Quality Assurance and Procurement Updates

Joint UNICEF, UNFPA and WHO meeting with manufacturers and suppliers

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The Global Fund

A 21st-century partnership organization to accelerate the end of HIV, tuberculosis and malaria as epidemics

Founded in 2002, the Global Fund is the leading contributor of resources in the fight against AIDS, tuberculosis and malaria. It mobilizes and invests nearly US$4 billion a year to support countries and communities most in need. It has an active portfolio of over 430 active grants in over 100 countries, implemented by local experts.
Quality assurance is ensuring that the health products that are purchased (everything from medication to microscopes) and used by Global Fund-supported programs are safe, effective, of good quality and available to the patient.

Key stakeholders in quality assurance include:
- Manufacturers
- National regulatory authorities
- Quality control laboratories and pharmacovigilance centers
- National procurement systems
- International agencies
- Technical partners
- Health care providers
Content Overview

1. TGF QA Policy for Pharmaceuticals
2. TGF QA Policy for Diagnostics
3. Procurement Update
Global Fund Quality Assurance Policy for Pharmaceutical Products ("QA Policy"):

Implementers of programs for AIDS, TB, HepB & C or Malaria who want to use Global Fund grants to purchase medicines must ensure that those pharmaceutical products meet the Global Fund’s quality standards as set out in the Quality Assurance Policy for Pharmaceutical Products.

1. Clinical criteria
2. Quality criteria and selection process
3. ERP Process
4. Global Fund’s list of pharmaceutical products
5. Monitoring product quality

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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

*PR: Principal Recipient*
2. Quality Criteria and Selection Process

• All medicines must be
  - Authorized for use by drug regulatory authority in recipient country

• In addition, ARVs, anti-TB, medicines to treat Hepatitis B and C and antimalarial 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)
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
- ERP provides **time limited** recommendations to The Global Fund
- GF decision **valid for a period of maximum 12 months**
3. ERP Process For Pharmaceutical Products

Invitation to Antiretroviral (HIV/AIDS), Antihepatitis B and C, Antituberculosis and Antimalarial Medicines Manufacturers to Submit an Expression of Interest for Product Evaluation by the Global Fund Expert Review Panel for Pharmaceutical Products

- List of priority medicine
- 2 ERP Cycles per calendar year
- The overall timeline of cycle is 22 weeks
- No additional data management within an ERP cycle
Timeline of the ERP process for Pharmaceutical Products

I. Design of the EoI
   • 4 weeks

II. Publication & Communication of the EoI
   • 8 weeks

III. Management of Submissions
   • 2 weeks

IV. ERP Review
   • 6 weeks

V. Management of Reports & Decision
   • 2 weeks

KEY DELIVERABLES

• Finalized list of Pharmaceutical products to include in the EoI
• EoI published on TGF website
• Manufacturer are invited to submit a Product Questionnaire
• Manufacturer are informed about the screening outcome of the Product Questionnaire
• ERP Review
• TGF receives the ERP Reports
• Inform Manufacturer about the outcome of the ERP Review
• Update TGF List of Pharmaceutical products

Timeline of the Ad-Hoc ERP process for pharmaceuticals products

I. Design of the EoI
- 2 weeks

II. Publication & Communication of the EoI
- 4 weeks

III. Management of Submissions
- 1 week

IV. ERP Review
- 4 weeks

V. Management of Reports & Decision
- 1 week

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Criteria of the Ad-Hoc ERP process for pharmaceuticals products

- The need for an Ad-Hoc ERP review process is justified by supply security risks that could lead to treatment interruptions or the inability to introduce and/or scale up treatment, or to respond to an emerging new treatment guidelines.

