



# Guide to Global Fund Policies on Procurement and Supply Management of Health Products

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# 1. INTRODUCTION

## PURPOSE

**1.1** The purpose of this guide is to outline the policies and principles that govern the procurement and supply management of health products financed by the Global Fund. The provisions of this guide are incorporated by reference into the grant agreement between the grant recipients and the Global Fund pursuant to the Global Fund Grant Regulations (2014).<sup>1</sup> As used in this guide, the term “health products” includes: (i) pharmaceutical products; (ii) durable and non-durable in-vitro diagnostic products, microscopes and imaging equipment; (iii) long-lasting insecticidal 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 the 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 grant recipient. The grant recipient under a grant agreement with the Global Fund may, through separate contractual arrangements require other implementers (e.g. sub-recipient/s, sub-sub recipient or procurement agent), to fulfil certain obligations, but under the terms of the grant agreement the grant recipient remains accountable for compliance with obligations set out in the grant agreement and this guide. Unless the context requires otherwise, the term “recipient” or “recipients” used in this guide refer to the actors<sup>2</sup> involved in procurement and supply management activities financed by Global Fund-supported programs.

**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, detailed or referenced in this guide that aim to:

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

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

**1.4** As mentioned above, the provisions of the guide are incorporated by reference into the grant agreement. In the event of non-compliance, the Global Fund reserves the right to exercise the remedies set out under the grant agreement.

**1.5** In addition to elaborating the obligations that apply to the procurement and supply management of health products for Global Fund-supported programs this guide also sets out certain best practices which it strongly recommends recipients to apply in the procurement and supply management of health products.

**1.6** This version replaces the July 2016 version of this guide.

## 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, and is available through the link below. Recipients are required to routinely check the Internet site of the Global Fund for updates and comply with those updates. <https://www.theglobalfund.org/en/sourcing-management/policies-principles/>

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

**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 at <https://www.theglobalfund.org/en/sourcing-management/policies-principles/>

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

<sup>1</sup> See Section 5.2(1) of the Global Fund Grant Regulations (2014).

<sup>2</sup> Such as a grantee, Principal Recipient, sub-recipient, sub-sub-recipient or procurement agent.

## 2. 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 systems, rules, processes and procedures 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. The recipient may also choose to utilize the Global Fund's Pooled Procurement Mechanism – including the e-procurement platform of [wambo.org](http://wambo.org) – to support recipients in attaining cost-effective and efficient procurement of health products.

**2.3** For those health products for which the Global Fund determines 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:

- i. the Pooled Procurement Mechanism<sup>3</sup> or
- ii. 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 the Pooled Procurement

Mechanism or other regional and global procurement services or agents acceptable to the Global Fund.

**2.5** All procurement of medicines to treat multidrug-resistant tuberculosis shall be performed through a designated procurement agent of the Global Drug Facility. 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:

- i. a current detailed multidrug-resistant tuberculosis (MDR-TB) expansion plan (including the number of MDR-TB patients to be treated and the list and quantifications of the medicines to be procured for the MDR-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 DR-TB, both of which were developed in collaboration with a technical partner acceptable to the Global Fund; and
- ii. for each disbursement request for the procurement of MDR-TB medicines, a pro forma invoice issued by the designated procurement agent of the Global Drug Facility.

**2.6** Whenever the recipient plans to procure pediatric antiretroviral (ARV) medicines to treat children infected with HIV using grant funds, to facilitate the adequate and timely supply of those medicines, the recipient has an obligation to procure those medicines through one of the procurement entities that is a member of the ARV Procurement Working Group.<sup>4</sup>

<sup>3</sup> The Pooled Procurement Mechanism was previously referred to as the "voluntary pooled procurement" in Board Decision GF/B15/DP15, approved on 27 April 2007.

