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To Fight AIDS, Tuberculosis and Malaria

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Implementation of the Quality Assurance Policy

Outline: This paper provides the Portfolio Committee with an update on the status of the implementation of the revised Quality Assurance Policy as adopted at the Tenth Board Meeting in April 2005, and its related activities.

Background

In April 2005, the Board of the Global Fund approved changes to the Global Fund's Quality Assurance policy related to procurement of Single- and Limited-Source Pharmaceutical Products. The decision altered the policy as adopted at the Third Board Meeting for procurement under Option (c). Accordingly, Principal Recipients (PRs) may – in specific circumstances - use Global Fund resources to procure pharmaceutical products, provided that the products are selected in accordance with the following, in order of priority:

(c)(i) The manufacturer has submitted an application for product approval to the WHO Pre-qualification Program or a stringent regulatory authority AND is manufactured at a site that is compliant with standards of Good Manufacturing Practices (GMP), as certified after inspection by WHO or a stringent regulatory authority;

(c)(ii) The product is manufactured at a GMP-compliant manufacturing site as certified after inspection by WHO or a stringent regulatory authority.

The Board decision further requires that PRs should notify the Secretariat of their intention to procure products under Option (c) and the Secretariat should contract an independent third party to conduct random quality analysis of products procured under provisions (c)(i) and (c)(ii).

Status

In order to comply with the Board decision and to manage the activities within QA, the Secretariat:

1. Is in the process of finalizing the contract with an independent Quality Control Agent (QCA) to conduct the random quality analysis;
2. Has set up various processes and tools to manage, support and monitor compliance with the policy.

1. Contracting a QCA

In order to comply with this Board requirement, the Secretariat decided to implement the quality analysis in two phases: an interim and short-term arrangement that would allow the Global Fund to comply with the Board request for a rapid implementation of control activities and a long-term solution which should be developed, available for and ideally used by a broad group of partners, constituencies and other entities who have similar needs for quality control testing.

The interim and short-term solution was never implemented because the proposal that was submitted in July 2005 to the WHO Contract Review Committee (CRC) was withdrawn in December 2005 when the Request for Proposal (RFP) for the long-term solution was issued.

The long-term solution was developed in close cooperation with a broad group of partners who contributed valuable advice and guidance. A smaller group of partners actively participated in the development of the concept, the RFP and the final evaluation of offers.

The process for the selection of the QCA took more time than expected due to the fact that both the quality and number of bids received in response to the initial RFP were unacceptable, and a second RFP had to be issued.

The due date for submission of proposals was 30 March 2006. Following receipt of the additional clarifications requested from bidders, the offers were evaluated on 21 April 2006. Based on these evaluations, a recommendation was forwarded to CRC end April 2006.

In early August 2006 the Global Fund received approval from CRC to contract the company SGS Nederland B.V. (SGS) for sampling, pre-shipment inspection and testing services.

The Global Fund will finalize the contract with SGS in September, after which a series of meetings with SGS are planned to specify and agree on the operational details of the agreement. The QCA is expected to be fully operational from October 2006.

2. Initiatives to manage, support and monitor compliance with QA policy

In order to assist PRs and manufacturers in fulfilling the requirements of the QA policy, the Secretariat has implemented the following initiatives:

- Training of PRs in regional and local workshops and of Global Fund staff in Geneva;
- Development and publication of a Global Fund Compliance List;
- Development of a database for tracking notifications of PRs' intent to procure pharmaceuticals under Option (c);
- Monthly reporting of compliance based on past procurement as reported through the Price Reporting Mechanism (PRM);
- Development of database for tracking manufacturers' GMP compliance;
- Recruitment of technical officer to manage the Compliance List and aspects of quality control testing
- Development of Standard Operating Procedures for all processes and activities

Compliance List

The Global Fund Compliance List has been developed in order to assist PRs in exploring options with respect to procurement of single/limited source pharmaceuticals. The list is an overview of classified products and manufacturers based on their compliance with the requirements of the various options available under the QA Policy. Accordingly, products are classified as A, B, Ci or Cii as per the standards described in the policy.

Database for tracking intent to procure under Option (c)

As described in the QA Policy, PRs are requested to notify the Secretariat of their intent to procure products under Option (c). Consequently, PRs have to comply with the policy at two levels: firstly, in notifying the Secretariat and, secondly, in procuring products in accordance with the policy.

Notification allows the Secretariat to validate the compliance as well as engage the QCA for the random quality analysis. In order to monitor this activity. a tracking tool for notifications has been developed. Analysis of the notifications shows that only very few PRs have notified the Secretariat prior to procuring pharmaceuticals under Option (c).

Compliance as reported through the PRM

The increased use of the PRM has allowed the Secretariat to initiate monitoring of the pharmaceutical products purchased. A database has been developed in which the limited source pharmaceutical products related to the entries/orders in the PRM have been classified according to the QA standards listed in the policy. The limited use of the PRM has only lately allowed meaningful analysis of the PRs' compliance with respect to procurement of products in accordance with the QA Policy. Based on PRM entries as of 31 August 2006, the analysis shows that less than ten percent of the entries are non-compliant.

GMP compliance tracking tool

Due to the significance of manufacturer GMP compliance for procurement under Option (c), it has been considered important to develop a GMP compliance tracking tool. This tool will allow the Secretariat to track and monitor the validity of the manufacturers' GMP certificates and, if necessary, to de-list suppliers that do not have a valid GMP certification.

Recruitment of technical officer

The recruitment process for a technical officer to manage the various aspects of the quality control testing and the Compliance List has been finalized. The start date for the candidate is 1 October 2006.

Next steps

During the past year the infrastructure of the QA activities has been developed and implemented. The next step is to operationalize the QA Policy, which will include the following activities:

- Further training of PRs in the importance in complying with the policy. This activity will be conducted through country-specific workshops.
- Institutionalizing of the processes and procedures related to the quality analysis conducted by the QCA (SGS).
- Active monitoring of compliance and taking appropriate steps in case of non-compliance.
- Establishing of robust relations with various important technical partners, including WHO and the US Food and Drug Administration, stringent regulatory authorities, and others.
- Converting "prototype" databases into robust IT reporting systems.