GUIDE TO GLOBAL FUND POLICIES ON

Procurement and Supply Management of Health Products

JUNE 2012

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

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Introduction

Purpose

1.1 The purpose of this guide is to inform those carrying out a program that is financed through a Global Fund grant of the policies and principles that govern the procurement and supply management of health products financed by the Global Fund. The grant agreement governs the legal relationship between the Principal Recipient and the Global Fund and the provisions of this guide set out legal obligations that are applicable to the procurement of health products financed out of the grant funds as provided for under the terms of the grant agreement. As defined in the grant agreement, "health products" includes: (i) pharmaceutical products; (ii) durable and non-durable in vitro diagnostic products, microscopes and imaging equipment; (iii) mosquito nets; and (iv) consumable/ single-use health products (including condoms, insecticides, therapeutic nutritional support, general laboratory items and injection syringes), which are financed out of grant funds.

1.2 The responsibility for carrying out the program, and therefore for the award and administration of contracts financed under the program, rests with the Principal Recipient. The Principal Recipient may, through separate contractual arrangements, require a sub-recipient(s), sub-sub recipient or a procurement agent to fulfil certain obligations, but under the terms of the grant agreement the Principal Recipient remains accountable for compliance with legal obligations set out in the grant agreement and in this guide. Unless specific reference to Principal Recipients or sub-recipients is required, the term "recipient" or "recipients" is used in this guide to refer to the actors involved in procurement and supply management activities financed by the Global Fund for the purposes of the program.

1.3 Procurement and supply management activities are fundamental to program performance. In order to ensure access to effective and quality-assured health products, the Global Fund has developed a set of policies and principles on procurement and supply management that aim to:

- support the timely procurement of quality-assured health products in adequate quantities;
- attain cost efficiencies in procurement and supply management activities;

- ensure the reliability and security of distribution systems;
- encourage appropriate use of health products; and
- enable the monitoring of all procurement and supply management activities.

1.4 The provisions of the guide are incorporated by reference into the grant agreement and recipients are therefore bound to comply with the provisions set out in this document, unless the context requires otherwise. In the event of non-compliance the Global Fund reserves the right to exercise the remedies set out under the grant agreement, including those specified in article 19(c) of the standard terms and conditions.

1.5 In addition to explaining the legal obligations that apply to the procurement and supply management of health products for the program, this guide also sets out certain best practices which it strongly recommends recipients to apply in the procurement and management of health products.

1.6 This guide replaces the November 2009 *Guide to the Global Fund's Policies on Procurement and Supply Management*.

Updates to the guide and further guidance

1.7 This guide may be amended or updated from time to time at the Global Fund's sole discretion. Recipients are required to routinely check the website for updates and to comply with those updates. Any amendment or update will be published on the Global Fund website and is available at http://www.theglobalfund.org/documents/psm/PSM_ProcurementSupplyManagement_Guidelines_en

1.8 In this guide, users will find a useful list of Internet links to more detailed guidance documents relating to procurement.

1.9 Recipients are also expected to familiarize themselves with the information lists and notes relating to procurement and supply management of health products which are available from the Global Fund procurement and supply management microsite http://www.theglobalfund.org/en/procurement/

1.10 A list of definitions and acronyms is set out at the end of the guide.

II. Ensuring adequate procurement and supply management of health products

Applicable laws

2.1 When procuring and managing the supply of health products, recipients undertake to comply at all times with applicable laws, including with any required authorizations relating to those health products in a timely manner pursuant to the requirements established by the relevant regulatory authority in the country in which those products will be utilized.

Procurement and supply management responsibilities

2.2 The recipient may, except when otherwise required by the Global Fund, use its own procurement and supply management arrangements or, at its own discretion, a contracted local, regional or international procurement and/or supply management agent, selected in a competitive manner, to conduct health products procurement and/or supply management.

2.3 For those health products for which the Global Fund determines, through the procurement and supply management assessment, that the recipient's procurement and/or supply management capacity is insufficient, the Global Fund may, in its sole discretion, require a recipient to use:

- the procurement support services established by the Global Fund to support countries in addressing grant bottlenecks which are associated with the procurement and supply management of health products, including the voluntary pooled procurement mechanism and capacity-building services[1], or

- other established procurement and/or supply management agents or services acceptable to the Global Fund.

