November 2006

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 & Abbreviations

CCM	Country Coordinating Mechanism
CTD	Common technical document
EML	Essential medicines list
GLC	Green Light Committee
GMP	Good manufacturing practices
ICH	International Conference on Harmonization
INN	International Non-proprietary Name
LFA	Local Fund Agent
MDGs	Millennium Development Goals
MDR-TB	Multidrug-resistant tuberculosis
NDRA	National Drug Regulatory Authority
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PR	Principal Recipient
PSM	Procurement and supply management
STG	Standard treatment guidelines
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TCO	Total cost of ownership
WHO	World Health Organization

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Introduction

The Global Fund to Fight AIDS, Tuberculosis and Malaria (henceforth referred to as the Global Fund) was established to attract, manage and disburse additional resources through a new public/private partnership that will make a sustainable and significant contribution to the reduction of infections, illness and death, thereby mitigating the impact caused by HIV/AIDS, tuberculosis 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 bed nets and condoms, among others – will be crucial in achieving this goal.

In order to provide medicines and other health products to as many people as possible, the Global Fund has adopted a set of policies and principles on procurement and supply management (PSM) that aim to support the procurement of quality-assured medicines 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 and evaluate the procurement process. The purpose of this guide is to explain those policies for the benefit of Global Fund recipients.

GLOBAL FUND PROCUREMENT POLICIES AND PRINCIPLES

The central objective of Global Fund procurement policies is to procure quality-assured products at the lowest price and in accordance with national and international law. Procurement must be conducted in a transparent fashion.

The Global Fund Board has identified several guiding policies and principles with which recipients needs to comply. The Global Fund recognizes that the varied situations found in grant recipient countries will result in programs being implemented differently. To this end, this document 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, therefore, choose the means that are most appropriate to their programs.

RESPONSIBILITIES FOR PROCUREMENT AND SUPPLY MANAGEMENT

Principal Recipients (PRs) are responsible for ensuring that all procurement and supply management conducted under its grant(s), including that conducted by other entities (such as sub-recipients), conforms to Global Fund requirements. Hence PRs are required to have systems in place to monitor the performance of other actors conducting procurement or supply management under the program. Although PRs are the ones ultimately responsible, this guide is written for the benefit of both PRs and other actors as all recipients (including sub-recipients) are governed by the same policies. Unless specific reference to either type of Global Fund recipient is required, the term "recipients" is used in these guidelines to refer to all actors involved in the procurement and supply management process.

DEFINITIONS OF KEY TERMS

For purposes of clarity, this section provides the Global Fund's definition of three key terms: "procurement and supply management", "health products", and "non-health products".

The Global Fund uses the following definition of "procurement and supply management":

The term "procurement and supply management" refers to all management activities required for getting sufficient health products of assured quality procured at the lowest price and in accordance with national and international laws to the end users in a reliable and timely fashion.

The following definition is used for "health products":

The term "health products" includes pharmaceutical products, diagnostic technologies and supplies, bed nets, insecticides, aerial sprays against mosquitoes, other products for prevention (e.g., condoms) or laboratory equipment and supportive products (e.g., microscopes and reagents).

The following definition is used for "non-health products":

The term "non-health products" refers to all products other than "health products", including vehicles, computers, construction materials, and services (including technical assistance).

NON-HEALTH PRODUCT PROCUREMENT

Most of this guide focuses on policies on health products. However, the same general principles that apply to health products – namely that the PR is responsible for procurement, and is required to conduct 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 non-health products.

HEALTH PRODUCTS OTHER THAN PHARMACEUTICALS

The principles for procurement and quality assurance of pharmaceuticals, as described in this guide, also apply to diagnostics and other non-pharmaceutical health products (e.g., bed nets, insecticides, etc.): namely that the PR is responsible for procurement, and is required to conduct competitive purchasing in order to obtain the lowest possible price for products of assured quality.

For durable products, the lowest possible price should take into account the total cost of ownership (TCO). TCO includes the cost of reagents and other consumables as well as costs for annual maintenance.

