Procurement and Supply Management of Pharmaceuticals and other Health Products.

13 December 2007
Stop TB workshop on
Global Fund grant negotiation and implementation

Sophie Logez
PSM Team
Objectives

• Describe the key Policy elements of Procurement and Supply Management;
• Describe the PSM evaluation process
• Review the key components of the PSM plan;
• Explain the Price reporting mechanism;
• Introduce the Global Fund Quality Assurance policy for pharmaceutical products.
• Overview of the Global Fund’s policies on Procurement and Supply Management (PSM)

• Preparation of the PSM plan
  ➢ PSM plan development
  ➢ PSM plan review

• Price Reporting Mechanism (PRM)

• The Global Fund’s Quality Assurance policy for pharmaceutical products
The Global Fund’s approach to PSM

• **Principles** and minimum **standards**, not detailed procedures
• Build upon **existing systems**
• Distinction between health and non-health products
• How products arrive in a country and what happens to them subsequently
• **PR responsible** for all PSM activities (whether directly implemented or sub-contracted).
• Description of the PSM systems, capacity and planning in the **PSM plan**
Key documents:
Guide to the Global Funds’s Policies on PSM

- Outlines all GF’s PSM Policies and principles
  - Procure quality-assured products at the lowest possible price
  - Adhere to National and International Laws
  - Conduct procurement in a transparent and competitive manner

- Based on Global Fund Board decisions
- Outlines what PR’s need to do
Key documents: (2) Guide to Writing a PSM Plan

- Describes PR’s institutional capacity for PSM and elements of PSM cycle
- Use of existing data and systems
- Short & concise: not more than 20 pages
- Development of PSM should be started early: bottleneck for many PRs
- Include annexes with information on products to be procured (e.g., quantities, estimated prices, inclusion in WHO EML, Patent status etc.)
Timeline for preparing the PSM plan

- Technical collaboration

PSM section of the proposal:
- PSM experts
- Laboratory expert
- Regulatory authorities

Preparation of the PSM plan (Team work, Technical support)

Proposal Writing

Phase 1
- Proposal approved
- Grant signature

Phase 2
- Phase 2 review

Planning phase

Implementation phase
PSM Plan Approval Process

Proposal recommended for funding

PR submits PSM Plan to Global Fund

GF & LFA assessment process

Revise Plan

Implementation of program in line with Grant

Global Fund approval & disbursement

In case PR lacks capacity:
- To develop PSM Plan – may seek TA from Partners
- To conduct procurement – may use a Procurement Agent while building internal capacity.
Presentation Outline

• Overview of the Global Fund’s policies on Procurement and Supply Management (PSM)

• Preparation of the PSM plan
  ➢ PSM plan development
  ➢ PSM plan review

• Price Reporting Mechanism (PRM)
• The Global Fund’s Quality Assurance policy for pharmaceutical products
# Procurement and Supply Management Plan

For the period from year ______ to year ______

<table>
<thead>
<tr>
<th>Proposal/grant title:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Recipient(PR):</td>
<td></td>
</tr>
<tr>
<td>Country:</td>
<td></td>
</tr>
<tr>
<td>Component:</td>
<td></td>
</tr>
<tr>
<td>Round:</td>
<td></td>
</tr>
<tr>
<td>Phase 1 or Phase 2:</td>
<td></td>
</tr>
<tr>
<td>Grant number:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product category</th>
<th>Year 1 (US$)</th>
<th>Year 2 (US$)</th>
<th>Year 3 (US$) if applicable</th>
<th>Total phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Pharmaceuticals</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Health products &amp; commodities (excluding pharmaceuticals)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Health equipment (X-rays, laboratory equipment, etc.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Services (related to PSM e.g., QA, MIS, RUD, etc.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Non-health products and services (e.g., vehicles, computers, construction, financial consultants, etc.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total grant size (US$)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total procurement as % of grant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Person (name, title, department) with overall responsibility for this grant. Provide name and contact details (tel., e-mail, etc.).

Person (name, title, department) with overall responsibility for all PSM activities. Provide name and contact details (tel., e-mail, etc.).

