Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Global Fund Quality Assurance Policy for Pharmaceutical Products

The revised QA Policy

- Clinical criteria
- Quality criteria
- Selection process of FPPs
- Independent Expert Review Panel
- Monitoring product quality

Clinical criteria

- 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

- For all antiretrovirals, anti-tuberculosis and anti-malarial finished pharmaceutical products (FPPs)

  – Prequalified by the WHO Prequalification Programme or authorized for use by a Stringent Drug Regulatory Authority (SRA);

  or

  – Recommended for use by an Expert Review Panel (ERP), If <2 WHO prequalified or SRA authorized products available in the procurement process

The Expert Review Panel

- An independent panel of experts with TORs approved by Portfolio Committee
- Hosted by WHO
- 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 for a time limited period
- ERP experts: representative of a wide range of expertise in the pharmaceutical and medical fields and preferably include at least 2 members with recent work experience in an SRA

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 no or only few prequalified products or SRA authorized product are available on the market
- Published on our web site:

  http://www.theglobalfund.org/en/procurement/quality/?lang=

Documentation submitted by Manufacturers for ERP review

For each product awaiting WHO-prequalification or SRA authorization

- A covering letter expressing interest to submit the product to the ERP for review
- An acceptance letter from the WHO Prequalification Programme stating the WHO reference number assigned by WHO to this specific product, or
- An acceptance letter from the SRA confirming that the submission for the product has been accepted for review
- GMP status
- A completed Pharmaceutical Product Questionnaire and all annexes as applicable
- A non-returnable product sample as requested in Section VIII of the questionnaire

- Documentation should be submitted in hard copy and electronically

Technical Areas of ERP review

Product questionnaire dossier :

- product registration information;
- **regulatory (licensing) status of the FPP and manufacturing facility**;
- 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 labeling information;
- **active pharmaceutical ingredient** (API) characteristics and certification; and
- **safety and efficacy data for innovator products or human bioequivalence data for generic products**.

The Global Fund Secretariat Responsibilities

- to manage the receipt of product questionnaire dossiers sent by manufacturers according to the EoI
- to provide complete product questionnaire and associated documents to the ERP Coordinator for review
- to notify manufacturers of the outcome of the ERP's review of their respective FPP dossiers
- to maintain on its website an updated list of FPPs that have been recommended for use by the ERP.

ERP Responsibilities

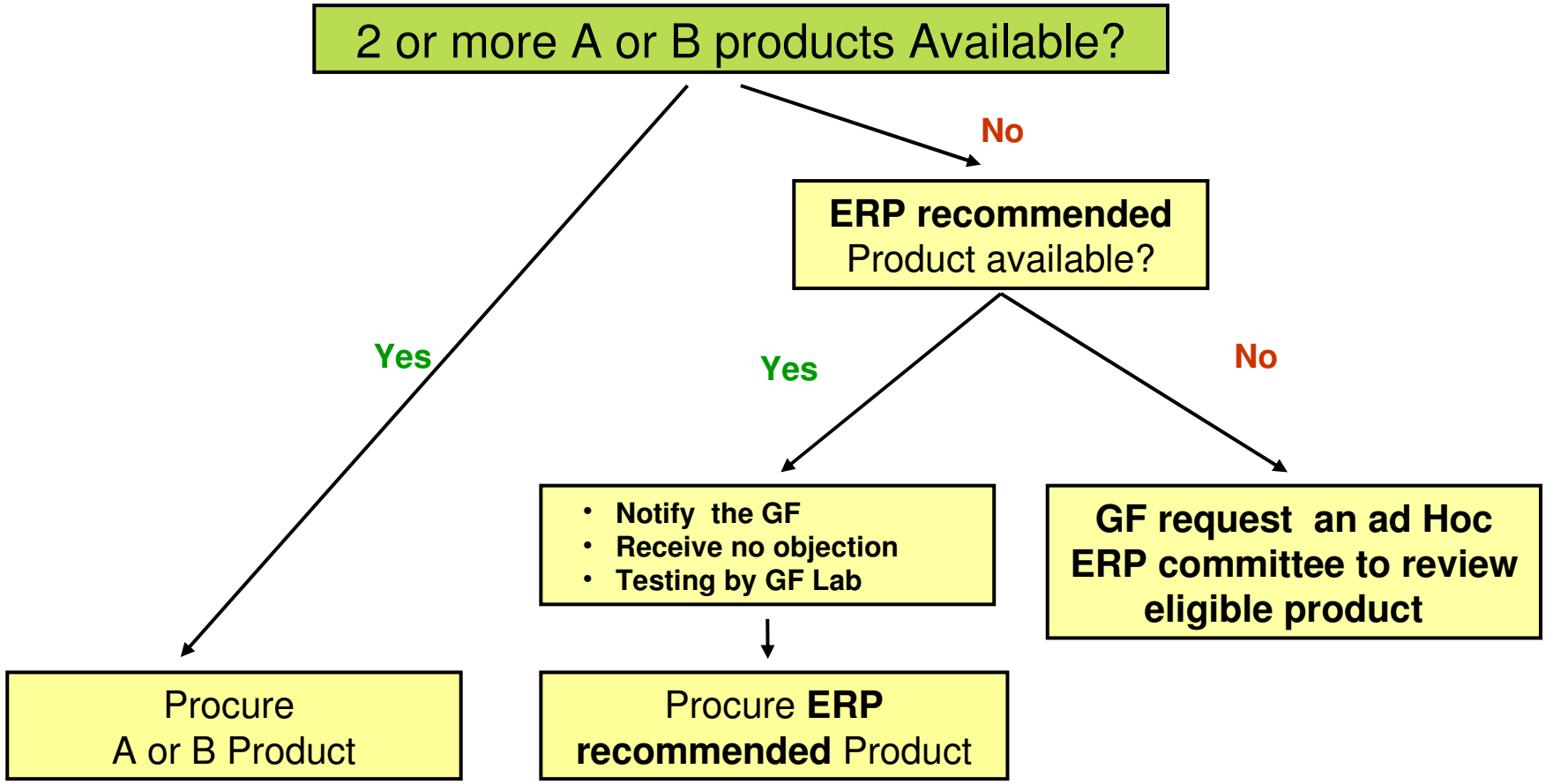
The ERP coordinator

- Manages the selection of ERP members
- Ensures that ERP members remain current with latest SRA guidelines
- Arranges the timely review of the dossiers received
- Coordinate ERP members' advice - regarding the acceptability or non-acceptability for procurement of each specific FPP;
- Drafts the respective communications to the Global Fund and ensures timely delivery of the reports.

First ERP review

- EoI published in Dec 2008 for antimalarial products
- Review of dossier by ERP in May 2009
- 3 antimalarial medicines have been recommended by the ERP for a time limited period (July 2010)
- No notification received for procurement of ERP recommended products since 1July 09
- Second ERP review planned first week of October 2009

Selection of finished pharmaceutical products for ARVs, Anti-TB or Anti Malarial product



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

Notification and pre-shipment QC

	Since 1 July 2009
Notification: PR notify the Secretariat if he intends to procure:	**ERP-recommended products**
Secretariat **Agrees**: →Pre-shipment QC **Objects**: →PR should reconsider	"
Pre-shipment QC: Arranged and paid by GFATM Secretariat	**As advised by ERP**
Online reporting of QC results:	By Secretariat to online **PQR system**

Monitoring quality product

QA Policy
• Monitoring quality of products all along the supply chain • Systematic random quality control testing • Recipients report testing results to Global Fund

Implications for the manufacturers: methods used for quality control of products not published in pharmacopoeia to be provided by the manufacturers to PR for QC

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.