

November 2009

GUIDE TO THE GLOBAL FUND'S POLICIES ON

# Procurement and Supply Management



Investing in our future

**The Global Fund**

To Fight AIDS, Tuberculosis and Malaria

# List of Terms

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<b>ARVs</b>	antiretrovirals
<b>ERP</b>	Expert Review Panel
<b>GDF</b>	Global Drug Facility
<b>GLC</b>	Green Light Committee
<b>LFA</b>	Local Fund Agent
<b>PR</b>	Principal Recipient
<b>PSM</b>	procurement and supply management
<b>TB</b>	tuberculosis
<b>TRIPS</b>	Trade-related Aspects of Intellectual Property Rights
<b>UNDP</b>	United Nations Development Programme
<b>UNFPA</b>	United Nations Population Fund
<b>UNICEF</b>	United Nations Children's Fund
<b>WHO</b>	World Health Organization
<b>WHOPES</b>	WHO Pesticide Evaluation Scheme

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# Introduction

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) was established to attract, manage and disburse additional resources through a new public/private partnership to make a sustainable and significant contribution to the reduction of infections, illness and death, thereby mitigating the impact caused by HIV, tuberculosis (TB) and malaria in countries in need and contributing to poverty reduction as part of the Millennium Development Goals. Access to and availability of health products – medicines, diagnostics and preventive technologies such as insecticide-treated nets and condoms, among others – are crucial in achieving this goal.

In order to improve access to effective and affordable pharmaceutical and other health products, the Global Fund has adopted a set of policies and principles on procurement and supply management that aim to support the timely procurement of quality-assured pharmaceutical and other health products in sufficient quantities, reduce cost inefficiencies, ensure the reliability and security of the distribution system, encourage appropriate use of health products and continuously monitor all procurement and supply management activities.

Procurement and supply management activities are fundamental to program performance. To avoid stock-outs and treatment disruption it is of paramount importance to carefully plan all such activities early enough and to react promptly to any problems that may arise.

The purpose of this guide is to explain the procurement and supply management policies for the benefit of Global Fund recipients. This new edition includes the revised Quality Assurance Policy for Pharmaceutical Products as approved by the Global Fund Board in November 2008, effective as of 1 July 2009.

## DEFINITIONS OF KEY TERMS

For purposes of clarity, this section provides the Global Fund's definition of some key terms.

### **Procurement and supply management:**

The term "procurement and supply management" refers to all activities required to ensure the continuous and reliable availability of sufficient quantities of quality-assured, effective products to end-users, procured at the lowest possible prices in accordance with national and international laws.

### **Health products:**

Health products include pharmaceutical products and other health products (such as bed nets, laboratory and radiology equipment, and supportive products) and single-use health products (such as condoms, rapid and nonrapid diagnostic tests, insecticides and injection syringes).

### **Pharmaceutical products:**

Pharmaceutical products include an active pharmaceutical ingredient in its finished dosage form that is intended for human use.

### **Nonhealth products:**

Nonhealth products refer to all products and services other than health products that are procured to support activities related to the procurement, distribution and use of health products, including but not restricted to vehicles, computers, construction materials and technical assistance.

Unless specific reference to Principal Recipients or sub-recipients is required, the term "recipients" is used in these guidelines to refer to all actors involved in procurement and supply management activities.

## **GLOBAL FUND PROCUREMENT AND SUPPLY MANAGEMENT POLICIES AND PRINCIPLES**

Procurement and supply management systems play an essential role in preventing treatment disruption for patients in need. The objective of the Global Fund procurement and supply management policies and principles is to ensure the efficient procurement, distribution and use of health products meeting agreed quality standards at the lowest possible price and in accordance with national and international laws

Procurement must be conducted in a competitive and transparent manner and in accordance with international pharmaceutical procurement guidelines as outlined in the interagency guidelines *Operational Principles for Good Pharmaceutical Procurement*.<sup>1</sup> In addition, the Principal Recipient shall ensure that the procurement and supply management complies with the principles set out in the interagency guidelines *A Model Quality Assurance System for Procurement Agencies*.<sup>2</sup>

The Global Fund recognizes that the varied situations found in grant recipient countries will result in programs being implemented differently. This document therefore does not present prescriptive procedures, but minimum standards to which recipients must adhere. In many cases there are different ways to comply with such standards. Recipients may use the means that are most appropriate to their programs.