<sup>4</sup> GF/B23/DP21: Global Fund Market-Shaping Strategy and Market-Shaping Interventions for ARVs, Twenty-Third Board Meeting, Geneva, Switzerland, 11 -12 May 2011, available at <https://www.theglobalfund.org/en/board/decisions/>



## PROCUREMENT PRINCIPLES

**2.7** The procurement of goods and services, including in particular health products, with grant funds shall be conducted in a manner that is based on the principles set out below:<sup>5</sup>

- i. **Value for money:** Procurement shall be conducted with the aim of obtaining value for money; In particular, the Global Fund will not finance health products purchased at a price higher than the reference price for such products, where one exists. Such reference price is set based on the globally negotiated price lists and catalogue of the Global Fund for specific health and non-health products, either via the Pooled Procurement Mechanism (e.g., through wambo.org)), prices negotiated by partners or through partner platforms such as Stop TB Partnership's Global Drug Facility. Please see the Global Fund Guidelines for Grant Budgeting (as amended from time to time) for more details
- ii. **Competition:** Procurement shall be carried out on a competitive basis to the maximum practical extent.
- iii. **Efficient and Effective Procurement:** Procurement shall be conducted in a manner that maximizes the efficient use of Global Fund resources and ensures that the goods and/or services procured effectively meet the requirements of the users.
- iv. **Impartiality, Transparency and Accountability:** Procurement shall be conducted in an impartial, transparent and accountable manner.
- v. **Procurement ethics:** Procurement shall comply with Global Fund's Code of Conduct for Suppliers, and Code of Conduct for Recipient of Global Fund Resources.

**2.8** Recipients shall ensure that all procurement and supply management activities for health products adhere to the WHO Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement.<sup>6</sup>

**2.9** In accordance with good pharmaceutical procurement practices, each recipient shall use transparent and competitive procedures for the purchase of health products in order to achieve value for money. National or domestic preference in procurement decisions is not acceptable to the Global Fund, except if mandatory under applicable laws.

**2.10** Recipients will apply national laws and applicable international obligations in the field of intellectual property, and will use their best efforts to use the flexibilities provided in the Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement and interpreted in the Doha Declaration,<sup>7</sup> in a manner that achieves value for money for products of assured quality.

**2.11** 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.

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

**2.13** Where practices differ from the WHO Interagency Guidelines, recipients shall demonstrate compliance with comparable systems for competitive bidding within a group of prequalified 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

**2.14** Recipients shall ensure that the procurement of health products complies with the principles set forth in the WHO Model Quality Assurance System for Procurement Agencies (MQAS)<sup>8</sup> and shall develop and fully maintain at all times a Quality Assurance system in accordance with those principles.

Recipients should ensure that the relevant norms and standards which are necessary for the adequate implementation of the MQAS are established and implemented.

<sup>5</sup> The Global Fund Procurement Policy and Procurement Regulations (as amended from time to time). Available at <https://www.theglobalfund.org/en/sourcing-management/policies-principles/>

<sup>6</sup> Interagency Guidelines: Operational Principles for Good Pharmaceutical Procurement. WHO Geneva, 1999 available at [www.who.int/3by5/en/who-edm-par-99-5.pdf](http://www.who.int/3by5/en/who-edm-par-99-5.pdf)

<sup>7</sup> World Trade Organization (WTO) Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, Doha, 14th November 2001

<sup>8</sup> WHO Model Quality Assurance System for Procurement Agencies (MQAS), available at [www.who.int/entity/medicines/areas/quality\\_safety/quality\\_assurance/TRS986annex3.pdf?ua=1/](http://www.who.int/entity/medicines/areas/quality_safety/quality_assurance/TRS986annex3.pdf?ua=1/)

- 2.15** Recipients shall comply with, and shall ensure that each of its contractors, agents, and sub-recipients comply with, the WHO Guide for Good Storage Practices<sup>9</sup> and WHO Good Distribution Practices.<sup>10</sup>

## AVOIDING DIVERSION

- 2.16** Recipients shall ensure that operating procedures and controls 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 receiving procedures (with a process for reconciliation and confirmation of orders/deliveries) and inventory management, internal audit systems, and good governance structures to ensure the sound operation of these systems.

## 3. CAPACITY ASSESSMENT AND CAPACITY BUILDING/TECHNICAL ASSISTANCE

- 3.1** 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:
- i. the Global Fund has assessed the recipient's capacity to manage procurement and supply management activities under the program;
  - ii. the recipient has submitted to the Global Fund the required set of documents relating to procurement and supply management of health products, as required, consistent with Global Fund policies;<sup>11</sup> and
  - iii. approval by the Global Fund of the applicable list of health products they intend to purchase with grant funds, including any and all related procurement and supply management costs and implementation arrangements. Further guidance is available at <https://www.theglobalfund.org/en/sourcing-management/policies-principles/>
- 3.2** Recipients shall ensure that at all times the procurement and supply management activities to be financed by Global Fund-supported programs are carried out in accordance with the applicable

list of health products and procurement and supply management arrangements, as approved by the Global Fund. If the recipient plans to make any changes to the list of health products or the procurement and supply management implementation arrangements, 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.

