Pharmaceuticals Procurement
Global Fund’s requirements and past funding

JOINT UNICEF PHARMACEUTICAL SUPPLIER MEETING &
WHO PREQUALIFICATION OF MEDICINES PROGRAMME
3rd MEETING WITH MANUFACTURERS OF FINISHED PHARMACEUTICAL PRODUCTS AND
ACTIVE PHARMACEUTICAL INGREDIENTS
24–26 September 2012

Dr Joelle DAVIAUD,
Quality Assurance Specialist
What The Global Fund achieved?

3.6 million
People receiving antiretroviral treatment

9.3 million
New cases of infectious tuberculosis detected and treated

260 million (cumulative data for the last 3 years)
Malaria drug treatments,

270 million
Insecticide-treated nets were distributed to protect families from transmission
Global Fund’s procurement principles

- Procure **quality assured products**
- Conduct procurement processes in a **transparent and competitive** manner
- In the most adequate form to **support adherence** (Fixed dose combinations, children forms)
- At the **lowest possible price**
- Adhere to **National and International Laws**

On average, 37% percent of funds are used for medicines and health products procurement
Global Fund-financed medicines procurement reported in PQR: Purchase orders 2010-2012 to date (in million US$)

Total product value reported: 905 million US$

Source: PQR data as at 10 September 2012
Quality Assurance for Health Products

To ensure safe, effective health products and acceptable to end users.

Good Procurement Practices
Principal Recipients must procure all products in accordance with principles set out in the interagency guidelines

“A Model Quality Assurance System for Procurement Agencies”.

1- Prequalification of products and manufacturers
2- Purchase
3- Storage
4- Distribution
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 antimalarial products
     - WHO-prequalified (PQ) or authorized by a Stringent Regulatory Authority (SRA);
     - Found eligible for use by the Expert Review Panel, (only if <2 WHO PQ or SRA authorized products available)

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

GMP assessment and dossier review
Expert Review Panel (ERP)

- A panel of experts (hosted by WHO Quality & Safety of Medicines)
- 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
  - adapted to include needed products which are not on the expression of interest list for WHO-prequalification
- Assesses abbreviated product dossiers submitted by manufacturers (questionnaire + annexes)
- Makes time limited recommendations: validity maximum 12 months
- Global Fund decides based on the advice of ERP
ERP Review Process

EOI publication: January & July

Mfg dossiers submission: March & Sept (2 months)

Conclusions sent to Mfg: June & December 2 weeks after ERP report receipt

Invitation by GF Eoi or ad-hoc request

Submission by manufacturers

GF: Eligibility screening

ERP: Confirm eligibility

ERP: Review submissions Prepare reports incl risk categories

ERP coordinator: Organize a session

Pool of experts

ERP coordinator: Prepare final communication

GMP status (confirmation by PQP inspectors)

Report to GF

GF to review the report and send conclusions to the manufacturers, update the GF list

ERP evaluation within 6-8 weeks
ERP report: May and November

Mfg dossiers submission: March & Sept (2 months)

Conclusions sent to Mfg: June & December 2 weeks after ERP report receipt

EOI publication: January & July
Categorization of products reviewed by ERP

Classification of products reviewed in four categories:

- Products classified in **Categories 1 and 2** may be considered for time-limited procurement.
- Products classified in **Category 3** may be considered for procurement only if there is no other option and the risk of not treating the disease is higher than the risk of using the product.
- Products classified in **Category 4** may not be considered for procurement under any circumstances.