## **RESPONSIBILITIES FOR PROCUREMENT AND SUPPLY MANAGEMENT**

Principal Recipients are responsible for ensuring that all procurement and supply management activities conducted under their grants – including those conducted by other entities such as sub-recipients and procurement agents – conform to Global Fund requirements as stipulated in the grant agreement. Principal Recipients are required to have systems in place to monitor the performance of other actors conducting procurement or supply management activities under their grants.

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<sup>1</sup> Operational principles for good pharmaceutical procurement [interagency document]. Geneva: World Health Organization (WHO); 1999. Document No.: WHO/EDM/PAR/99.5.

<sup>2</sup> UNDP; UNFPA; UNICEF; WHO; World Bank. A model quality assurance system for procurement agencies: recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products [interagency document]. Geneva: WHO; 2007. Document No.: WHO/PSM/PAR/2007.3. Available from: <http://www.who.int/medicinedocs/index/assoc/s14866e/s14866e.pdf>

## **HEALTH PRODUCTS OTHER THAN PHARMACEUTICAL PRODUCTS**

The principles for procurement and supply management as described in this guide also apply to health products other than pharmaceutical products (e.g. bed nets, condoms, diagnostics, insecticides) – namely that the Principal Recipient is required to conduct competitive and transparent purchasing in order to obtain quality assured, effective products at the lowest possible price in a timely manner.

For durable products the lowest possible price should take into account the total cost of ownership, which includes the cost of reagents and other consumables as well as costs for installation, training and regular maintenance. Procurement methods for durable products may include either lease or direct purchase. The recipient should ensure that service and maintenance of these products have been appropriately planned for.

## **NONHEALTH PRODUCTS**

This guide focuses on policies for health products. However, the same general principles that apply to health products – namely that the Principal Recipient is responsible for procurement, and is required to conduct transparent and competitive purchasing in order to obtain the lowest possible price for products of assured quality – are also applicable to the procurement and supply management of nonhealth products.

# Procurement and Supply Management Plan for Health Products

Once a proposal has been approved by the Global Fund Board and before grant disbursement for procurement and supply management activities is initiated, the Principal Recipient must submit for assessment and subsequent approval a procurement and supply management plan. The Principal Recipient should obtain a full understanding of the Global Fund's policies on procurement and supply management before preparing the plan. Principal Recipients are encouraged to consult the Global Fund website for further information on procurement and supply management and may contact their Fund Portfolio Manager for any additional clarifications required.

## **OBJECTIVE**

The procurement and supply management plan should provide information on the health products required by the program that will be funded under the new grant. It should describe (a) how the Principal Recipient will adhere to the Global Fund procurement and supply management policies and related provisions of the grant agreement; and (b) the systems and structures that will be used for managing these products for that grant. The Principal Recipient shall ensure that procurement under the program is carried out in accordance with the procurement and supply management plan. The procurement and supply management plan will also be used to review and monitor grant implementation.

## **CONTENTS**

The procurement and supply management plan should:

- describe how the Principal Recipient will ensure adherence to the Global Fund's procurement and supply management policies and principles;
- indicate which entity or entities will implement the various procurement and supply management activities;
- include details about the need for any technical assistance;

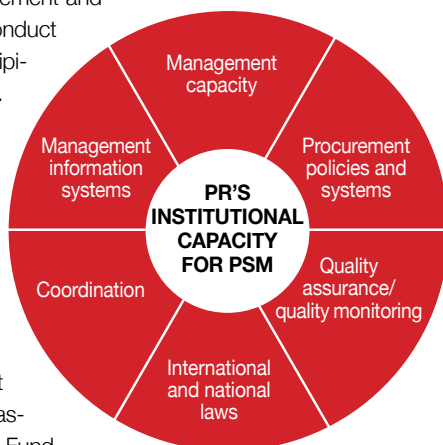


- if a country/Principal Recipient is receiving other sources of funding for the same disease, explain how the management of the products concerned will be coordinated and describe opportunities for national and/or regional coordination with other donors and partners;
- detail the activities of the procurement and supply management cycle as specified in the plan template;
- provide a list of key health products for the program as specified in the plan template, i.e. with their respective estimated quantities, unit costs with INCOTERM,<sup>3</sup> and total cost;
- include total cost of ownership for durable products, as well as cost associated with storage and distribution;
- encompass two years of implementation for new grants, and three years when submitting for grants in Phase 2 or under the Rolling Continuation Channel.