- 3.3** Short-term and long-term capacity building or technical assistance might be needed in order to strengthen systems and address challenges related to, but not restricted to selection, 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. Recipients are referred to the Global Fund information about Health Systems Strengthening for Global Fund Applicants,<sup>12</sup> the Guidelines for Grant Budgeting and Annual Financial Reporting (August 2014)<sup>13</sup> and the Operational Policy Manual.<sup>14</sup>

<sup>9</sup> WHO Guide to good storage practices for pharmaceuticals.

[www.who.int/entity/medicines/areas/quality\\_safety/quality\\_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf](http://www.who.int/entity/medicines/areas/quality_safety/quality_assurance/GuideGoodStoragePracticesTRS908Annex9.pdf)

<sup>10</sup> WHO good distribution practices for pharmaceutical products.

[www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/GoodDistributionPracticesTRS957Annex5.pdf](http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf)

<sup>11</sup> Further guidance on grant-making is available at: [www.theglobalfund.org/en/fundingmodel/process/](http://www.theglobalfund.org/en/fundingmodel/process/)

<sup>12</sup> Applying for Funding – Health Systems Strengthening for Global Fund Applicants, available at

[https://www.theglobalfund.org/media/4759/core\\_resilientsustainablessystemsforshealth\\_infonote\\_en.pdf](https://www.theglobalfund.org/media/4759/core_resilientsustainablessystemsforshealth_infonote_en.pdf)

<sup>13</sup> Finance and Audit – Guidelines for Grant Budgeting and Annual Financial Reporting, available at

[https://www.theglobalfund.org/media/3261/core\\_budgetingglobalfundgrants\\_guideline\\_en.pdf](https://www.theglobalfund.org/media/3261/core_budgetingglobalfundgrants_guideline_en.pdf)

<sup>14</sup> Operational Policies – Operational Policy Manual, available at: [https://www.theglobalfund.org/media/3266/core\\_operationalpolicy\\_manual\\_en.pdf](https://www.theglobalfund.org/media/3266/core_operationalpolicy_manual_en.pdf)

## 4. PURCHASING PHARMACEUTICAL PRODUCTS<sup>15</sup>

### COMPLIANCE WITH NATIONAL LAWS AND REGULATIONS

**4.1** 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<sup>16</sup> or other forms of authorization (such as authorizations for marketing or importation).

### COMPLIANCE WITH CLINICAL STANDARDS

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

**4.3** If a 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 or essential medicines list of the country, but not included in the WHO standard treatment guidelines or essential medicines list, or vice-versa, the recipient shall seek Global Fund's approval by providing a technical justification prior to launching the procurement process.

**4.4** 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 that comply with the relevant quality assurance policy.<sup>17</sup>

### COMPLIANCE WITH QUALITY STANDARDS

**4.5** In addition to national requirements, all ARV, antimalarial and anti-tuberculosis finished pharmaceutical products shall be:

- i. prequalified under the WHO Prequalification Programme (Option A); and/or
- ii. authorized for use by a Stringent Regulatory Authority (Option B); or
- iii. if only one or no Option A or Option B product is available<sup>18</sup>, permitted for time-limited procurement after review by the Expert Review Panel.

**4.6** 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, as per the approved indications. Such lists are updated monthly and are available at <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/>

<sup>15</sup> All information related to the Global Fund Quality Assurance Policy for Pharmaceutical Products is available at <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/>

<sup>16</sup> 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.

<sup>17</sup> GF/B23/DP22: Expediting Transition to Fixed-dose Combinations of Artemisinin-based Combination Therapies (ACTs), Twenty-Third Board Meeting, Geneva, Switzerland, 11 -12 May 2011

<sup>18</sup> 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.



## PROCESS FOR PROCURING PHARMACEUTICAL PRODUCTS REVIEWED BY THE EXPERT REVIEW PANEL

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- 4.7** 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<sup>19</sup>. Procurement of products examined by the Expert Review Panel 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.
- 4.8** As per paragraph 31 of the Global Fund Quality Assurance Policy for Pharmaceutical Products, Recipients shall inform the Global Fund in writing of each consignment of ERP products which is subject to randomized testing and release according to Global Fund published guidance

## MONITORING QUALITY

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- 4.9** Recipients shall monitor, or shall take measures to ensure adequate monitoring of, the quality of pharmaceutical products throughout the supply chain.
- 4.10** In collaboration with the relevant national pharmaceutical regulatory authority, recipients shall arrange 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.
- 4.11** Recipients shall arrange for those samples to be sent for quality control testing to national or other laboratories that are:
- i. prequalified by the WHO Prequalification Programme (as published by the WHO on regular basis); and/or
  - ii. accredited in accordance with ISO17025.
- 4.12** Recipients 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.