Supply security risks could be caused by a number of factors, including, but not limited to:

- Existing supplier(s) dedicate insufficient production capacity to meet demand;
- Supplier exit or risk of supplier exit from the market;
- Injunction(s)/suspension(s) by regulatory agencies or removal from procurement eligibility list(s) due to quality assurance variations;
- Sudden increase in demand; or
- Price barriers for existing product(s)
ERP – eligibility criteria for Priority Medicine

• Criteria 1 products (medicines invited to PQ)
  - Manufactured at GMP compliant facility
  - Submitted and accepted for assessment (PQ/SRA)
    Exceptions in problem areas:
    - Acceptable level of GMP compliance based on GMP risk assessment
    - Commitment to submit dossier to PQ/SRA

- Criteria 2 products (medicines not invited to PQ)
  (certain TB, Malaria and NTD medicines, amoxicillin)
  - Manufactured at a GMP compliant facility.
  - Submission to PQ/SRA not required.
Criteria for categorization of products and formulating ERP advise

The reviewed products will be classified into 4 categories:

• **Categories 1 and 2** can be considered, in principle, for time limited (12 months) procurement.

• **Category 3** can be considered only if there is no other option and the risks of not treating the disease is higher than the risk of using medicines not meeting all quality standards.

• **Category 4** cannot be considered under any circumstances

The following major product attributes will be used as a basis for comparing the products:

- GMP status of the manufacturing site - one of the eligibility criteria
- FPP manufacturing process and FPP specification
- Stability data
- Evidence of therapeutic equivalence
- API source and API quality
4. 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

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 each month
Published on the Global Fund webpage:
5. Monitoring product quality according to the QA Policy:

The quality of FPPs procured with Global Fund grant funds must be monitored. → Laboratory: WHO PQ lab ISO 17025 lab

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)

✓ Pre-Shipment QC Testing before Procuring ERP approved Products

✓ GDF is responsible for the QC testing activities for TB medicine procured through their services for the Global Fund
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Revised Global Fund Quality Assurance Policy for Diagnostic Products
37th Board meeting in Rwanda, 04th May 2017

The development of the QA Policy

– developed in 2009 with experts support (regulators, association of manufacturers, WHO)
– approved by the Board in 2010 based on the Market Dynamics Committee recommendation
– updated in 2014, noting needs for future revisions for the phase-in of specific products

The QA Policy is based on 3 sets of requirements

– **Clinical standards**: ensure consistency with WHO guidance and national guidelines
– **Quality standards**: establish minimum standards and additional standards for specific products
– **Quality of use**: refer to guidance for ensuring quality use and adequate outcome

Rationale for proposed policy revisions

– Alignment with new or updated WHO guidelines for key products
– Alignment with the Global Fund Policy on co-infection and co-morbidities (COIMs)

### Revisions related to changes/updates to normative guidance and policies

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td><strong>HIV self testing</strong></td>
<td>WHO guidelines encourage countries to pilot/explore self-testing to scale up testing. Global Fund supports operational research on HIV Self testing. Proposed revisions to the policy include specific quality requirements for HIV self testing RDTs (section 8).</td>
</tr>
<tr>
<td><strong>Procurement eligibility mRDTs</strong></td>
<td>As of 31 Dec 2017, WHO Prequalification Programme will determine procurement eligibility. Proposed revisions to the policy reflect alignment with these changes (section 8).</td>
</tr>
<tr>
<td><strong>PMS on IVDs</strong></td>
<td>In 2015, WHO guidance on Post-Market Surveillance of IVDs that describe measures to ensure on-going compliance of Diagnostics. Proposed revisions to the policy include this WHO guidance (section 13).</td>
</tr>
<tr>
<td><strong>G6PD testing</strong></td>
<td>WHO recommends G6PD testing in regions with high prevalence of G6PD deficiency prior to primaquine treatment. Proposed revisions include quality requirements for G6PD tests.</td>
</tr>
<tr>
<td><strong>Co-infections</strong></td>
<td>Proposed revisions include quality requirements for In-vitro diagnostics (IVDs) for Hepatitis B and C, Syphilis co-infections (section 8).</td>
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Successful replenishment for the 2017-2019 allocation period for implementing the Global Fund Strategy