2.4 In any case, where pooling of demand can attain better market outcomes (such as lower prices or improved lead times for health products of the required assured quality), the recipient shall use its best efforts to use capable regional and global procurement services or agents acceptable to the Global Fund, including the voluntary pooled procurement mechanism.

2.5 All procurement of medicines to treat multidrug-resistant tuberculosis (TB) shall be performed through a designated procurement agent of the Global Drug Facility, as delegated by the Green Light Committee Initiative. In advance of initiating procurement of such medicines, the recipient shall make available to the Global Fund, in form and substance satisfactory to the Global Fund, the following:

a) a current detailed multidrug-resistant TB expansion plan (including the number of multidrug-resistant TB patients to be treated and the list and quantifications of the medicines to be procured for the multidrug-resistant TB program reflecting the recipient's finalized forecast for the grant implementation period covered by the relevant grant agreement), and the national guidelines for programmatic management of multidrug-resistant TB, both of which have been developed in collaboration with a technical partner acceptable to the Global Fund; and

b) for each disbursement request for the procurement of multidrug-resistant TB medicines, a pro forma invoice issued by the designated procurement agent of the Global Drug Facility, as delegated by the Green Light Committee Initiative.

2.6 Whenever the recipient plans to procure pediatric antiretroviral (ARV) medicines to treat children infected with HIV using grant funds, so as to facilitate the adequate and timely supply of those medicines the recipient has an obligation to procure those medicines through procurement channels designated by the Global Fund, as specified from time to time on the Global Fund's procurement and supply management microsite, which shall be consulted prior to initiating such procurement.[2]

1 More information is available at the procurement and supply management microsite at http://www.theglobalfund.org/en/procurement/vpp/

2 GF/B23/DP21: Global Fund Market-Shaping Strategy and Market-Shaping Interventions for ARVs, Twenty-Third Board Meeting, Geneva, Switzerland, 11 -12 May 2011

III. Procurement principles, competitive purchasing and lowest possible price

3.1 Recipients shall ensure that all procurement and supply management activities for health products adhere to the *Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement*.[3]

3.2 In accordance with good pharmaceutical procurement practices, each recipient shall use transparent competitive procedures for the purchase of health products in order to obtain the lowest possible price with the required assured quality. National preference in procurement decisions is not acceptable to the Global Fund.

3.3 Recipients will use their best efforts to apply national laws and applicable international obligations in the field of intellectual property including the flexibilities provided in the Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement and interpreted in the Doha declaration[4] in a manner that achieves the lowest possible price for products of assured quality.

3.4 Recipients shall establish and at all times maintain systems acceptable to the Global Fund to monitor the performance of contractors, agents, manufacturers and sub-recipients conducting procurement and supply management activities

3.5 Recipients shall provide immediately, whenever requested by the Global Fund, all contractual documentation governing each transaction.

3.6 Where practices differ from the *Interagency Guidelines*, recipients shall demonstrate compliance with comparable systems for competitive bidding within a group of pre-qualified manufacturers, transparency and accountability to those systems, and the application of necessary quality assurance mechanisms, all of which shall be acceptable to the Global Fund.

Quality assurance systems

3.7 Recipients shall ensure that the procurement of health products complies with the principles set forth in the *Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies*[5] and shall develop and fully maintain at all times a quality assurance system in accordance with those principles.

3.8 Recipients shall comply with, and shall ensure that each of its contractors, agents, and sub-recipients comply with, the *World Health Organization (WHO) Guidelines for Good Storage Practices* and *WHO Good Distribution Practices.*[6]

Avoiding diversion

3.9 Recipients shall ensure that procedures acceptable to the Global Fund are put in place and are in full force at all times in order to prevent any diversion of health products throughout the supply chain, including the establishment and maintenance of reliable inventory management, internal audit systems, and good governance structures to ensure the sound operation of these systems.