The procurement and supply management plan template is available on the Global Fund website at <http://www.theglobalfund.org/en/procurement/guide/>

## PROCUREMENT AND SUPPLY MANAGEMENT PLAN APPROVAL PROCESS

Once the Principal Recipient has completed the procurement and supply management plan, the Local Fund Agent will conduct a comprehensive assessment of the plan and of the recipient's overall capacity for health product management. The objective of these assessments is to verify whether the plan is adequate and whether the Principal Recipient has the minimum required capacity to handle health product management activities and/or oversee the management of such activities carried out by sub-recipients in accordance with Global Fund requirements. This appraisal is a combination of an off-site review of assessments previously conducted, and an on-site evaluation in which the Local Fund Agent assesses relevant systems available in country. The assessment tool and reporting format used by the Local Fund Agent are available at <http://theglobalfund.org/en/lfa/documents/>



<sup>3</sup> International commercial terms.

The Principal Recipient or the entity being assessed should note that:

- if the Local Fund Agent finds that the procurement and supply management plan is adequate and that the requirements for adequate capacity are met as well, the Global Fund Secretariat will be in a position to start disbursing funds for health product procurement;
- however if the Local Fund Agent determines that the procurement and supply management plan and/or associated capacities are inadequate, the Global Fund may request that the Principal Recipient revise the plan and/or associated implementation arrangements (see subsections on technical assistance and subcontracted procurement and supply management activities on pages 12-13)
- in the event that a procurement and supply management plan is still not of acceptable quality after two reviews by the Local Fund Agent, the Global Fund may request that the Principal Recipient contract technical assistance in preparing the plan. Grant funds may be used by the Principal Recipient to pay for technical assistance from specialized entities.

## **IMPLEMENTING AND MODIFYING THE PROCUREMENT AND SUPPLY MANAGEMENT PLAN**

The recipient shall ensure that procurement and supply management under the program is carried out in accordance with the approved procurement and supply management plan.

Since the procurement and supply management plan covers two or three years of implementation, changes in the selection or the quantities of health products to be procured or the implementation arrangements may occur for various reasons, including changes in national or international treatment guidelines. With respect to significant changes, the Principal Recipient is required to highlight the proposed modifications and provide the Global Fund with a written rationale for them. The Local Fund Agent will assess the rationale and provide its recommendations to the Global Fund, which will confirm whether these changes are acceptable.

# Ensuring Adequate Health Product Management

In the event that their pharmaceutical and other health product management capacity is found insufficient by the Local Fund Agent, recipients have several options.

## **Technical assistance to strengthen procurement and supply management capacity**

Global Fund recipients may need technical assistance in order to successfully implement their programs. In the area of procurement and supply management, recipients may lack adequate capacity to conduct the required activities. Recipients may contract technical assistance where required for any procurement and supply management-related activity using grant funds budgeted for technical assistance. For instance, recipients could contract a supply chain management specialist to assist with strengthening the storage and distribution system, or an intellectual property rights specialist for analysis of the effects of national and international laws on the procurement process.

## **Subcontracted procurement and supply management activities**

- Subcontract (certain) functions to specialized agencies, e.g. procurement to procurement agencies or the Global Fund Voluntary Pooled Procurement service, storage and distribution to a supply chain management agent;
- Subcontract (certain) functions to specialized agencies while simultaneously building internal capacity. Capacity-building services and supply chain management assistance are also available through the Global Fund procurement support services.

Principal Recipients are also free to subcontract procurement and supply management activities even if the Local Fund Agent finds that adequate associated capacities exist. Subcontracted agencies should have acceptable capacity for the purposes of warehousing,

procurement, quality assurance or any other relevant function, and their selection should be conducted in a competitive and transparent manner. The Global Fund, through the Local Fund Agent, determines whether the proposed agency has the relevant capacity and can operate in accordance with Global Fund policies.

Even where the recipient has adequate procurement capacity, the use of capable regional and global procurement services (such as the Voluntary Pooled Procurement service) is encouraged wherever pooling of the recipient's requirements with those of other purchasers results in economies of scale and more coordinated and cost-effective procurement for products of assured quality.

### **Global Fund procurement support services**

To facilitate the timely access to health products required to implement Global Fund-supported programs the Global Fund has established procurement support services for its recipients, which include a Voluntary Pooled Procurement mechanism and capacity building services and supply chain management assistance. These services, which adhere to Global Fund procurement and supply management policies and principles, are made available to help address procurement bottlenecks and supply chain management challenges affecting grant performance.