Only products categorized in categories 1 and 2 are listed in the Global Fund list published on the GF website.
Seven rounds conducted so far

<table>
<thead>
<tr>
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<th>Dossiers reviewed</th>
<th>Successful</th>
</tr>
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<tbody>
<tr>
<td>ARVs</td>
<td>58</td>
<td>29 (50%)</td>
</tr>
<tr>
<td>Anti-TB products:</td>
<td>291</td>
<td>96 (33%)</td>
</tr>
<tr>
<td>Antimalarials:</td>
<td>68</td>
<td>22 (32%)</td>
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</table>

Common reasons for rejection of dossiers by ERP

- API manufacturer not compliant
- Efficacy data not submitted (anti-TB products)
- Unsatisfactory efficiency data: several major deficiencies (especially anti-TB products)
- Unsatisfactory specification, e.g. limits for impurities (especially ARV)
- Unacceptable comparator product
- Unsatisfactory stability results, e.g. out-of-limit results
- Insufficient stability data, e.g. from one batch only (especially ARVs)

ERP has become a trusted mechanism, with increasing requests for procurement of ERP reviewed anti-TB medicines and anti-malarials
Ensuring availability of needed products

ERP Review

• **does not replace** the full dossier assessment through WHO PQ program or SRA, it is complimentary to PQ when products is yet not prequalified
  - PQ - result product meeting international standards as assessed through inspections and dossier assessment
  - ERP- result comparative quality risk categorization of products of which none may yet meet PQ standards. It gives information about comparative potential quality risks of products assessed

• **interim option**, giving manufacturers not yet prequalified an opportunity for “business”.

• it can serve as a stand-alone **quality risk assessment for products not covered by PQP**

• **ERP provides advice to help procurement decisions but is independent of procurement**
Harmonization of quality standards save cost and time for manufacturers and buyers

Alignment of GDF and UNITAID QA policies with GF QA
- Uniform stringent standards
- easy reference for countries/users
- Unique message for manufacturers
  - Common Expression of interest for ERP review
  - Common Expert Review Panel (ERP) assessment
  - Common pre-shipment Quality Control testing
Procurement of non ATM products

• Selection done according to MQAS principle

• According the national and international laws

• Recommended to select non ATM products
  • prequalified by WHO when exist
  • manufactured in GMP compliant site when available on the market
## Overview of Quality Control Activities

<table>
<thead>
<tr>
<th>QC</th>
<th>All FPPs: Post-Shipment</th>
<th>ERP-reviewed FPPs Pre-Shipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsibility</td>
<td>PR or Sub-Recipient</td>
<td>Global Fund Secretariat,</td>
</tr>
<tr>
<td>When</td>
<td>After receipt in country, all along the supply chain</td>
<td>Before shipment to country, for ERP products notified and ACTS (AMFm program)</td>
</tr>
<tr>
<td>Frequency</td>
<td>Randomly according to testing plan defined by the country (risk based approach)</td>
<td>Mandatory for all Purchase Orders (PO)</td>
</tr>
<tr>
<td>Laboratory</td>
<td>WHO PQ lab ISO 17025 lab</td>
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</tr>
<tr>
<td>Methods</td>
<td>Int.Ph, US or British Ph, when possible. <strong>Manufacturers methods when no compendia methods</strong></td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Published on the Global Fund website with the CoA received from the laboratory (ies)</td>
<td></td>
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Procurement since January 2010 classified as per Global Fund QA Policy

ARVs: US$ 678 million

A: WHO-prequalified (including “A and B”)
B: SRA-authorized*

First-line TB incl. streptomycin: US$ 53 million

Second-line TB: USD 69 million

Antimalarials: US$ 106m

Source: PQR data as at 10 Sep 2012
Procurement since January 2010 classified per patent status

ARVs: US$ 678 million

First-line TB incl. streptomycin: US$ 53 million

Second-line TB: USD 69 million

Antimalarials: US$ 106m

Source: PQR data as at 10 Sep 2012
Conclusions

- Grant recipients have purchased increasing amounts of stringently quality-assured products with grant resources, mainly generic products.
- Time-limited use of ERP-reviewed products is still needed in TB and malaria.
- Harmonization of QA policies/ERP processes with GDF and UNITAID
  - increase access of assured QA medicines
  - Market shaping impact