Date of submission(s):
PSM plan: Institutional capacity

Management capacity
Responsibilities for each PSM activities

Procurement policies and systems
Adherence to Interagency Guidelines on Good Pharmaceutical Procurement (WHO 1999)
- Competitive bidding
- Transparent and accountable practices
- Appropriate quality assurance mechanism

Quality assurance system
Global Fund Quality Assurance policy
- Multi-source Pharmaceutical Products
- Single and Limited-source Pharmaceutical Products
Quality control testing activities
International and national laws

Adherence to laws with respect to
Intellectual Property Rights (IPR)

Coordination

With other source of funding targeting the same diseases: PEPFAR, the World Bank, etc…

Management information system capacity

- Description at central and regional level
- Type of data collected
- Capacity building plan
## PR’s institutional capacity for PSM: Management capacity

<table>
<thead>
<tr>
<th>Activity</th>
<th>Which Organization and/or Department is responsible for this function? If this function is being outsourced, then indicate this in the table</th>
<th>What type of organization is responsible for this function? (PR, SR or Procurement Agent)</th>
<th>Indicate if there is need for additional staff or technical assistance¹ (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement policies, systems and capacity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality assurance and quality control of pharmaceuticals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>International national laws (patents)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coordination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management Information Systems</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product selection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forecasting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procurement Planning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inventory management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distribution to other stores and end-users</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ensuring Rational Use</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ This column indicates whether additional staff or technical assistance is needed.

- MoH
- e.g. GDF
- Procurement Agent
Pharmaceutical Product Selection

- National or Institutional Standard Treatment Guidelines
- WHO Standard Treatment Guidelines
- National / WHO Essential Medicines List (EMLs)

2. Procurement and supply management cycle
   2.1 Product selection

   Please fill out the following table. For the Standard Treatment Guidelines and Essential Medicines Lists, indicate the year the STG/EML was last updated.

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Product (Generic Name)</th>
<th>WHO (Year updated)</th>
<th>National (Year updated)</th>
<th>Institutional (Year updated)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Listed in EML (yes/no)</td>
<td>Listed in STG (indicate 1st/2nd line treatment)</td>
<td>Listed in STG (indicate 1st/2nd line treatment)</td>
</tr>
<tr>
<td>ARVs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-Malarials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-TB</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PSM plan: the PSM cycle

Forecasting procedures
- Consumption data
- Morbidity data
- Health service capacity

Procurement and planning
- Which products, when, who, how and how much

Note:
Ensure budget consistency between:
- work plan
- annexes and the front page of the grant agreement
### Annex 1a: List of products to be procured

List all **pharmaceuticals** to be procured under this grant.

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Product</th>
<th>Strength</th>
<th>Estimated unit cost (US$)</th>
<th>Year 1 Estimated quantity</th>
<th>Year 1 Total cost (US$)</th>
<th>Year 2 Estimated quantity</th>
<th>Year 2 Total cost (US$)</th>
<th>Year 3 Estimated quantity</th>
<th>Year 3 Total cost (US$)</th>
<th>Procurement method</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARVs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Antimalarials</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Anti-TB</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All other pharmaceuticals</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td></td>
</tr>
</tbody>
</table>

**Procurement method**:

- **[1]**

**Procurement to be conducted by**: [ ]

**Procurement method**: [ ]
### Annex 1b: List of products to be procured

List the products and services to be procured under this grant.

<table>
<thead>
<tr>
<th>Prod. Cat.</th>
<th>Product</th>
<th>Estimated unit cost (US$)</th>
<th>Year 1 Estimated quantity</th>
<th>Year 1 Total cost (US$)</th>
<th>Year 2 Estimated quantity</th>
<th>Year 2 Total cost (US$)</th>
<th>Year 3 Estimated quantity</th>
<th>Year 3 Total cost (US$)</th>
<th>Procurement to be conducted by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Products</td>
<td>Rapid diagnostic test</td>
<td>--NA--</td>
<td></td>
<td>--NA--</td>
<td></td>
<td>--NA--</td>
<td></td>
<td>--NA--</td>
<td></td>
</tr>
<tr>
<td></td>
<td>All other diagnostic products, supplies, equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bed nets (LLINs, other)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>All other health products</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td></td>
</tr>
<tr>
<td>Health Equipment</td>
<td>Various health equipments</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td></td>
</tr>
<tr>
<td>Services</td>
<td>MIS systems</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td></td>
</tr>
<tr>
<td></td>
<td>QA strengthening</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td></td>
</tr>
<tr>
<td>Non-Health Products</td>
<td>All non-health products and services</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td>--NA--</td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL**

**TOTAL**

**TOTAL**
Inventory management

- Storage capacity at all levels
- Storage space requirements and strategy to meet needs
- Inventory management system

Distribution system

- Points of distribution and country coverage
- Average distribution schedule
- Logistic capacity and solutions if insufficient
- Challenges expected

Ensuring rational use of medicines

- Strategies to initiation of, adherence to and compliance with treatment
- Plan for monitoring adverse drug reaction and drug resistance
Review of the PSM plan

Local Fund Agent (LFA)
- Assess PSM systems and PR’s capacity to manage PSM according to GF policies on PSM
- Provide recommendations to the GF

The Global Fund will decide on PSM strategy:
- All PSM activities will be managed by the PR
- Subcontract certain PSM activities
- Subcontract PSM activities to a Procurement Agent.
• Modifying the PSM Plan during implementation

Modifying the plan, with respect to the selection or the quantities of items to be procured, for example, may be necessary, especially in instances where there are changes in national or international treatment guidelines.