Procurement methods for durable products may include either lease or purchase. The recipient should have a plan for service and maintenance of these products.

TECHNICAL ASSISTANCE FOR PROCUREMENT

Global Fund recipients may need technical assistance in order to successfully implement their proposals. In the area of procurement and supply management, recipients may lack adequate capacity to conduct responsible procurement of the magnitude and complexity as financed by the Global Fund. Recipients may therefore contract technical assistance in the area of procurement (where required) using funds budgeted in the grant. For instance, recipients could contract a supply chain management specialist to assist with strengthening the distribution system to safely and securely handle new products, or an intellectual property specialist for analysis of the effects of national and international laws on the procurement process.

Procurement and supply management plan

Once a proposal has been approved, a PR must describe how it will adhere to the Global Fund's procurement requirements in a basic Procurement and Supply Management (PSM) Plan. The PR should obtain a full understanding of this *Guide to the Global Fund's Policies on Procurement and Supply Management* before preparing the PSM plan.

OBJECTIVE

The objective of the PSM plan for health products is to outline how the PR will adhere to the Global Fund's procurement policies. The plan will also be used to measure performance during implementation.

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The PSM plan should:

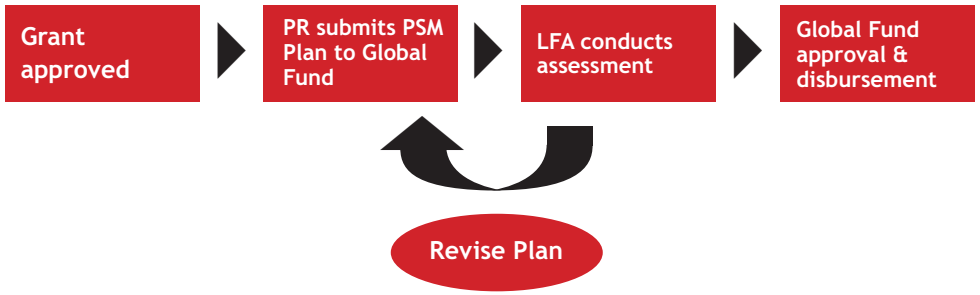
- Indicate which entity or entities will implement relevant procurement and supply management activities;
- Describe how the PR will ensure adherence to each of the Global Fund's procurement policies;
- Include a list of key health products with their respective estimated quantities, cost, registration status and patent status;
- Include details about technical assistance requested;
- Encompass two years of implementation.

The plan should be no more than 20 pages long.

TOWARDS DISBURSEMENT FOR PROCUREMENT

Once a PR has completed its PSM plan, the Local Fund Agent (LFA) will conduct a PSM assessment (and may make recommendations on capacity building). If the LFA finds that the PSM plan is adequate, and if all other relevant requirements (not related to procurement and supply management) are met as well, the Global Fund Secretariat may decide to start disbursements of funds for health product procurement.

However, if the LFA determines that the PSM plan is inadequate, the Global Fund will request that the PR revise the PSM plan; these steps are illustrated in the following figure:



QUALITY OF PROCUREMENT AND SUPPLY MANAGEMENT PLAN

In the event that a PSM Plan is not of acceptable quality after two reviews by the LFA, the Global Fund may request that the PR contract technical assistance in preparing the plan. Grant funds may be used by the PR to pay for technical assistance from specialized entities. If, despite these measures, the PR fails to develop an acceptable PSM Plan, the Country Coordinating Mechanism (CCM) may be asked to identify an alternate PR.

MODIFYING THE PROCUREMENT PLAN DURING IMPLEMENTATION

Since the PSM Plan covers two years of 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.

Procurement systems

The Global Fund requires that procurement conducted by or under the responsibility of PRs adhere to the Interagency Guidelines:Operational Principles for Good Pharmaceutical Procurement[1]. Where practices differ from the Interagency Guidelines, recipients must demonstrate to the LFA that there are: comparable systems for competitive bidding, (e.g. within a group of pre-qualified suppliers), transparent and accountable practices and appropriate quality assurance mechanisms. The Interagency Guidelines and the Global Fund's own guidelines are summarized below; for more details the reader should refer to the Interagency Guidelines.