**4.13** Recipients are required to provide to the Global Fund, or arrange for the provision of, the results of quality control tests. Recipients also acknowledge that the Global Fund is authorized to make those results publicly available. In case of non-compliance, Recipients are required to provide the same within a period of time which is commensurate to the anticipated risk for patient.

**4.14** If a 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 for and finance the quality control testing prior to delivery to the 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.

**4.15** Further guidance relating to quality monitoring of pharmaceutical products is available in the Global Fund’s Guidance for In-country Quality Monitoring of Pharmaceutical Products in Global Fund-supported Programs.<sup>20</sup>

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

## ADHERENCE TO TREATMENT PROTOCOLS, DRUG RESISTANCE AND ADVERSE EFFECTS

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- 4.17** Recipients acknowledge that the Global Fund strongly recommends the following as best practices and agree that they will use their best efforts to conform to these practices as set out below:
- i. 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;

<sup>19</sup> All information related to the Expert Review Panel process, including instructions to follow to procure an Expert Review Panel-reviewed product, is available at <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/>

<sup>20</sup> Guidance on In-country Quality Monitoring of Pharmaceutical Products in Global Fund-supported programs, available at: [https://www.theglobalfund.org/media/5901/psm\\_qcmonitoringqfprsvp\\_guide\\_en.pdf](https://www.theglobalfund.org/media/5901/psm_qcmonitoringqfprsvp_guide_en.pdf)

- ii. adherence to agreed treatment guidelines;
  - iii. application of measures to monitor and contain drug resistance; and
  - iv. application of measures to monitor adverse reactions of pharmaceutical products, including a pharmacovigilance system, according to existing international guidelines.
- 4.18** Recipients shall develop and maintain a system acceptable to the Global Fund for reporting to the appropriate regulatory authorities any Adverse Drug Reaction relating to pharmaceutical products and for facilitating communications with manufacturers, procurement agents, distributors and end-users.
- 4.19** Recipients shall provide to the Global Fund, or arrange for the provision of serious adverse drug reaction reports, relating to those products within a period of time which is commensurate to the anticipated risk for patient.
- 4.20** All adverse drug reactions related to ERP products should be reported to Global Fund Secretariat

## 5. PURCHASING DIAGNOSTIC PRODUCTS AND LABORATORY EQUIPMENT

### GENERAL PRINCIPLES

- 5.1** Recipients shall ensure that all procurement and supply management activities for diagnostic products (for purposes of this guide, this refers to diagnostic products financed out of grant funds) adhere to internationally accepted best practices for laboratory systems.<sup>21, 22</sup>
- 5.2** Recipients shall ensure that the list of health products is consistent with relevant national laboratory policies and strategic plans.<sup>23, 24, 25</sup>
- 5.3** Where applicable, the recipient shall utilize national quantification and forecasting data.
- 5.4** Recipients shall be aware of harmonized and standardized practices (e.g. national testing algorithms) when developing the list of health products.<sup>26</sup>

- 5.5** Recipients shall consider the laboratory physical infrastructure and biosafety level in developing an appropriate health products list.

- 5.6** Recipients shall ensure that the list of health products takes into account the structure, functioning and capacity of the laboratory system (human resources, network, communication system, and specimen transport systems at and between each level of service).

### COMPLIANCE WITH NATIONAL REGULATIONS

- 5.7** Recipients have an obligation to ensure that diagnostic products comply with the relevant quality standards established by the national regulatory authority.

<sup>21</sup> Consultation on technical and operational recommendations for clinical laboratory testing harmonization and standardization. World Health Organization, U.S. Center for Disease Control and Prevention, American Society for Clinical Pathology, 2008.

<sup>22</sup> Manual for procurement of diagnostics and related laboratory items and equipment. World Health Organization 2013

<sup>23</sup> Guidance for development of national laboratory strategic plans. Geneva, World Health Organization, US Centers for Disease Control and Prevention, Association of Public Health Laboratories, 2010.