The Voluntary Pooled Procurement mechanism is the short-term strategy whereby Principal Recipients can take advantage of the benefits of pooled purchasing to procure their health products through a cost-effective, efficient and reliable procurement mechanism. The capacity building services and supply chain management assistance provide technical support to enable countries to develop and/or strengthen their systems for efficient and sustainable procurement and supply chain management. Takeup of these services is on a voluntary basis and additional information is provided on the Global Fund procurement support services website at: <http://www.theglobalfund.org/en/procurement/vpp/>

### **PROCUREMENT FOR MULTIDRUG-RESISTANT TUBERCULOSIS**

To help limit resistance to second-line TB drugs and to be consistent with the policies of other international funding sources, all procurement of pharmaceutical products to treat multidrug-resistant TB must be conducted through the Green Light Committee (GLC) of the Stop TB Partnership. The Global Drug Facility (GDF) coordinates all procurement and delivery functions for all GLC-approved programs.

More information on the GLC and GDF can be obtained from the World Health Organization (WHO) representative in the recipient country or from <http://www.who.int/tb/challenges/mdr/en/index.html> and <http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/>

## **PROCUREMENT SYSTEMS**

### **Efficient and transparent management**

Different procurement and supply management activities and responsibilities (product selection, forecasting, product specification, prequalification of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function, avoiding at all levels any possible conflicts of interest.

Procurement and supply management activities should be planned properly and performance should be monitored regularly.

Procurement procedures should be transparent, follow formal written procedures throughout the process and use explicit predefined criteria to award contracts. Annual external audits to verify procurement office accounting records are required to ensure transparency and compliance with procurement policies.

### **Financing and competition**

Mechanisms should be put in place to ensure reliable financing for the procurement of products required by end-users. Good financial management procedures should be followed to maximize the use of financial resources.

### **Competitive procurement methods: lowest possible price**

Procurement should be based on competitive and transparent procurement methods in order to achieve the lowest price possible for quality-assured products, except in the case of small or emergency orders. In addition procurement should be effected in the largest possible quantities reasonable under the requirements of the program in order to achieve economies of scale.

Recipients should also, upon request of the Local Fund Agent, demonstrate the existence of a full set of contractual documentation to govern each transaction.

## **MONITORING PROCUREMENT PERFORMANCE**

The Principal Recipient shall monitor the performance of suppliers with respect to the quality of the goods and services they supply. The Principal Recipient is required to submit procurement information for key health products to the Global Fund electronically for publication over the Internet through the Price & Quality Reporting mechanism.

## Price & Quality Reporting

The Price & Quality Reporting system is designed to keep track of procurement and quality information for key health products procured with Global Fund financing.

The system provides Principal Recipients, the Global Fund and other interested parties with the opportunity to compare prices and conditions achieved across grants, countries and regions. In addition it forms a basis for stakeholders to develop long-term demand forecasts.

Currently six categories of health products procured with grant funds are required to be reported by Principal Recipients:

- antiretrovirals (ARVs)
- antimalarial pharmaceutical products
- anti-TB pharmaceutical products
- bed nets
- condoms
- rapid diagnostic tests.

Upon receipt in the country of any such health products purchased with grant funds, the Principal Recipient shall promptly report to the Global Fund the prices it has paid and other information related to the quality of these products, using the Price & Quality Reporting system available on the website of the Global Fund at <http://pqr.theglobalfund.org>.

**The Global Fund is monitoring Principal Recipient compliance with Price & Quality Reporting requirements. Disbursement of grant funds is subject to compliance. The Local Fund Agent monitors the data entered by the Principal Recipient for completeness and accuracy.**

Quality assurance refers to the management activities required to ensure that the pharmaceutical products and other health products that reach patients are safe, effective and acceptable to the patient. These activities may include, but are not limited to, approval by national drug regulatory authorities, prequalification, quality control and good storage and distribution practices. In addition to the quality assurance requirements for pharmaceuticals, this section outlines the requirements for nonpharmaceutical health products.

# Quality Assurance

## **PROCUREMENT PRACTICES TO ASSURE QUALITY**

In addition to the Global Fund's existing policies for procurement practices, Principal Recipients must ensure that all pharmaceutical products are procured in accordance with the principles set out in the interagency guidelines *A Model Quality Assurance System for Procurement Agencies*.<sup>2</sup>

## **COMPLIANCE WITH NATIONAL REGULATIONS**

Pharmaceuticals and other health products procured with Global Fund resources must at all times comply with national regulations and, where applicable, be authorized by the national drug regulatory authority in the country in which they are used, following its standard practices for registration (or other forms of authorization, such as authorizations for special use).