For significant changes, the PR is required to provide to the Global Fund a written rationale and highlight the proposed modifications. The LFA will assess the proposed rationale and provide its recommendations to the Global Fund, which will confirm whether these changes are acceptable.
Presentation Outline

• Overview of the Global Fund’s policies on Procurement and Supply Management (PSM)

• Preparation of the PSM plan
  ➢ PSM plan development
  ➢ PSM plan review

• Price Reporting Mechanism (PRM)

• The Global Fund’s Quality Assurance policy for pharmaceutical products
Price Reporting Mechanism

PRM keeps track of purchase information for medicine procured with GF funds. PRs have full access to these information from their countries by Internet.

PRM allows PRs to not only maintain secure records of its own procurement activity, but also to compare its activity to the activity of other PRs.

The real-time information contained help the Secretariat keep track of procurement prices, supplier performance, product quality, and overall procurement efficiency of country operations.
15th Board meeting, April 2007, Decision point

“The Secretariat shall rapidly strengthen its existing PRM, with the objective of enhancing the completeness and quality of self-reported data as an essential foundation of sound market dynamics and procurement practices”
It is mandatory to enter procurement data for the following health products in the PRM before making subsequent Disbursement Request:

- ARVs,
- TB medicines,
- ACTs,
- Bed nets,
- Condoms.
<table>
<thead>
<tr>
<th>Country Name</th>
<th>Grant No</th>
<th>Therapeutic Category</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Dosage Form</th>
<th>Strength (or Concentration)</th>
<th>Type of Package</th>
<th>Total of units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>AFG-202-G01-T-00</td>
<td>anti-Malaria</td>
<td>ARTESUNATE</td>
<td>ARSUMAX</td>
<td>oral solid</td>
<td>50mg</td>
<td>multi-dose pack</td>
<td>321,2</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-202-G01-T-00</td>
<td>Malaria Prevention</td>
<td>Long Lasting Nets (LLNs)</td>
<td>PermaNet</td>
<td>injectable</td>
<td>1g/ml</td>
<td>multi-dose pack</td>
<td>16,70</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-405-G02-T</td>
<td>anti-TB</td>
<td>STREPTOMYCIN</td>
<td></td>
<td>injectable</td>
<td>1g/ml</td>
<td>multi-dose pack</td>
<td>40,06</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-405-G02-T</td>
<td>anti-TB</td>
<td>ISONIAZID 75MG, RIFAMPICIN 150MG</td>
<td></td>
<td>oral solid</td>
<td>75 mg, 150 mg</td>
<td>multi-dose pack</td>
<td>409,2</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-405-G02-T</td>
<td>anti-TB</td>
<td>ETHAMBUTOL, ETHAMBUTOL 400MG/ISONIAZID 150MG</td>
<td></td>
<td>oral solid</td>
<td>400 mg, 550 mg</td>
<td>multi-dose pack</td>
<td>4,084</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-405-G02-T</td>
<td>anti-TB</td>
<td>PYRAZINAMIDE</td>
<td>PYRAZIMAMID</td>
<td>oral solid</td>
<td>400mg</td>
<td>multi-dose pack</td>
<td>104,4</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-405-G02-T</td>
<td>anti-TB</td>
<td>PYRAZINAMIDE</td>
<td>PYRAZINAMID</td>
<td>oral solid</td>
<td>400mg</td>
<td>multi-dose pack</td>
<td>104,4</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-405-G02-T</td>
<td>anti-TB</td>
<td>ISONIAZID, RIFAMPICIN, ETHAMBUTOL, PYRAZINAMIDE</td>
<td>RIFAMPICIN</td>
<td>oral solid</td>
<td>75 mg, 150 mg, 275 mg, 400 mg</td>
<td>multi-dose pack</td>
<td>1,144</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>AFG-506-G03-M</td>
<td>Malaria Prevention</td>
<td>Long Lasting Nets (LLNs)</td>
<td>PermaNet</td>
<td>injectable</td>
<td>1g/ml</td>
<td>multi-dose pack</td>
<td>454,3</td>
</tr>
<tr>
<td>Angola</td>
<td>AGC-308-501-M</td>
<td>Malaria Prevention</td>
<td>Long Lasting Nets (LLNs)</td>
<td>Vestedgaard</td>
<td>injectable</td>
<td>1g/ml</td>
<td>multi-dose pack</td>
<td>2,566</td>
</tr>
<tr>
<td>Angola</td>
<td>AGC-308-501-M</td>
<td>Malaria Prevention</td>
<td>Long Lasting Nets (LLNs)</td>
<td></td>
<td>injectable</td>
<td>1g/ml</td>
<td>multi-dose pack</td>
<td>150,0</td>
</tr>
</tbody>
</table>
Summary and conclusions