<sup>24</sup> WHO. Technical and operational considerations for Implementing HIV viral load testing: interim technical update. World Health Organization, 2014 is available at: [www.who.int/hiv/pub/arv/viral-load-testing-technical-update/en/](http://www.who.int/hiv/pub/arv/viral-load-testing-technical-update/en/)

<sup>25</sup> A Practical Handbook for National TB Laboratory for Strategic Plan Development. Second English Edition, February 2014, is available at: [www.stoptb.org/wg/gli/assets/documents/Lab\\_Strategic\\_Handbook\\_Participants\\_Manual.pdf](http://www.stoptb.org/wg/gli/assets/documents/Lab_Strategic_Handbook_Participants_Manual.pdf)

<sup>26</sup> USAID | DELIVER PROJECT, Task Order 1. 2009. Laboratory Logistics Handbook: A Guide to Designing and Managing Laboratory Logistics Systems. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1.

## COMPLIANCE WITH CLINICAL STANDARDS

- 5.8** Recipients shall ensure that the procurement of all diagnostic products complies with applicable national guidelines and/or is in conformity with WHO guidance. Recipients shall provide a copy of the relevant guidance with the list of health products provided in advance to the Global Fund upon its request.
- 5.9** 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 recipients intend to procure a diagnostic product that:
- was not specified in the grant proposal approved by the Global Fund; and/or
  - is consistent with national guidelines, but not with WHO guidance or vice-versa.

## COMPLIANCE WITH QUALITY STANDARDS<sup>27</sup>

- 5.10** Recipients shall procure only diagnostic products that have been manufactured at a site that complies with the requirements of:
- ISO 13485<sup>28</sup> for in-vitro diagnostic products and imaging equipment; or
  - ISO 9000<sup>28</sup> series for any other diagnostic product (such as microscopes).
- 5.11** Recipients shall require and ensure that the manufacturer and manufacturing site of diagnostic products is disclosed in all applicable tender and procurement-related documentation.
- 5.12** In addition, in-vitro diagnostic products for HIV, tuberculosis malaria and hepatitis B, hepatitis C and syphilis co-infections, as well as in-vitro products providing information that is critical for patient treatment of these diseases, such as testing for G6PD deficiency, must meet any one of the following standards:
- prequalification by the WHO Prequalification of In Vitro Diagnostics Programme; or
  - for tuberculosis: recommendation by relevant WHO programme; or

- authorization for use by one of the Regulatory Authorities of the Founding Members of GHTF when stringently assessed (high risk classification). This option is not applicable to RDTs for HIV-Self-Testing; or
- acceptability for procurement using grant funds, as determined by the Global Fund based on the advice of the WHO Expert Review Panel.<sup>29</sup>

- 5.13** The Global Fund maintains on its website a 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 <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/>

## PROCESS FOR PROCURING DIAGNOSTIC PRODUCTS REVIEWED BY THE EXPERT REVIEW PANEL

- 5.14** Before procuring diagnostic 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. Procurement of products examined by the Expert Review Panel 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

- 5.15** Recipients shall arrange for the monitoring of the quality of diagnostic products procured with grant funds in line with relevant WHO guidelines on Post-Market Surveillance of In Vitro Diagnostics. The cost of conducting quality control activities may be budgeted for in Global Fund grants. Recipients must submit the results of quality control testing to the Global Fund.
- 5.16** Recipients shall use best efforts to develop and maintain a mechanism to report defects relating to diagnostic products to the appropriate regulatory authorities and to the Global Fund

<sup>27</sup> All information related to the Global Fund Quality Assurance Policy for Diagnostic Products is available at <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/diagnostic-products/>

<sup>28</sup> Or an equivalent Quality Management System recognized by one of the Regulatory Authorities of the Founding Members of GHTF

<sup>29</sup> 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 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 Global Harmonization Task Force.

and facilitate appropriate communications with manufacturers, procurement agents, distributors and end users.

- 5.17** The costs to the Recipient of conducting any relevant quality assurance and capacity building measures related to the procurement, supply management and use of Diagnostic Products with grant funds, as far as they are not covered from other funding sources, may be included in the relevant Global Fund grant budget, which is subject to approval by the Global Fund.