3 Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement. WHO Geneva, 1999. Available at http://www.who.int/3by5/en/who-edm-par-99-5.pdf

4 World Trade Organization (WTO) Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, Doha, 14th November 2001

5 Interagency Guidelines: 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, WHO/PSM/PAR/2007.3, available at http://www.who.int/medicines/publications/ModelQualityAssurance.pdf

6 See Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies.

IV. Capacity assessment, procurement plan, and capacity building/ technical assistance

4.1 Due to the complexity and significant risks associated with procurement and supply management activities, recipients are only authorized to proceed with procurement and supply management activities after:

a) the Global Fund has assessed the recipient's capability to manage procurement and supply management activities under the program;

b) the recipient has submitted to the Global Fund the required set of documents relating to procurement and supply management of health products[7], as required, consistent with Global Fund policies; and

c) approval by the Global Fund of the applicable procurement plan or procurement and supply management plan. Further guidance is available at http://www.theglobalfund.org/en/procurement/

4.2 Recipients shall ensure that at all times the procurement and supply management activities to be financed under the program are carried out in accordance with the applicable procurement plan or procurement and supply management plan, as approved by the Global Fund. If the recipient plans to make any changes to the procurement plan or the procurement and supply management plan, as approved by the Global Fund, it shall provide in advance details of those proposed changes to the Global Fund and shall not initiate those changes unless they have been approved by the Global Fund.

4.3 Short-term and long-term capacity building or technical assistance might be needed in order to address challenges related to, but not restricted to, quantification/ forecasting, procurement planning, storage, inventory control, logistics management information systems, quality assurance systems (including quality control) and intellectual property management. Additionally, recipients may wish to consider measures to strengthen the capacity of national institutions such as medical stores and national regulatory authorities and other in-country mechanisms, systems and tools.[8] Recipients are referred to the Global Fund information about the capacity-building service process[9], the *Guidelines for Budgeting in Grant Proposals*[10], and the *Operational Policy Note on Costed Technical Assistance Plans*.[11]

7 When the Pharmaceutical and other Health Products Management Country Profile is available for a country, the recipient is required to submit to the Global Fund a procurement plan reflecting the detailed list of health products to be financed out of the grant funds. If the country profile is not yet available, the recipient is required to prepare a procurement and supply management plan.

8 See Information Note: Pharmaceutical Systems Strengthening and Pharmacovigilance, July 2011, available at http://www.theglobalfund.org/en/application/infonotes/

9 Procurement Support Services. Capacity-building Services/Supply Chain Management Assistance Process, available at http://www.theglobalfund.org/documents/psm/Psm_Cbsprocess_Guide_En/

10 Guidelines for Budgeting in Global Fund Grants, available at http://www.theglobalfund.org/documents/core/guidelines/Core_BudgetingInGlobalFundGrants_Guideline_en/

11 Operational Policy Note on Costed Technical Assistance Plans (OPN 6.1.6), available at http://www.theglobalfund.org/documents/core/manuals/Core_OperationalPolicy_Manual_en/

V. Procuring pharmaceutical products[12]

Compliance with national laws and regulations

5.1 Recipients have an obligation to ensure that finished pharmaceutical products (for the purposes of this guide, this refers to pharmaceutical products financed out of grant funds) comply with the relevant quality standards established by the national pharmaceutical regulatory authority in the country of use, including authorization for use of the finished pharmaceutical products to be procured following its standard practices for registration[13] or other forms of authorization, such as authorizations for marketing or importation.

Compliance with clinical standards

5.2 Recipients are not authorized to procure medicines using grant funds unless those medicines appear in the current national, institutional and/or WHO's Standard Treatment Guidelines and/or Essential Medicines Lists. Recipients shall provide a copy of the relevant guidelines or list with the procurement plan or the procurement and supply management plan provided in advance to the Global Fund.

