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

18th 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

<table>
<thead>
<tr>
<th>If &lt;2 choices of A/B products:</th>
<th>Until 30 June 2009</th>
<th>From 1 July 2009</th>
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</thead>
<tbody>
<tr>
<td>Ci (WHO application+ GMP)</td>
<td>Products recommended by the Expert Review Panel (ERP) after review of clinical, safety &amp; quality data</td>
<td></td>
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<tr>
<td>Cii (GMP)</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Eligible products:</th>
<th>Eligible for ERP review if:</th>
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</thead>
<tbody>
<tr>
<td>Ci/Cii:</td>
<td>◦ Application to WHO-PQ or an SRA was accepted AND</td>
</tr>
<tr>
<td>•Applied for WHO prequalification (PQ) or to SRA</td>
<td></td>
</tr>
<tr>
<td>•Manufacturing site GMP-compliant (WHO-PQ, SRA/ PIC/S)</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>How to identify products</th>
<th>Interim ERP recommendations (time-limited) are published on the Global Fund’s website: Global Fund List</th>
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<tbody>
<tr>
<td>PRs must prove that products meet the above criteria and Global Fund list</td>
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</table>
Selection of finished pharmaceutical products for ARVs, Anti-TB or Anti Malaria FPP

2 or more A or B products Available?

Yes

- Notify TGF
- Receive no objection
- Testing by TGF Lab

Procure A or B Product

No

ERP recommended
Product available?

Yes

- GF request an ad Hoc ERP committee to review eligible product

No

Procure ERP recommended Product

Product unavailability definition:
Inability to supply sufficient quantity of product within 90 days from date of order
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


- **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-
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

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
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
Price & Quality Reporting

How PQR Works?

The Global Fund

Principal Recipient

Price

Quality

Delivery Conditions

Verify Data

Local Fund Agent

Monitor

Price Comparison

Quality Monitoring

Market Information

Reports

Reports

Principal Recipients

General Public

Partners
Price & Quality Reporting

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/
Thank you