## COMPETITIVE PROCESS FOR DIAGNOSTIC PRODUCTS

- 5.18** Recipients shall undertake a competitive process for the award of contracts for diagnostic products so as to achieve value for money, 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 [www.theglobalfund.org/en/sourcing/](http://www.theglobalfund.org/en/sourcing/) and in the Global Fund's Viral Load and Early Infant Diagnosis Selection and Procurement Tool available at <https://www.theglobalfund.org/en/sourcing-management/health-products/viral-load-early-infant-diagnosis/>
- 5.19** Recipients shall ensure that the procurement process is open and competitive. However, there are some circumstances whereby specific products may be procured upon approval from the Global Fund. These circumstances are:
- i. National validated testing algorithm
  - ii. Closed equipment testing systems that require reagents and consumables that are specific to a diagnostic platform;
  - iii. National standardized and harmonized practices.

## PROCUREMENT OF LABORATORY DIAGNOSTIC EQUIPMENT

- 5.20** Recipients shall ensure there is an explicit provision in the procurement contract for maintenance,<sup>30,31</sup> training (user and biomedical engineers), preventive and corrective maintenance schedules for the expected life of the equipment.

- 5.21** Recipients shall ensure that resources for equipment management systems to monitor instrument lifespan and supplier performance are available. Recipients may use grant funds for such activities.

- 5.22** Recipients shall ensure that the investments in diagnostics and equipment is aligned with the laboratory workforce capacity or provisions made to strengthen the workforce capacity.

- 5.23** Recipients shall ensure that the procurement of diagnostics and laboratory diagnostics equipment is effectively coordinated.

- 5.24** Recipients shall balance investments in laboratory diagnostics equipment and diagnostics with investments in quality management systems at the service delivery level.

- 5.25** Recipients should ensure that the procurement of laboratory diagnostics equipment and diagnostics is in line with protocols on biosafety and biosecurity set forth by WHO and by international health regulations.

## MEDICAL LABORATORY SERVICES

- 5.26** Recipients shall ensure that the laboratory diagnostics equipment and diagnostics are used in line with protocols on biosafety and biosecurity set forth by WHO and by international health regulations.

- 5.27** Recipients shall ensure that testing sites are operated within a quality management system using internationally accepted standards,<sup>32,33</sup> and in particular that:

- i. The diagnostic products are only used by appropriately trained and suitably qualified individuals;
- ii. The environment intended for the utilization of those diagnostic products is suitable;
- iii. The laboratory organizes calibration and maintenance of the diagnostic equipment;
- iv. The laboratory participates in external quality assessment programs.

<sup>30</sup> Maintenance manual for laboratory equipment, 2nd ed. Geneva, World Health Organization, 2008.

<sup>31</sup> Consultation on technical and operational recommendations for clinical laboratory testing harmonization and standardization. World Health Organization, U.S. Centers for Disease Control and Prevention, American Society for Clinical Pathology, 2008.

<sup>32</sup> Laboratory Quality Management System: Handbook. World Health Organization, 2011.

<sup>33</sup> WHO Guide for the Stepwise Laboratory Improvement Process Towards Accreditation in the African Region, World Health Organization, 2013.

**5.28** Recipients may request the Global Fund to include the cost of implementing a quality management system in testing sites for the relevant program.

**5.29** Recipients should ensure the use of national quality services indicators based on intra and inter-laboratory performance comparison e.g. rate of invalid runs, rate of invalid test devices/cartridge, EQA/proficiency testing schemes.

## 6. PURCHASING OTHER HEALTH PRODUCTS

### PROCUREMENT OF PUBLIC HEALTH PESTICIDES

- 6.1** Recipients are only authorized to procure long-lasting insecticidal nets and other pesticides with the grant funds when:
- i. long-lasting insecticidal nets and other pesticides are recommended for use by the WHO Pesticide Evaluation Scheme (WHOPES)<sup>34</sup>; and
  - ii. are compliant with specifications indicated in WHOPES.
- 6.2** To ensure that long-lasting insecticidal nets and other pesticides comply with quality assurance requirements, recipients shall do the following:
- i. Random pre-shipment testing conducted by an independent quality control lab;
  - ii. Sampling and randomization performed according to WHO-related guidelines. Sampling of nets can also be based on the sampling procedures for “inspection by attributes” of the standards of the ISO 2859 series;
  - iii. Sampling to be done by an independent sampling agent;
  - iv. Testing by an independent ISO 17025-accredited laboratory having the test methods in its scope of accreditation,