PROCUREMENT SYSTEM MANAGEMENT CAPACITY

As part of a comprehensive assessment of the PR's capacities, the PSM plan and the PR's procurement and supply management capacity is assessed by the LFA. The objective of this assessment is to verify whether the PR has the minimum required capacity to handle procurement and supply management in accordance with Global Fund requirements. This assessment is a combination of an off-site review of assessments previously conducted, and an on-site assessment, in which the LFA assesses relevant systems in-country. The assessment tool and reporting format used by the LFA are available at www.theglobalfund.org.

SUBCONTRACTED PROCUREMENT AGENCY

In the event that local procurement and supply management capacity is insufficient, recipients have three options:

a) Start procurement and supply management activities only after appropriate capacity is established;
b) Subcontract (certain) functions to specialized agencies;
c) Subcontract (certain) functions to specialized agencies while simultaneously building internal capacity.

[1] Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement. WHO, Geneva, 1999. WHO/EDM/PAR/99.5 http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip49e/whozip49e.pdf

PRs are also free to subcontract PSM activities even if the assessment finds that adequate capacity exists. The PR may subcontract PSM activities to an agency with acceptable capacity for the purposes of warehousing, procurement, quality assurance, or any other relevant function, provided the selection is conducted in a competitive and transparent manner. The Global Fund neither endorses nor recommends specific agencies and it will, through the LFA, determine whether the proposed agency has the capacity for procurement and supply management in accordance with Global Fund policies.

Even where the recipient has adequate procurement capacity, the use of capable regional and global procurement services is encouraged wherever pooling of the recipient's requirements with those of other purchasers results in lower prices for products of assured quality.

TRANSPARENT AND FORMAL WRITTEN PROCEDURES

Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection 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.

As stated, procurement procedures should be transparent, follow formal written procedures throughout the process and use explicit criteria to award contracts. Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources. Recipients should also, upon request of the LFA, demonstrate the existence of a full set of contractual documentation to govern each transaction.

COMPETITIVE PROCUREMENT METHODS: LOWEST PRICE

Procurement should be based on competitive procurement methods in order to achieve the lowest price, 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.

PRODUCT SELECTION

Global Fund resources may be used only to procure medicines that appear in current national, institutional or World Health Organization (WHO) standard treatment guidelines (STGs) or essential medicines lists (EMLs). Unlisted products may be procured only if the PR states a specific rationale for doing so in its proposal to the Global Fund. Medicines should always be listed by their International Non-proprietary Name (INN) (i.e., their generic name).

FORECASTING OF NEEDS

Order quantities for health products procurement should be based on reliable estimates of actual need. The recipient must systematically and regularly update forecasts of the quantities of pharmaceutical and other health products needed for the program.

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

Quality assurance

Quality assurance refers to the management activities required to ensure that the medicines (or other health products) that reach patients are safe, effective and acceptable to the patient. These activities may include, but are not limited to, (medication) registration, pre-qualification and quality control. In addition to the quality assurance requirements for pharmaceuticals, this section outlines the requirements for non-pharmaceutical health products.

ROLE OF NATIONAL DRUG REGULATORY AUTHORITY

Pharmaceuticals procured with Global Fund resources are subject to authorization by the National Drug Regulatory Authority (NDRA) in the country in which they are used, following its standard practices for drug registration (or other forms of authorization, such as authorizations for special use) for pharmaceutical products.

MULTI-SOURCE PHARMACEUTICAL PRODUCTS

Multi-source pharmaceutical products are pharmaceutically equivalent products that may or may not be therapeutically equivalent. Multi-source pharmaceutical products that are therapeutically equivalent are interchangeable. Multi-source pharmaceutical products tend to be available from a wide range of manufacturers around the world.

They are off-patent products with publicly available quality assurance standards, analytic methods and reference substances for the finished dosage form; that is, for which there is monograph for finished dosage form publicly available in one or more Pharmacopoeias (e.g., British Pharmacopoeia, United States Pharmacopoeia and others).