12 All information related to the Global Fund Quality Assurance Policy for Pharmaceutical Products is available at http://www.theglobalfund.org/en/procurement/quality/pharmaceutical

13 In order to expedite the authorization of use for needed finished pharmaceutical products, national pharmaceutical regulatory authorities are encouraged to accept, as relevant, the following documentation (together with all necessary information to perform quality control testing of the products and with necessary reference standards):

a) for finished pharmaceutical products that have been prequalified by the WHO Prequalification Programme: the prequalification approval letter and supporting documentation, including WHO prequalification report and the manufacturer's summary of information relating to quality, safety and efficacy; and

b) for finished pharmaceutical products that have been authorized for use by a Stringent Pharmaceutical Regulatory Authority: the executive summary of the Common Technical Document for the Registration of Pharmaceutical Products for Human Use, or its sections relating to quality, safety and efficacy.

5.3 If the recipient plans to procure a medicine that: (i) was not specified in the grant proposal approved by the Global Fund; and/or (ii) is included in the relevant standard treatment guidelines/essential medicines list of the country, but not included in the standard treatment guidelines or essential medicines list of WHO, or vice versa, the recipient shall provide a technical justification to the Global Fund prior to launching the procurement process.

5.4 Recipients shall procure artemisinin-based combination therapy (ACTs) for the treatment of uncomplicated malaria only as fixed-dose combinations after they have received written notification from the Global Fund of the availability of at least two fixed-dose combination products which comply with the relevant quality assurance policy.

Compliance with quality standards

5.5 In addition to national requirements, all ARV, antimalarial and anti-TB finished pharmaceutical products shall be:

a) prequalified under the WHO Prequalification Program (Option A); and/or
b) authorized for use by a Stringent Regulatory Authority (Option B); or
c) if only one or no Option A or Option B product is available, permitted for time-limited procurement after review by the Expert Review Panel.

5.6 The Global Fund maintains on its website non-exhaustive lists (for orientation purposes) indicating finished pharmaceutical products known to the Global Fund to be compliant with the above requirements. Such lists are updated monthly and are available at http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/#Lists

Process for procuring pharmaceutical products reviewed by the Expert Review Panel

5.7 Before procuring finished pharmaceutical products that have been subject to a review by the Expert Review Panel, recipients shall inform the Global Fund in writing by submitting a duly completed notification form.[14] Procurement of Expert Review Panel-reviewed products can only proceed after the recipient receives a "no objection" letter from the Global Fund for the requested selection, and the relevant procurement contract shall not exceed twelve months.

Monitoring quality

5.8 Recipients shall monitor, or shall take measures to ensure adequate monitoring of, the quality of pharmaceutical products throughout the supply chain system.

5.9 In collaboration with the relevant national pharmaceutical regulatory authority, recipients shall arrange

14 All information related to the Expert Review Panel process, including instructions to follow to procure an Expert Review Panel-approved product, is available at http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/#General

for random samples of finished pharmaceutical products to be taken at different points in the supply chain from the point of initial receipt of the products to delivery to patients.

5.10 The recipient shall arrange for those samples to be sent for quality control testing to national or other laboratories that are:

a) prequalified by the WHO Prequalification Programme (as published by WHO on a regular basis); and/or

b) accredited in accordance with ISO17025.

5.11 The recipient may request the Global Fund to include the cost of conducting quality control activities within the budget as part of the procurement and supply management cost for the relevant program.

5.12 The recipient is required to provide to the Global Fund, or arrange for the provision of, the results of quality control tests. The recipient also acknowledges that the Global Fund is authorized to make those results publicly available.

5.13 If the recipient plans to procure a finished pharmaceutical product which has been evaluated and recommended for procurement by the Expert Review Panel, the Global Fund will arrange and finance the quality-control testing prior to delivery to that recipient. The recipient shall ensure that any contract with a manufacturer relating to the procurement of those products specifically allows for the Global Fund, its representatives or agents to undertake sampling, to obtain the manufacturer's specifications, and to make the results of such testing public.