- Fifth Replenishment Conference in Canada: September 2016
- Donors pledged over US$ 12.9 billion for the next three years
- Nearly US$ 1 billion more than the previous replenishment conference in 2013
- Countries were informed of their funding envelopes in December 2016 to take them through 2020

<table>
<thead>
<tr>
<th>Funding envelopes</th>
<th>Amount</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>5,098</td>
<td>105</td>
</tr>
<tr>
<td>Malaria</td>
<td>3,227</td>
<td>71</td>
</tr>
<tr>
<td>TB</td>
<td>1,842</td>
<td>98</td>
</tr>
</tbody>
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*Health products = 40-60% spend depending on category*

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

STRATEGIC ENABLERS: Innovate and differentiate along the development continuum + Support mutually accountable partnerships

- **MAXIMIZE IMPACT AGAINST HIV, TB AND MALARIA**
- **BUILD RESILIENT & SUSTAINABLE SYSTEMS FOR HEALTH**
- **PROMOTE & PROTECT HUMAN RIGHTS AND GENDER EQUALITY**
- **MOBILIZE INCREASED RESOURCES**

- **c** Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines and technologies
- **d** Support efforts to stimulate innovation and facilitate the rapid introduction and scale-up of cost-effective health technologies and implementation models
Pooled Procurement Mechanism health product spend 2017

PPM spend is approximately 55% of the total Global Fund health product spend
PPM spend on Diagnostics and RDTs is $103m and $80m respectively

“Core products”
- represent +/- 85% of procurement value
- between 25% and 70% of procurements financed by the Global Fund are channeled through PPM (depending on the category)

Acronyms:
ARVs  Antiretroviral drugs
LLINs  Long-Lasting Insecticide treated nets
RDTs  Rapid Diagnostic Tests

Source: 2017 PSA data; includes procurement service agent fees, freight, insurance, QA and other costs
GF utilizes a number of procurement channels - with the Pooled Procurement Mechanism (PPM) representing around 55% total GF health product spend (depending on product category).
Maximizing Value through Supplier Relationship Management

Previous approaches only focused on the price value lever. Value creation has been extended across a range of levers which will increase in importance as cost is optimized.

- **Price**
  - Previously: Managed periodically by Tender
  - Now: Largely Ignored

- **Security of Value Created**
  - Lower
  - Higher

- **Other Elements**
  - Performance
  - Projects to support objectives
  - Process improvement
  - Engagement & Commitment

- **Ongoing management**
The wambo.org vision

wambo.org is built upon the vision of an online procurement platform which can tackle several challenges faced by PRs

An innovative online procurement platform with several important benefits

- **Search and compare** price and lead time across suppliers
- **Select desired specifications, order terms and place order**
- **Track and trace requisition, direct payment**
- **Easy reporting, allowing for better, more specific forecasting**

- **Reduces market complexity and need for intermediaries**
- **Decreases administrative burden; for PPM PRs, automates PPM ordering**
- **Acceleration of the procurement process**
- **PRs able to procure more efficiently**
Transaction level data: procured & delivered
Price and Quality Reporting - PQR

Price & Quality Reporting

Price & Quality Reporting is an online database that collects data on purchases made by Global Fund supported programs, including:

- Medicines (ARVs, ACTs, etc.)
- Health products (nets, laboratory reagents, etc.)
- Equipment (microscopes, diagnostic machines, etc.)
- Other supplies

As part of its effort to be as transparent as possible, the Global Fund publishes this data, including:

- Supplier or manufacturer data
- Dosage
- Unit cost
- Packaging information
- Shipping or other related costs
- Total cost of the transaction

Anyone can access the Price & Quality Reporting database. Registration is necessary only if you will be entering data (such as Principal Recipients or Local Fund Agents).

Reports can easily be downloaded from the database, and are based on data updated daily.

- PQR Login
- Price Reference Report: A summary of main international reference prices and recent market data
- Transaction Summary: A listing of transactions, either the complete set or a requested subset
- D4T Calculators
- Download In English

Thank you for your attention