National drug regulatory authorities are encouraged to expedite registration by accepting, in lieu of national requirements, the WHO prequalification inspection and supporting dossiers or the executive summary of the common technical document or summary parts for quality, safety and efficacy, (for products procured under Option A below), together with all necessary information to perform quality control testing of products and necessary reference standards (for products procured under Option B below).

## **QUALITY STANDARDS FOR PHARMACEUTICAL PRODUCTS<sup>4</sup>**

Grant funds may only be used to procure finished pharmaceutical products that have been authorized for use by the national drug regulatory authority in the country where the products will be used.

<sup>4</sup> The Global Fund Board revised its Quality Assurance Policy for Pharmaceutical Products at its eighteenth meeting November 2008 and at its twentieth meeting (November 2009). Available from: [www.theglobalfund.org/en/procurement/quality/](http://www.theglobalfund.org/en/procurement/quality/)

## **Additional quality standards for antiretrovirals, antimalarial and/or anti-TB pharmaceutical products**

In addition to the requirement for authorization from the national drug regulatory authority, grant funds may only be used to procure ARVs, antimalarial and/or anti-TB pharmaceutical products that meet one of the following quality standards:

- the product is prequalified under the WHO Prequalification Programme (Option A) or authorized for use by a stringent drug regulatory authority (see Annex) (Option B);<sup>5</sup> or
- the product has been recommended for use by the Expert Review Panel, as described in paragraph below.

Such products may only be procured with grant funds in accordance with the selection process specified below.

## **SELECTION PROCESS FOR PROCURING ANTIRETROVIRALS, ANTIMALARIAL AND/OR ANTI-TB PHARMACEUTICAL PRODUCTS**

- If there are two or more finished pharmaceutical products available<sup>6</sup> for the same product formulation that are either prequalified by WHO or authorized for use by a stringent drug regulatory authority, the Principal Recipient may only use grant funds to procure a product which meets either of those standards.
- If a Principal Recipient determines that there is only one or no finished pharmaceutical product available which is prequalified by WHO or authorized for use by a stringent drug regulatory authority and it wishes to use grant funds to procure an alternate product, it must request confirmation from the Global Fund that the Principal Recipient's determination is accurate and that the alternate product is eligible for procurement based on the advice of the Expert Review Panel.<sup>7</sup> If the Global Fund provides this confirmation the Principal Recipient may enter into a contract with a supplier for the procurement of such an alternate product at any time until the end of the panel's recommendation period. In any case, the duration of the contract

<sup>5</sup> Either approved or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union regulation (EC) No. 726/2004 or United States FDA tentative approval.

<sup>6</sup> Available means the manufacturer can supply the requested quantity of the finished pharmaceutical product within not less than 90 days of the requested delivery date.

<sup>7</sup> The Expert Review Panel was created at the request of the Global Fund and is hosted by WHO. Its purpose is to review the potential risks/benefits associated with the use of a finished pharmaceutical product that is not yet WHO pre-qualified or authorized for use by a stringent drug regulatory authority.