5.14 Further guidance relating to quality monitoring of pharmaceutical products is available in the Global Fund's *Guidance for Reinforcing and/or Establishing Pharmaceutical Quality Control Systems and Related Stock Management Activities in Countries Supported by the Global Fund*.[15]

Adherence to treatment protocols, drug resistance and adverse effects

5.15 Recipients acknowledge that the Global Fund strongly recommends the following as best practices and agrees that it will use its best efforts to conform to these practices as set out below:

a) implementation of mechanisms to encourage patients to adhere to their prescribed treatments, including the use of fixed-dose combinations, once-a-day formulations, blister packs, and peer education and support;

b) adherence to agreed treatment guidelines;

c) application of measures to monitor and contain drug resistance; and

d) application of measures to monitor adverse reactions of pharmaceutical products, including a pharmacovigilance system, according to existing international guidelines (more information is available in the *Information Note on Pharmacovigilance*).[16]

15 Guidance for Reinforcing and/or Establishing Pharmaceutical Quality Control Systems and Related Stock Management Activities in Countries Supported by the Global Fund, available at http://www.theglobalfund.org/WorkArea/DownloadAsset.aspx?id=7045

16 See footnote 8

VI. Purchasing diagnostic products

Compliance with national regulations

6.1 Recipients have an obligation to ensure that diagnostic products (for purposes of this guide, this refers to diagnostic products financed out of grant funds) comply with the relevant quality standards established by the national regulatory authority.

Compliance with clinical standards

6.2 Recipients shall ensure that the procurement of all diagnostic products comply with applicable national guidelines and/or are in conformity with WHO guidance. Recipients shall provide a copy of the relevant guidance with the procurement plan or procurement and supply management plan provided in advance to the Global Fund.

6.3 Recipients shall describe, in generic terms, the type of diagnostic products to be procured and shall submit a technical justification acceptable to the Global Fund if the recipient intends to procure a diagnostic product that: (i) was not specified in the grant proposal approved by the Global Fund; and/or (ii) is consistent with national guidelines, but not with WHO guidance or vice versa.

Compliance with quality standards[17]

6.4 Recipients shall procure only diagnostic products that have been manufactured at a site which complies with the requirements of:

a) ISO13485[18] for in vitro diagnostic products and imaging equipment; or

17 All information related to the Global Fund Quality Assurance Policy for Diagnostic Products is available at http://www.theglobalfund.org/en/procurement/quality/diagnostics/

18 Or an equivalent quality management system recognized by a regulatory authority member of Global Harmonization Task Force.

b) ISO9000 series for any other diagnostic product such as microscopes.

6.5 Recipients shall require and ensure that the manufacturer and manufacturing site of diagnostic products is disclosed in all applicable tender and procurement-related documentation.

6.6 Rapid diagnostic tests and other immunoassays for the detection of HIV or malaria shall be:

a) recommended for use in HIV or malaria programs by WHO based on a technical review of quality and performance indicators; or
b) authorized for use by a regulatory authority member of Global Harmonization Task Force[19]; or
c) determined by the Global Fund to be acceptable for procurement following advice from the Expert Review Panel.

6.7 The Global Fund maintains on its website non-exhaustive lists for orientation purposes indicating products known to the Global Fund to be compliant with above requirements and/or the link with relevant lists available elsewhere. Such lists are updated regularly and are available at http://www.theglobalfund.org/en/procurement/quality/diagnostics/

Monitoring quality

6.8 For rapid diagnostic tests, the recipient shall ensure that lot testing is performed as and when required by the Global Fund on its website at http://www.theglobalfund.org/en/procurement/quality/diagnostics

6.9 Recipients shall support and participate in external quality assessment programs.

6.10 Recipients shall organize calibration and maintenance of the diagnostic equipment.

6.11 Recipients shall ensure that diagnostic products are only used by appropriately trained and suitably qualified individuals in an environment intended for the utilization of those diagnostic products.

6.12 Recipients shall develop and maintain a system acceptable to the Global Fund for reporting to the appropriate regulatory authorities any defects relating to diagnostic products and for facilitating communications with manufacturers, procurement agents, distributors and end-users in the event of defects of diagnostic products.

6.13 The recipient may include the cost of conducting quality assurance activities within the budget for the relevant program.