Quality assurance standards are publicly available for most medicines necessary to the control of tuberculosis and malaria and to manage opportunistic infections in HIV/AIDS.

For such multi-source products, there are no additional requirements other than (as described above) that verification of compliance with quality standards must be conducted in accordance with relevant requirements of the NDRA in the recipient's country.

SINGLE- AND LIMITED-SOURCE PHARMACEUTICAL PRODUCTS

Single- and limited-source pharmaceuticals are products for which there are no publicly-available quality assurance standards, analytic methods, and reference substances for the finished dosage form; that is, for which there is no publicly available monograph for finished dosage form in the International Pharmacopoeia, the British Pharmacopoeia or the United States Pharmacopoeia.
Grant funds may be used to procure a single- or limited-source pharmaceutical product provided that such product meets one of the following standards:

a) Have been found to be acceptable by the UN Procurement Quality and Sourcing Project (also known as the WHO Prequalification Project[2]); or
b) Have been authorized for consumption in their country by a stringent regulatory authority[3]; or
c) Have been authorized by the NDRA in the recipient's country, provided that this clause shall only apply until 30 April 2005.

After 30 April 2005 grant funds may only be used to procure single or limited-source pharmaceutical products that meet the requirements of the two standards set out in a) and b), provided that:

(1) Contracts entered into by the PR on or before 30 April 2005 with suppliers for products that qualified for purchase under clause c) may be honoured until such contracts expire or otherwise terminate.

(2) After 30 April 2005, the PR may not enter into any new contracts, nor extend any existing contracts, for the supply of products that would have qualified for purchase under clause c) prior to 30 April 2005.

(3) If the PR determines that there is only one or no equivalent pharmaceutical product that meets the standards of either a) or b), or if the PR determines that the products that meet these standards are unavailable (a product is defined as "unavailable" when its manufacturer is unable to supply a sufficient quantity of the finished product within 90 days of the date of order) and represents the same to the Global Fund, and the Global Fund does not object, then grant funds may be used to procure another equivalent pharmaceutical product, provided that such product is selected in accordance with the following, in order of priority:

[2] See: www.who.int/medicines and http://mednet3.who.int/prequal/
[3] For the purposes of this policy, a "stringent drug regulatory authority" is defined as a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and/or the International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. See the Annex for a list of these countries.

i) the manufacturer has submitted an application for approval of such product to the WHO Prequalification Program or a stringent regulatory authority and such product is manufactured at a site that is compliant with the standards of good manufacturing practices (GMP), as certified (after inspection) by the WHO or a stringent regulatory authority; or

ii) if the manufacturer of such product has not submitted an application for approval of such product to the WHO Prequalification Program or a stringent regulatory authority, such product is manufactured at a GMP-compliant manufacturing site, as certified (after inspection) by the WHO or a stringent regulatory authority.

If the PR intends to procure products pursuant to the criteria in clause 3 (i) or (ii) above, the PR shall promptly notify the Global Fund in writing, prior any delivery of such products.

(4) Procurement of products according to criteria in clause 3) (i) or (ii) above should be time-limited and the PR should procure products meeting the criteria in clauses a) or b) above as soon as possible.

For products that have passed the WHO Prequalification Project review, NDRAs are encouraged to expedite registration by accepting this WHO pre-qualification inspection and supporting dossiers in lieu of national requirements.

For products that have been authorized by stringent drug regulatory authorities, NDRAs are encouraged to expedite registration by accepting, in lieu of national requirements, the Executive Summary of the Common Technical Document (CTD) or summary parts for quality, safety and efficacy together with all necessary information to perform quality control testing of products and necessary reference standards.

QUALITY CONTROL REQUIREMENTS FOR PHARMACEUTICALS

For all pharmaceutical products

As an element of quality assurance, quality control refers to the testing of samples against specific standards of quality. The entity responsible for quality assurance under a grant must systematically draw samples of each pharmaceutical batch purchased with Global Fund resources. Samples should randomly be subjected to quality control testing in order to monitor compliance with quality standards. The cost of such testing may be included in the Global Fund grant budget.