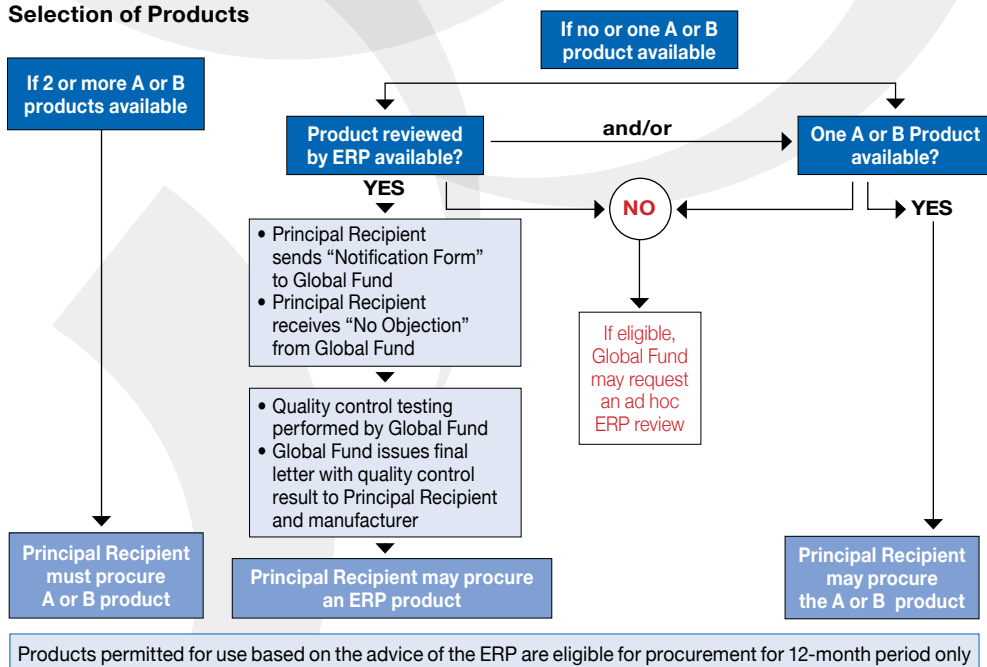


shall not exceed 12 months, i.e. the Principal Recipient may not place an order for that product under the contract more than 12 months, after the contract was signed.

The Global Fund will maintain on its website an up-to-date list of all products eligible for procurement based on the advice of the Expert Review Panel.<sup>8</sup> If a Principal Recipient requests to procure an eligible product that does not appear on the list, the Global Fund shall invite the manufacturer to submit an application, together with the required documentation, for review by the panel.

Recommendations by the Expert Review Panel are valid for 12 months during which time the product is expected to obtain prequalification from the WHO or authorization from a stringent drug regulatory authority. Under exceptional circumstances the Global Fund may request the panel to consider extending its recommendation period for an additional 12-month period.

## Selection of Products



<sup>8</sup> Available from: <http://www.theglobalfund.org/en/procurement/erpproducts/?lang=en>

## MONITORING QUALITY OF FINISHED PHARMACEUTICAL PRODUCTS

The quality of finished pharmaceutical products procured with Global Fund grant funds must be monitored. The cost of conducting quality control activities may be budgeted for in the Global Fund grant. Principal Recipients must submit to the Global Fund the results of quality control tests, which may be made publicly available by the Global Fund.

In collaboration with the national drug regulatory authority, Principal Recipients must ensure that random samples of finished pharmaceutical products are obtained at different points in the supply chain – from initial receipt of the products in country to delivery to end-users – for the purpose of monitoring their quality. Such samples must be sent for quality control testing to national drug regulatory authority laboratories or laboratories recognized by the national authority, WHO-prequalified laboratories or Global Fund-contracted laboratories.

To ensure the national drug regulatory authority laboratories or laboratories recognized by the national authority have adequate capacity for full pharmacopoeial testing, they must meet one of the following criteria:

- prequalified by the WHO Prequalification Programme (see annex), or
- accredited in accordance with ISO17025.

The Global Fund will provide guidance that may be used for quality control testing and reporting of results.<sup>9</sup> Technical assistance aimed at strengthening national drug regulatory authority laboratories or laboratories recognized by the national authority may be budgeted for in Global Fund proposals.

### **Finished pharmaceutical products eligible for procurement based on the advice of the Expert Review Panel**

When a Principal Recipient procures a finished pharmaceutical product that has been permitted for use based on the advice of the Expert Review Panel, the Global Fund will make the necessary arrangements for randomly selected samples of the product to be tested for quality control purposes (in accordance with advice provided by the ERP) prior to the delivery of that product by the manufacturer to the designated recipient. The Principal Recipient will ensure that its contract with the manufacturer affords the Global Fund and its authorized agents access rights that allow for such sampling to be undertaken. The cost of the sampling and testing of the product will be borne by the Global Fund.

## **QUALITY STANDARDS FOR HEALTH PRODUCTS OTHER THAN PHARMACEUTICAL PRODUCTS**

Grant funds may be used to procure health products other than pharmaceutical products only if they are selected from lists of prequalified products (if any) and comply with quality standards applicable in the country where such products will be used (if any).