Competitive process for diagnostic products

6.14 Recipients shall undertake a competitive process for the award of contracts for diagnostic products so as to achieve the lowest possible price, taking into account the total cost of ownership, including the additional costs of training, if any, and validation of new diagnostic algorithms. Further guidance is provided in *Quick Facts on Procuring Rapid Diagnostic Tests* available at http://www.theglobalfund.org/en/procurement/

19 The Global Fund reserves the right to seek advice from the Expert Review Panel to determine acceptability for procurement by Global Fund recipients of a diagnostic product authorized by an authority member of the Global Harmonization Task Force if such approval has been granted for export only, or such product belongs to a category exempted of thorough controls by the authority member of the Global Harmonization Task Force.

VII. Purchasing other health products

7.1 Recipients are only authorized to procure the following products with grant funds when:

a) long-lasting insecticidal mosquito nets are recommended for use by the WHO Pesticide Evaluation Scheme (WHOPES)[20] and other pesticides are compliant with specifications indicated in WHOPES; and

b) condoms are compliant with specifications indicated in *WHO-UNFPA Standards and Guidelines for Condoms Procurement*.[21]

7.2 Health products other than pharmaceutical products, diagnostic products, long-lasting insecticidal mosquito nets, other pesticides, and condoms shall be selected from the applicable list of pre-qualified products, if any, and shall comply with the quality standards applicable in the country where such products will be used.

7.3 Further guidance relating to the procurement of public health pesticides is available in the *WHO Guidelines for Procuring Public Health Pesticides*.[22]

20 The list of pesticides recommended by WHOPES (insecticides for internal residual spray, insecticides for treatment of mosquito nets, long-lasting insecticidal mosquito nets and mosquito larvicides) is available at http://www.who.int/whopes/en

21 Male Latex Condom: Specifications, Prequalification and Guidelines for Procurement, WHO/ UNFPA/ UNAIDS/ FHI, 2010, available at http://www.who.int/rhem/prequalification/9789241599900/en/index.html

22 WHO Guidelines for Procuring Public Health Pesticides. WHO/HTM/NTD/WHOPES/2012.4, is available at http://www.who.int/whopes/resources/en/

VIII. Reporting price and quality

8.1 Recipients shall promptly submit through electronic means the information required by the Global Fund for publication over the internet through the Price and Quality Reporting mechanism.[23] Upon receipt in the country of health products in the categories indicated below, recipients shall promptly report to the Global Fund the price paid for those health products and other information related to the quality of the health products, as specified in, and using the form required by, the Price and Quality Reporting system available from the website of the Global Fund at http://pqr.theglobalfund.org/Screens/PQRLogin.aspx?Lang=en-GB

8.2 Recipients are required to report unit prices independently of freight and insurances charges, which must be separately itemized.

8.3 Recipients are currently required to report six categories of health products:

- ARVs;
- antimalarial pharmaceutical products;
- anti-TB pharmaceutical products;
- long-lasting insecticidal mosquito nets;
- condoms; and
- rapid diagnostic tests.

This list may be updated from time to time on the Global Fund's procurement and supply management microsite.

8.4 In order to ensure the accuracy and completeness of reporting by recipients, the Global Fund requires that Local Fund Agents verify all data entries on an ongoing basis, as relevant. Recipients are required to provide access to Local Fund Agents of the required documentation to verify reporting to the Price and Quality Reporting mechanism.

8.5 Entering procurement information in the Price and Quality Reporting system for relevant health product categories is a prerequisite for disbursements to be approved, and disbursements may be delayed if such Price and Quality Reporting entries are not duly completed.

23 Price and Quality Reporting's User Manual is available at http://www.theglobalfund.org/documents/psm/PSM_PQRQuick_Guide_en/

Definitions

Applicable laws means any federal, national, supranational, state and local laws, rules and regulations, ordinances, administrative statutes, codes, orders or requirements of any country or jurisdiction applicable to a recipient, as the context may require.

Available means that the relevant manufacturer can supply the requested quantity of the finished pharmaceutical product within not more than 90 days of the requested delivery date.

Diagnostic product means any durable and non-durable in vitro diagnostic product and microscopes and imaging equipment used in Global Fund-financed programs for diagnosis, screening, surveillance or monitoring purposes.