For pharmaceutical products meeting criteria described in clause 3 (i) or (ii)

The Global Fund is responsible for contracting an independent third party to conduct random quality analysis of products being procured pursuant to the criteria in clause 3) (i) or (ii) in the section above to ensure the quality of such products. The location of the sampling will be exclusively conducted at the manufacturing site and only if the results of the quality test are favorable will the products be released for delivery. In case a product fails the test, the Global Fund will reject the product for procurement with Global Fund resources.

NDRA laboratories or laboratories recognized by the NDRA should be used for quality monitoring. To ensure the respective laboratories have adequate capacity for full pharmacopoeial testing, they must meet one of the following criteria:

a) Acceptance for collaboration with WHO Prequalification Project[4];
b) Accreditation in accordance with ISO17025 or EN45002;
c) Acceptance by a stringent authority.

PRE-QUALIFICATION AND MONITORING OF SUPPLIERS

Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process that considers product quality, service reliability, delivery time and financial viability.

QUALITY ASSURANCE OF NON-PHARMACEUTICAL HEALTH PRODUCTS

For all other non-durable products, the same principles as for pharmaceuticals should be followed, namely that a PR is required to select from lists of pre-qualified products (where they exist) or products accepted by stringent regulatory authorities or products accepted by national standards.

[4] Currently three laboratories have been pre-qualified: the Research Institute for Industrial Pharmacy and the Centre for Quality Assurance of Medicines (both in South Africa) and the Laboratoire National de Contrôle des Produits Pharmaceutiques, LNCPP (in Algeria).

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 [the Doha Declaration]) in a manner that achieves the lowest possible price for products of assured quality.

In the event that a PR 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, using funds budgeted in the Global Fund grant, contract the necessary expertise.

Distribution and inventory management

The recipient should minimize the risk of stock-outs through effective management of procurement and logistics systems, which should include (but are not limited to) appropriate economic order quantity, buffer stock, procurement period, storage capacity and conditions and product demand. In addition, the recipient must implement and ensure that sub-recipients implement procedures that will avoid the diversion of Global Fund-financed health products from their intended and agreed-upon purpose. These procedures should include the establishment and maintenance of reliable inventory management, first-expiry/first-out stock control systems, internal audit systems, and good governance structures.

Appropriate use

It is strongly recommended that recipients implement mechanisms to encourage adherence to treatment (including but not limited to the use of fixed-dose combinations, once-a-day formulations, blister packs, and peer education and support), to monitor and contain resistance and to monitor adverse drug reactions according to existing international guidelines. The cost of such activities may be included in the Global Fund grant budget.

TREATMENT OF 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 medications to treat multidrug-resistant tuberculosis (MDR-TB) must be conducted through the Green Light Committee (GLC) of the Stop TB Initiative.

More information on the GLC can be obtained from the WHO representative in the recipient country or from: www.who.int/tb/dots/dotsplus/management/en/index.html.

Monitoring and evaluation

The PRs are required to submit the prices that were paid for pharmaceuticals with Global Fund resources for publication on the website of the Global Fund, under the Price Reporting Mechanism page. The specific format is available on the Global Fund's website (www.theglobalfund.org/prm).

Annex: Countries with stringent regulatory authorities

PHARMACEUTICAL INSPECTION COOPERATION SCHEME (PIC/S) PARTICIPATING REGULATORY AUTHORITIES www.picscheme.org/		
Australia	Greece	Norway
Austria	Hungary	Portugal
Belgium	Iceland	Romania
Canada	Ireland	Singapore
Czech Republic	Italy	Slovak Republic
Denmark	Latvia	Spain
Finland	Liechtenstein	Sweden
France	Malaysia	Switzerland
Germany	Netherlands	United Kingdom

PARTICIPATING REGULATORY AUTHORITIES TO THE INTERNATIONAL CONFERENCE ON HARMONIZATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH) www.ich.org
European Union member states
Japan
United States

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