Remaining challenges

- Not enough quality assured finished products available for certain pediatric formulations, second-line anti-TB products and fixed-dose combinations.
- Changes in API sources are a challenge for consistent product quality.
- Lack of qualified API sources causes price increases (artemisinin-based products, anti-TB products).
- Need to extend harmonization of QA criteria among the main donors and partners.
Recommendations to manufacturers

To ensure availability of adequate (medicine/formulation) products to patients:

- Submit dossier to WHO Prequalification program and /or SRA
- Submit dossier for ERP review for the medicines/formulations for which not enough products are currently on the market (refer to EoI published by WHO PQ and GF/GDF, GF/UNITAID)
- Respond as soon as possible to WHO PQ questions as ERP is temporary solution

To ensure efficient ERP process and increase number of products on the market:

- Ensure that all required details are provided, in full, in the submission.
- The recommendations of the ERP after review of the dossier, shall be compiled with, in full, during the next submission.
- Where additional data are requested, the same shall be provided, in full, to avoid unnecessary back and forth communications.

To ensure appropriate Quality control testing/quality monitoring:

- Provide all necessary information to PRs to conduct quality control testing.
How Manufacturers can access to the information on Global Fund Pharmaceuticals Procurement?

Past procurement: Price Quality Reporting (PQR)
Forecast for 2013/2014: available Q4 2012
Price Quality Reporting: PQR

“Disclosure of information on prices paid for purchases by Fund Recipients is a matter of principle and will facilitate a process leading to lower prices”

October 2002, 3rd Board Meeting

Recipients must report to the on-line Reporting system the information concerning quality and price for all transactions for:

ARVs, Anti Malatials, Anti TBs, Condoms, Nets and RDTs

- Share
  - Communicate market information to Principal Recipients

- Monitor
  - Improve transparency
  - Benchmark prices and monitor QA compliance

- Analyze
  - Influence policy and decision-making
REPORTING PRICES AND QUALITY

The Price and Quality Reporting (PQR) Tool is a web-based system used by the Global Fund to collect transaction level procurement information from Principal Recipients on key health products. The system’s goals are to:

- Communicate market information to Principal Recipients;
- Improve transparency;
- Enable the Global Fund to monitor adherence to its Quality Assurance Policy;
- Help the Global Fund and its partners better understand and influence the market for pharmaceutical products.
Partnerships in Quality Assurance

- Collaboration with WHO
  - prequalification for pharmaceuticals, diagnostics, and pesticides
  - disease programs
- Collaboration/information sharing with other donors and agencies involved in supply
  - USAID, UNITAID, UNICEF, UNDP, MSF, ICRC...
- Policy harmonization with partners
  - GDF, UNITAID
- Regular communication with manufacturers
  - meetings
Quality Assurance for Health Products

QUALITY ASSURANCE INFORMATION

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

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

Procurement Practices to Assure Quality

In addition to the Global Fund’s existing policies for procurement practices, Principal Recipients ensure all pharmaceutical products are procured in accordance with the principles set out in the interagency...
Information to Suppliers

Revised Quality Assurance Policy for Pharmaceutical Products

Effective Date: July 1, 2009

- Annex 1 - full text of the revised QA Policy
- Information Letter for Manufacturer on revised QA Policy
  1. Invitation for manufacturers of selected medicines to submit an Expression of Interest (EoI) to have Finished Pharmaceutical Products reviewed by the Expert Review Panel (ERP);
     1st Invitation for Malaria pdf - 54 KB
     1st Invitation for Tuberculosis pdf - 56 KB
     1st Invitation for HIV/AIDS pdf - 56 KB
     Technical questionnaire for FPP doc - 442 KB;
  2. guidelines on the ERP process.
     The Global Fund Secretariat will soon publish guidelines on the ERP process.

Voluntary Pooled Procurement and Capacity Building services

- Introductory Letter to Manufacturers
- A meeting was held with LLIN manufacturers on 15 January 2009 in Geneva.
- An introductory note has been distributed to ARV and ACT manufacturers.
- A meeting will be held with ARV and ACT manufacturers on 5 February 2009 in Geneva.
THANK YOU