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The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Report of the Portfolio Committee

New Delhi, 8 November

K. Sujatha Rao, Chair of the Portfolio Committee



Eighteenth Board Meeting

New Delhi, India 7-8 November 2008



El Fondo Mundial
De la Lucha contra el SIDA, la tuberculosis y la malaria



全球基金
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The Global Fund
To Fight AIDS, Tuberculosis and Malaria



Le Fonds mondial
de lutte contre le SIDA, la tuberculose et le paludisme



Глобальный фонд
для борьбы со СПИДом, туберкулезом и малярией

الصندوق العالمي
لمكافحة الإيدز والتبؤ و الملاريا



10th PC Meeting

Information

- Technical Review Panel (TRP) Replenishment
- Country Coordination Mechanisms Update
- Local Fund Agent Tender Process
- Round 9 Eligibility



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Outline

Decision

- Global Fund's Quality Assurance Policy for Pharmaceutical Products
 1. Overview of Board Mandate to the PC
 2. Review Process and PC Oversight
 3. Concerns with Existing Policy
 4. Features of the New Policy
 5. Portfolio Committee Input and Approval



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1.1 Overview of Board Mandate

- 16th Board (November 2007):
 - The Secretariat should carry out a review of the QA Policy for Pharmaceutical Products
 - PC will oversee the review
- 9th PC (February 2008):
 - Endorsement of the Secretariat methodology of review
 - Approval and input into the ToR of the Technical Advisory Group (TAG)
 - Circulation of initial TAG report to PC (June 2008)
- 10th PC (September 2008)
 - Presentation of the report on the QA policy review and the proposed revised QA Policy



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2.1 Review Process

- Four phases of Review
 1. Analytical Phase
 - Collection of data
 - Analysis of partners' QA policies
 - Implementer's feedback
 2. Establishment of the Technical Advisory Group
 - Analysis of technical documents and id'd weaknesses of existing QA policy
 - Drafting of recommendations and proposed new policy
 3. Extensive consultation with partners
 4. Submission of outcomes to the PC



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3.1 Concerns with Existing Policy

- Selection, in limited cases, of medicine formulations and dosages that are not consistent with WHO standard treatment guidelines (STGs)
- Adequacy of the Global Fund's QA standards for limited and single source (Ci and Cii options) and multi-source products
- Absence of harmonized QA standards among key partners



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4.1 Features of Proposed QA Policy

- New Clinical Criteria
- New Quality Criteria
- Strengthened Monitoring Product Quality
- Establishment of Expert Review Panel



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4.2 Features of Proposed QA Policy

Clinical Criteria	
Existing QA Policy	Revised QA Policy
Medicines listed in WHO or national or institutional Standard Treatment Guidelines (STGs)	Medicines listed in WHO or national or institutional Standard Treatment Guidelines (STGs) PRs/Applicant required to provide technical justification for selection of unlisted products in one of the STGs



4.3 Features of Proposed QA Policy

Quality Criteria	
Existing QA Policy	Revised QA Policy
<p>Categorization of pharmaceutical products:</p> <p>1. Multi-source Products Authorized for use by Drug Regulatory Authority (DRA) in recipient country.</p> <p>2. Single and Limited-source Products In addition to 1., PR has 4 options: Option A: prequalified by WHO, or Option B: authorized by a Stringent Regulatory Authority (SRA) or Option Ci: - Submission of dossier to WHO or SRA - GMP-compliant site, or -Option Cii: GMP-compliant site</p>	<p>Eliminate products categorization between multisource and single/limited source</p> <p>1. Quality criteria for all products Authorization for use in the recipient countries</p> <p>2. Quality criteria for ARVs, anti-TB and antimalarials: in addition to 1., Selection of FPPs either WHO prequalified or SRA authorized Or recommended by: Expert Review Panel: - Submission of dossier to WHO or SRA - GMP-compliant site - Technical review of dossier of FPPs</p>



4.4 Features of Proposed QA Policy

Strengthened Monitoring Quality Product	
Existing QA Policy	Revised QA Policy
Systematic random quality control testing	Systematic random quality control testing PR to report testing results to Global Fund



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4.5 QA Policy

Establishment of an Expert Review Panel

– Purpose:

- Conduct technical review of dossier of FPPs
- Provide time-limited recommendations (max. 12 months)

– Hosting arrangements:

- To be negotiated with WHO with funding from the Global Fund

– Terms of Reference to be finalized with input from the PC and partners



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5.1 PC Input and Approval

- The PC:
 - Commended the Secretariat for a very thorough review in line with the Board's requests and parameters established for the review
 - Endorsed the option for the Expert Review Panel
 - Reviewed the proposed Decision Point and requested amendments to:
 - Explore possibilities for establishing a Quality Assurance Policy for diagnostic products
 - Explicit mention of the hosting arrangements of the Expert Review Panel within WHO



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Decision Point

Recommended Decision Point 1 (1/3):

The Board approves the Quality Assurance Policy for Pharmaceutical Products (“QA Policy”) as set out in Annex 1 to the Report of the Portfolio Committee (GF/B18/5). 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 (as approved at the Third Board meeting and amended at subsequent Board meetings).

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Decision Point

Recommended Decision Point 1 (2/3):

The Board authorizes the Secretariat to request the World Health Organization (WHO) to host the Expert Review Panel described in the QA Policy, and to conclude the necessary arrangements with the WHO.

The Board delegates to the Portfolio Committee the responsibility for overseeing the implementation of the QA Policy, including the establishment of the Expert Review Panel. The Board requests the Secretariat to provide the Portfolio Committee with an update on the implementation of the QA Policy at the Portfolio Committee's final meeting in 2009, and thereafter, as requested by the Portfolio Committee.

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Decision Point

Recommended Decision Point 1 (3/3):

The Board also requests the Secretariat, under the oversight of the Portfolio Committee, to review the current status of quality assurance for diagnostic products and make recommendations. The Board requests the Portfolio Committee to report the findings of this review at the Board's final meeting in 2009.

The budgetary implications of this decision point in 2009 amount to US\$ 1,245,000 which includes an allocation for 2 staff positions. (The cost will be covered by the budget contingency.)



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