### **Quality standards for long-lasting insecticidal nets**

Grant funds may only be used to procure long-lasting insecticidal nets that are recommended for use by the WHO Pesticide Evaluation Scheme (WHOPES).<sup>10</sup>

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<sup>10</sup> Available from: [http://www.who.int/whopes/Long\\_lasting\\_insecticidal\\_nets\\_Jan09.pdf](http://www.who.int/whopes/Long_lasting_insecticidal_nets_Jan09.pdf)

## National and International Laws

Recipients must procure their products in accordance with national and international laws. The Global Fund encourages recipients to apply the flexibilities provided within national laws and in the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), as interpreted in the Declaration on the TRIPS Agreement and Public Health (Doha Declaration), to achieve the lowest possible price for products of assured quality.

In the event that a Principal Recipient does not have the requisite capacity to assess the national and international intellectual property rights issues that apply to the desired products in their country, it may contract the necessary expertise using funds budgeted for this purpose in the Global Fund grant.

## Coordination

To facilitate adequate use of resources and prevent stock-outs and treatment disruption, the Global Fund encourages the harmonization and coordination of efforts regarding the management of pharmaceuticals and other health products where applicable. In cases where a recipient is receiving other sources of funding for the procurement of products for the same disease component, the recipient must indicate how the various streams of funding – such as from UNITAID or basket funds – will be utilized, e.g. funding for first-line versus for second-line ARVs, funds for additional geographical areas not targeted by the Global Fund grant. Although the detailed funding arrangements are not required, a detailed explanation of how the procurement and supply management of the health products provided by various donors will be planned, coordinated and monitored is required.

# Management Information Systems

Recipients should ensure that there is a system in place to collect and report on both patient- and inventory-related information. This information should be analyzed and used to guide decision-making, e.g. on future procurements, distribution requirements, requests for additional funding.

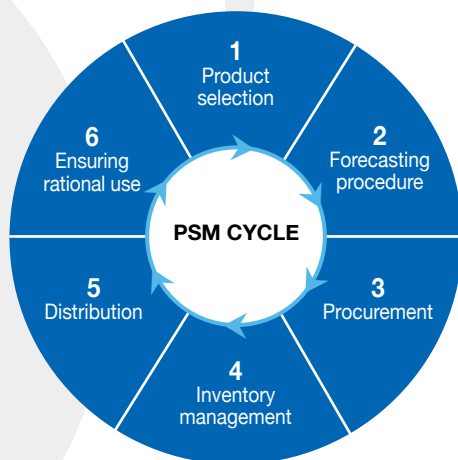
In the event that a Principal Recipient does not have the requisite capacity in management information systems, it may contract the necessary technical assistance using funds budgeted for this purpose in the Global Fund grant.

# Procurement and Supply Management Cycle

The Global Fund requires that procurement and supply management conducted by or under the responsibility of Principal Recipients adhere to principles outlined in the interagency guidelines *Operational Principles for Good Pharmaceutical Procurement*<sup>1</sup> and interagency guidelines *A Model Quality Assurance System for Procurement Agencies*.<sup>2</sup> Where practices differ from these interagency guidelines, recipients must demonstrate to the Local Fund Agent that there are:

- comparable systems for competitive procurement, e.g. within a group of prequalified suppliers;
- transparent and accountable practices; and
- appropriate quality assurance mechanisms in procurement and throughout the supply chain.

The interagency guidelines and the Global Fund's own guidelines are summarized below; for more details Principal Recipients should refer to the interagency guidelines.



## SELECTION OF MEDICINES

Global Fund grant funds may only be used to procure medicines that appear in current national or institutional standard treatment guidelines or essential medicines list, or the WHO standard treatment guidelines or essential medicines list.

A Principal Recipient must submit a technical justification to the Global Fund if it would like to procure a medicine that:

- was not specified in the grant proposal approved by the Global Fund; and
- is included in the relevant national or institutional standard treatment guidelines or essential medicines list but not in those of WHO, or vice versa. The Global Fund Secretariat may, if it deems necessary, refer that technical justification to the Global Fund Technical Review Panel for review.

Medicines should always be listed by their international nonproprietary name, i.e. their generic name.

## FORECASTING OF NEEDS

Order quantities for health product procurement should be based on reliable estimates of actual need. Principal Recipients should justify the forecasting of needs, explaining the methodology as well as the data, information and assumptions used. The recipient must systematically and regularly update forecasts of the quantities of health products needed for the program. At the time of procurement Principal Recipients should review the quantities actually required against what was forecast.

Initial forecasts for new activities may be based on morbidity, adjusting for the potential demand in light of realistic estimates of the anticipated capacity to deliver services. Forecasts for ongoing activities should generally be based on past consumption data.