Expert Review Panel means a panel of independent experts to review the potential risks/benefits associated with the use of finished pharmaceutical products or diagnostic products, and to make recommendations to the Global Fund as to whether such products may be procured with Global Fund grant resources. Such panel is hosted by WHO's Quality and Safety of Medicines department in the case of pharmaceutical products.

External quality assessment means a program that assesses the performance of laboratories or testing sites using an external agency or facility, which may include proficiency testing, rechecking or retesting or on-site evaluations, or a combination of the above.

Finished pharmaceutical product means a medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labeling.

Global Harmonization Task Force means the group established to encourage convergence in regulatory practices related to ensuring the safety, effectiveness, performance and quality of medical devices, promoting technological innovation and facilitating international trade and is comprised of representatives from medical device regulatory authorities and other regulated industry participants. (Further information and membership details are available at http://www.ghtf.org/)

Health products includes: (i) pharmaceutical products; (ii) durable and non-durable in vitro diagnostic products, microscopes and imaging equipment; (iii) mosquito nets; and (iv) consumable/single-use health products (including condoms, insecticides, therapeutic nutritional support, general laboratory items and injection syringes), which are financed out of grant funds.

In vitro diagnostic product means a medical device, whether used alone or in combination with other devices, intended by the manufacturer for in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes, including reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus and other articles (Global Harmonization Task Force Document SG1/N045:2008).

Long-lasting insecticidal mosquito net is a factory-treated mosquito net made with netting material that has insecticide incorporated within or bound around the fibers. The net must retain its effective biological activity without retreatment for at least 20 WHO standard washes under laboratory conditions and three years of recommended use under field conditions.

Pharmaceutical products or medicines means an active pharmaceutical ingredient that is intended for human use.

Pharmaceutical and other health products management country profile and procurement plan OR procurement and supply management plan refers to the set of documents that recipients intending to procure health products with grant funds must submit to the Global Fund for approval. These documents are intended to provide information on the procurement and supply management processes and systems, any strengthening measures for the procurement and management of health products, a complete list of health products to be procured using grant funds, associated costs, and all assumptions used for quantification.

Procurement and supply management refers to all procurement, supply and distribution 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.

Quality assurance is the totality of the arrangements to ensure that health products are of the quality required for their intended use, including quality monitoring.

Quality control is part of quality monitoring and includes all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that health products conform to established specifications.

Quality monitoring means all activities undertaken to ensure that health products continue to conform to the manufacturer's established quality specifications during the storage, distribution and use of such products, including quality control in a laboratory.

Recipient means any entity that receives grant funds (such as a Principal Recipient, sub-recipient, sub-sub-recipient or procurement agent), as the context may require.

Stringent pharmaceutical regulatory authority means a regulatory authority participating in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (www.ich.org). Current participants are set out below for general reference only:

- 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)
- In addition, three special regulatory schemes offer stringent assessment of medicines used exclusively outside the ICH region: Canada S.C. 2004, c. 23 (Bill C-9) procedure, Art. 58 of European Union Regulation No. 726/2004, and United States Food and Drug Administration tentative approval.

Total cost of ownership means the total amount of all direct and indirect monetary costs related to the procurement, storage and distribution of a diagnostic product by a recipient, including the price of the product itself, any reagents and other consumables, transportation, customs clearance, insurance, in-country distribution and storage, quality assurance (including quality monitoring, training, and validation of new diagnostic algorithms), and, as applicable, operating costs including cost of installing, servicing, commissioning and maintaining equipment.

WHO Prequalification Programme means the programme managed by WHO which prequalifies: (a) pharmaceutical and other health products that are considered to be acceptable for procurement by the United Nations and specialized agencies; and (b) laboratories for quality control of such products.

Abbreviations

ARV	Antiretroviral
ISO	International Standard Organization
UNFPA	United Nations Population Fund
WHO	World Health Organization
WHOPES	WHO Pesticide Evaluation Scheme

The Global Fund to Fight AIDS, Tuberculosis and Malaria
Chemin de Blandonnet 8
1214 Vernier
Geneva, Switzerland
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