- v. Testing according to WHO specifications and methods of the Collaborative International Pesticides Analytical Council (CIPAC) (if existing). The WHO specifications are available at: [www.who.int/whopes/quality/newspecif/en/](http://www.who.int/whopes/quality/newspecif/en/). The methods which have been evaluated and accepted by CIPAC are published regularly in CIPAC handbooks (available at [www.cipac.org/index.php/methods-publications/handbooks/](http://www.cipac.org/index.php/methods-publications/handbooks/))

**6.3** Further guidance relating to the procurement of public health pesticides is available in the WHO Guidelines for Procuring Public Health Pesticides.<sup>35</sup>

### PROCUREMENT OF MALE AND FEMALE CONDOMS

- 6.4** Recipients are only authorized to procure male condoms that are compliant with specifications indicated in WHO-UNFPA Guidelines for Male Condoms Procurement.<sup>36</sup>
- 6.5** The condoms (male and female) should comply with national regulatory policies of the country of use before being imported into a country.
- 6.6** It is strongly recommended to recipients to select condoms (male and female) from the list of prequalified condoms published by United Nations Population Fund (UNFPA). If condoms selected are not on the UNFPA list, the recipient must ensure that the following specifications are met:
- i. The manufacturing facility conforms to ISO 13485-latest specifications or equivalent quality management system;

<sup>34</sup> 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 [www.who.int/whopes/en/](http://www.who.int/whopes/en/)

<sup>35</sup> WHO Guidelines for Procuring Public Health Pesticides. WHO/HTM/NTD/WHOPES/2012.4, at [www.who.int/malaria/publications/atoz/9789241503426\\_pesticides/en/](http://www.who.int/malaria/publications/atoz/9789241503426_pesticides/en/)

<sup>36</sup> WHO and UNFPA Standards and Guidelines for Condoms Procurement Male Latex Condom: Specifications, Prequalification and Guidelines for Procurement, WHO/UNFPA/UNAIDS/FHI, 2010, available at: [www.who.int/rhem/prequalification/9789241599900/en/index.html](http://www.who.int/rhem/prequalification/9789241599900/en/index.html)



- ii. The condoms meet Directive 93/42/CEE or other equivalent requirements for authorization for use by one of the Regulatory Authorities of the Founding Members of GHTF
- iii. The pre-shipment quality control testing was performed in an ISO 17025- accredited laboratory that has been accredited for testing condoms;
- iv. The testing was done as per ISO 4074 (latest edition) as recommended by WHO, and
- v. The test reports are reviewed by a competent expert acting under supervision of the Principal Recipient for compliance with the above specifications.

**6.7** Recipients are only authorized to procure female condoms if they are compliant with generic specifications indicated in WHO-UNFPA Guidelines for Female Condoms Procurement.<sup>37</sup>

## MONITORING QUALITY OF MALE AND FEMAL CONDOMS

- 6.8** Recipients shall monitor, or shall take measures to ensure adequate monitoring of the quality of condoms throughout the supply chain.
- 6.9** In collaboration with the relevant national regulatory authority, Recipients shall arrange for random samples of finished condoms to be taken at different points in the supply chain.
- 6.10** Recipients shall arrange for those samples to be sent for quality control testing to national or other laboratories that are accredited in accordance with ISO 17025.

**6.11** Recipients may request the Global Fund to include the cost of conducting quality control activities of condoms within the budget, as part of the procurement and supply management cost, for the relevant program.

**6.12** Recipients are required to provide to the Global Fund, or arrange for the provision of, the results of quality control tests. In case of non-compliance, the recipients is required to provide the same within a period of time which is commensurate to the anticipated risk for patient. Recipients also acknowledge that the Global Fund is authorized to make those results publicly available.

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

## PROCUREMENT OF OTHER HEALTH PRODUCTS

**6.14** Health products other than pharmaceutical products, diagnostic products, long-lasting insecticidal 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. WASTE MANAGEMENT

**7.1** Recipients shall ensure the safe disposal of unusable pharmaceuticals products and other health products using methods that involve minimal risks to public health and the environment. Guidance is provided in WHO-related guidelines.<sup>38, 39</sup>

**7.2** Recipients shall ensure that laboratories undertake to comply with applicable laws and relevant WHO guidance for the management of health care waste, including laboratory waste.<sup>39</sup>

<sup>37</sup> WHO/UNFPA Female Condom Generic Specification, prequalification and guidelines for procurement, 2012 is available at [www.who.int/reproductivehealth/publications/family\\_planning/female\\_condom\\_specification.pdf?ua=1](http://www.who.int/reproductivehealth/publications/family_planning/female_condom_specification.pdf?ua=1)