## INVENTORY MANAGEMENT

Recipients should ensure that systems meeting the minimum requirements as outlined in internationally recognized standards for good storage practices are in place as referenced in the guidelines *Model Quality Assurance System for Procurement Agents* (Module 4).<sup>11</sup>

<sup>11</sup> WHO Expert Committee on Specifications for Pharmaceutical Preparations. *Guide to good storage practices for pharmaceuticals*. Thirty-seventh Report. Geneva: WHO; 2003. Technical Report Series; no. 908. Annex 9. Available from: [http://Whqlibdoc.who.int/trs/WHO\\_TRS\\_908.pdf](http://Whqlibdoc.who.int/trs/WHO_TRS_908.pdf)

Recipients should also ensure that sufficient storage space and storage conditions are available at all levels of the distribution chain. Total storage capacity available should take into account additional procurement under the Global Fund grant as well as current procurement and other in-country activities.

The recipient should minimize the risk of stock-outs through effective management of procurement and inventory levels, which should include but are not limited to appropriate order quantity, buffer stock, storage capacity, conditions and logistic management information systems.

In addition recipients must implement procedures that will avoid the diversion of Global Fund-financed health products from their intended and agreed-upon purpose, and that provide adequate management of the products. These procedures should include the establishment and maintenance of reliable inventory management and management information systems, internal audit systems and good governance structures.

## **DISTRIBUTION**

Recipients should ensure that systems meeting the minimum requirements as outlined in internationally recognized standards for good distribution practices are in place as referenced in the guidelines *Model Quality Assurance System for Procurement Agencies* (Module 5).<sup>2</sup>

Health products should be transported in such a way that their integrity is not impaired and storage conditions are maintained.

Vehicles and equipment used to distribute, store or handle health products should be suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their stability and packaging integrity, and prevent contamination of any kind. Every precaution should be taken to minimize the risk of theft and fraud.

The procurement and supply management plan should also provide detailed information on distribution plans, differentiating the different levels of the supply system (central medical stores, regional stores and treatment sites).



## RATIONAL USE OF HEALTH PRODUCTS

Recipients must ensure that mechanisms are in place to ensure health worker adherence to programmatic guidelines (e.g. prescriber adherence to treatment guidelines) and to encourage patient adherence to treatment (e.g. the use of fixed-dose combinations, once-a-day formulations, blister packs, and peer education and support).

In addition recipients must ensure that systems are in place to monitor and contain resistance and to monitor (and treat) adverse drug reactions according to existing international guidelines<sup>12</sup> (pharmacovigilance). The cost of such activities may be included in the Global Fund grant budget.

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<sup>12</sup>E.g. Uppsala Monitoring Centre. *The importance of pharmacovigilance: safety monitoring of medical products*. Geneva: WHO; 2002. Available from: <http://www.who.int/medicinedocs/en/d/Js4893e/>. *Safety of medicines: a guide to detecting and reporting adverse drug reactions*. Geneva: WHO. Document No.: WHO/EDM/QSM/2002.2. Available at: <http://Apps.who.int/medicinedocs/en/d/Jh2992e>

## Annex

**Stringent drug regulatory authorities are regulatory authorities participating in the international conference on harmonization of technical requirements for registration of pharmaceuticals for human use (ICH) ([www.ich.org](http://www.ich.org)):**

- **MEMBERS:** European Medicines Agency - on behalf of European Union member states, Japan and the United States.
- **OBSERVERS:** European Free Trade Association represented by Swiss Medic and Health Canada (observers may change from time to time).
- **ASSOCIATES** through mutual recognition agreements: Australia, Norway, Iceland and Liechtenstein (associates may change from time to time).
- Three special regulatory schemes offer stringent assessment of medicines used exclusively outside the ICH region.<sup>5</sup>

**Quality Control laboratories prequalified by the WHO Prequalification Programme:**

quality control laboratories that meet international norms and standards for the analysis of products and prequalified by WHO are available at: [http://apps.who.int/prequal/lists/PQ\\_QCLabsList.pdf](http://apps.who.int/prequal/lists/PQ_QCLabsList.pdf)



## **The Global Fund to Fight AIDS, Tuberculosis and Malaria**

Chemin de Blandonnet 8  
1214 Vernier  
Geneva, Switzerland

phone +41 58 791 1700  
fax +41 58 791 1701

[www.theglobalfund.org](http://www.theglobalfund.org)  
[info@theglobalfund.org](mailto:info@theglobalfund.org)

ISBN 92-9224-188-5