- Start early with PSM Plan development
- Leverage existing systems and data
- Keep it simple, be short and concise
- Out-source to specialized agencies when capacity is lacking
- Follow up with Price Reporting Mechanism
- Track
  - Funds requested
  - Funds received
  - Value of products that have been purchased
  - Value of products that have been distributed
  - Value of products that have been dispensed
Presentation Outline

• Overview of the Global Fund’s policies on Procurement and Supply Management (PSM)

• Preparation of the PSM plan
  ➢ PSM plan development
  ➢ PSM plan review

• Price Reporting Mechanism (PRM)

• The Global Fund’s Quality Assurance policy for pharmaceutical products
The Global Fund QA Policy

Multi-Source Pharmaceutical Products
• Products off-patent and product standards are available in the public domain (e.g.: IP, BP and USP)
• Products tend to be available from a wide-range of manufacturers

Must comply with quality standards and requirements of Drug Regulatory Authority in the recipient country.

Single and Limited-Source Pharmaceutical Products
• Products for which there are no publicly available QA standards, analytical methods, and reference substances for the finished dosage form (No monograph in IP, BP or USP)
• Products tend to be available from one or limited number of manufacturers

Must procure single or limited source pharmaceutical product that meets the criteria approved by the Global Fund Board.
QA Policy for single- and limited-source pharmaceutical products

Option A: Products pre-qualified by WHO (UN procurement quality and sourcing project)

Option B: Products registered by a stringent regulatory authority

Option Ci: The manufacturer has submitted an application for pre-qualification to the WHO or approval from a stringent regulatory authority and the manufacturing site is GMP compliant as certified by WHO or a stringent regulatory authority.

Option Cii: The product is manufactured at a GMP compliant manufacturing site as certified by WHO or a stringent regulatory authority.
The Global Fund QA Policy

Number of Option A or B manufacturers producing equivalent products

- 2 or more manufacturers of equivalent products
- Less than 2 manufacturers of equivalent products

PR has to procure from one of the A or B suppliers

If products unavailable, PR informs Secretariat and then:

C1: Manufacturer has submitted an application to WHO Prequalification Project or a Stringent NRA and the manufacturing site is GMP compliant. IF NOT, THEN

C2: Manufactured in GMP compliant manufacturing facility.
Obligations

- **PR**
  - Promptly notify the Global Fund in writing if they plan to procure any products classified as Ci or Cii, before any delivery
  - Shall obtain documentation of the application and/or GMP compliance

- **Global Fund**
  - Contracted SGS laboratory (Belgium) to conduct random quality analysis of products procured under Option Ci and Cii

**Note:** PR is responsible for sampling and random quality control of products procured under Options A/B and multi-source products
• **Order of priority** for procurement of TB medicines is:
  – either Options A or B,
  – then option Ci, if less than 2 suppliers A and/or B
  – then option Cii, if less than 2 suppliers A, B and/or Ci

• Procurement of medicines classified as Ci and Cii is time-limited: PR shall revert to medicines classified as A or B as soon as 2 or more classified A or B become available.
The Global Fund List of TB products for first line treatment

Development of a list of limited and single source (first line) TB medicines found compliant with Global Fund Policy on Quality Assurance and classified according A,B,Ci,Cii options.

**Objective:**

providing recipients with information that will assist them in their procurement options for limited and single source medicines only.

http://www.theglobalfund.org/en/about/procurement/quality/

The List is not for use to pre-select and/or invite only manufacturers on the list to participate in any tender for supply of pharmaceutical products.

The List is updated on a regular basis: when new information is received from manufacturers and/or publication of monographs for finished products in Pharmacopeias.
To monitor compliance with the QA policy, it is paramount that purchases of TB medicines are reported in the Price Reporting Mechanism (PRM).

It is a requirement for PRs to notify the GF Secretariat before procuring single and limited-source pharmaceutical products that are classified according to category Ci and Cii.

Implementation of corrective measures if non-compliance with notification requirements for Ci and Cii.