<sup>38</sup> WHO Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies (WHO/EDM/PAR/99.2) at: [www.who.int/water\\_sanitation\\_health/medicalwaste/unwantpharm.pdf](http://www.who.int/water_sanitation_health/medicalwaste/unwantpharm.pdf)

<sup>39</sup> WHO. Safe management of wastes from health-care activities. – 2nd ed. World Health Organisation, 2014, at: [www.who.int/water\\_sanitation\\_health/publications/safe-management-of-wastes-from-healthcare-activities/en/](http://www.who.int/water_sanitation_health/publications/safe-management-of-wastes-from-healthcare-activities/en/)

## 8. REPORTING PRICE AND QUALITY

**8.1** Recipients shall promptly submit, via electronic means, the information required by the Global Fund for publication over the internet through the Price and Quality Reporting mechanism.<sup>40</sup> Upon receipt of health products in the country 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 & Quality Reporting mechanism available on the Global Fund website at <https://www.theglobalfund.org/en/sourcing-management/price-quality-reporting/> by selecting either “Price Reference Report” or “Transaction Summary”.

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

**8.3** Recipients are currently required to report the following categories of health products:

- i. ARVs;
- ii. anti-malarial pharmaceutical products;
- iii. anti-TB pharmaceutical products;
- iv. anti-hepatitis C pharmaceutical products;
- v. long-lasting insecticidal nets;
- vi. insecticides for indoor residual spraying activities;
- vii. condoms; and
- viii. diagnostic tests for HIV, TB, malaria, and co-infections such as syphilis, hepatitis B and hepatitis C.

This list may be updated from time to time on the Global Fund’s website.

**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 in the Price & Quality Reporting mechanism, and other requirements under this guide.

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

## DEFINITIONS

**Antiretroviral (ARVs)** Pharmaceutical products for treatment and prevention of HIV (prevention of mother-to-child transmission, pre-exposure prophylaxis, where indicated and post-exposure prophylaxis).

### **Anti-malarial pharmaceutical products**

Pharmaceutical products for curative treatment and for prophylaxis of malaria

### **Anti-Tuberculosis pharmaceutical products**

Pharmaceutical products for curative treatment and prophylaxis of tuberculosis. Injectable diagnostics agents e.g. tuberculin, purified protein derivatives should be considered under this category.

**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.

**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. The panel is hosted by the World Health Organization Essential Medicines medicines and Health Products health products Department

**External quality assessment (EQA)** 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 labelling.

**Global Harmonization Task Force (GHTF)** refers to 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. As of 2012, GHTF has been replaced by the **International Medical Device Regulators Forum (IMDRF)**, a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the GHTF and aims to accelerate international medical device regulatory harmonization and convergence. Further details are available at [www.imdrf.org/](http://www.imdrf.org/)

**Health products** includes: (i) pharmaceutical products; (ii) durable and non-durable in-vitro diagnostic products, microscopes and imaging equipment; (iii) long-lasting insecticidal 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 the 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/NO45:2008).

**Long-lasting insecticidal 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.

**List of health products and procurement and supply management implementation arrangements** 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, with quantities and 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 grantee, Principal Recipient, sub-recipient, sub-sub-recipient or procurement agent).

**Stringent Pharmaceutical Regulatory Authority (or Stringent 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](http://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** means the World Health Organization

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

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## ACRONYMS

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<b>ACT</b>	Artemisinin-based Combination Therapy
<b>ARVs</b>	Antiretroviral
<b>CIPAC</b>	Collaborative International Pesticides Analytical Council
<b>GHTF</b>	Global Harmonisation Task Force
<b>IMDRF</b>	International Medical Device Regulators Forum
<b>ISO</b>	International Standard Organization
<b>MDR-TB</b>	Multi-drug resistant tuberculosis
<b>MQAS</b>	Model Quality Assurance System for Procurement Agencies (WHO)
<b>UNFPA</b>	United Nations Population Fund
<b>USAID</b>	United States Agency for International Development
<b>WHO</b>	World Health Organization
<b>WHOPES</b>	WHO Pesticide Evaluation Scheme
<b>WTO</b>	World Trade Organization





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

Chemin de Blandonnet 8  
1214 Vernier, Geneva  
Switzerland

[theglobalfund.org](http://theglobalfund.org)

T +41 58 791 1700

F +41 58 791 1701