results

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV: People on ARV treatment</td>
<td>1.1 million</td>
<td>1.75 m</td>
<td>2.3 m</td>
<td>2.8m</td>
</tr>
<tr>
<td>TB: People treated under DOTS</td>
<td>2.8 million</td>
<td>3,9 m</td>
<td>5.4 m</td>
<td>7m</td>
</tr>
<tr>
<td>Malaria: Insecticide-treated nets distributed</td>
<td>30 million</td>
<td>59 m</td>
<td>88 m</td>
<td>122m</td>
</tr>
</tbody>
</table>

Funding of 825 grants in 145 countries
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

QA Policy for Pharmaceutical Products

Clinical Criteria

- Medicines listed in WHO or National or Institutional Standard Treatment Guidelines;

Quality Criteria

For all products: Authorization for use in the recipient countries;

For ARVs, anti-TB and anti-malarial products:
- WHO Prequalified or authorized by a Stringent Regulatory Authority;
- Recommended for use by an Expert Review Panel, only if ≤2 WHO PQed or SRA authorized products available;

Monitoring Quality

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

---

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;

<table>
<thead>
<tr>
<th>ERP reviewed product</th>
<th>Total</th>
<th>ARV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permitted for use by ERP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>– pre qualified by WHO</td>
<td>51</td>
<td>28</td>
</tr>
<tr>
<td>– approved by SRA (USFDA)</td>
<td>18</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>
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;

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;
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 each month on the Global Fund webpage;

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

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!
Importance for Manufacturers

• To Submit product dossier to either WHO PQ or SRA and produce products in GMP (WHO/ICH/PICH) complaint 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;

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;
THANK YOU!