Unitaid

PROCUREMENT OF HEALTH PRODUCTS

An Operational Guideline for Unitaid Grantees

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1. BACKGROUND

Unitaid is a global health initiative, established to provide sustainable, predictable, and additional funding to significantly impact market dynamics to reduce prices and increase the availability and supply of high-quality commodities for the prevention, diagnosis, and treatment of HIV and AIDS, HCV, malaria, and tuberculosis (TB), primarily for people living in low-resource settings.[i]

2. PURPOSE

The intent of this document is to provide clear guidance to grantees on the principles, norms, standards, and procedures that apply when Unitaid funds are used for procurement. Recognizing the importance of harmonizing Unitaid's procurement approach with established international best practices, this guideline is the result of a comprehensive desk review of the procurement practices of other organizations including, but not limited to, the Global Fund, WHO, the World Bank, and UNICEF.

Although this guideline broadly defines the required procurement approach, it is the grant agreement concluded between WHO (on behalf of Unitaid) and the grantees, including the project plan, budget, logical framework, and associated procurement strategy, that governs the legal relationship between Unitaid and grantees and establishes the terms of collaboration for a Unitaid-funded project.

The guideline may be amended or updated from time to time at Unitaid's sole discretion. Grantees are required to routinely check the Unitaid website for updates. Any amendment or update will be published on the Unitaid website at www.unitaid.org.

In the references section of this guideline, users will find useful references to web links with more detailed, international best-practice documents relating to procurement.
Hereinafter reference to grantees includes, if relevant, any of grantee's sub-contracted procurement and/or other agent(s) and/or sub-grantees.

3. SCOPE

The guideline covers procurement of HIV and AIDS, HCV, TB, and malaria-related health products financed by Unitaid. These health products include the following categories that are aligned with the six strategic objectives set out in *Unitaid's Strategy, 2013-2016*:[ii]

1. Point of care (POC) diagnostics for HIV and AIDS, HCV, TB, and malaria
2. Paediatric medicines to treat HIV and AIDS, HCV, TB, and malaria
3. Emerging medicines and/or regimens as well as new formulations, dosage forms, or strengths of existing medicines that will improve the treatment of HIV and AIDS, HCV and co-infections (e.g., viral hepatitis)
4. Artemisinin-based combination therapies (ACTs) and emerging medicines, that, in combination with appropriate diagnostic testing, will improve the treatment of malaria
5. Second-line TB medicines, and emerging medicines and regimens that will improve treatment of both drug-sensitive and multidrug-resistant TB (MDR-TB)
6. Products for the prevention of HIV and AIDS, HCV, TB, and malaria, notably devices for male circumcision, microbicides, and vector-control tools to prevent malaria transmission

4. PRINCIPLES

The following principles, derived from Unitaid's Constitution, guide its strategic actions, decisions, and operations at all levels **including procurement by grantees**:

- Unitaid is **transparent and efficient** in its governance, agreements, and operations.
- Unitaid focuses its activities on achieving **global impact**, benefiting all developing countries in a way that is **sustainable**. Its time-limited investments in improving health product markets aims to achieve significant **leverage** by increasing global access to products, generating positive externalities for global health, and achieving a multiplicative return on the funds invested.
- Unitaid supports promising **innovative** approaches to improving global health.
- Unitaid's prioritization and project selection process is underpinned by the objective of maximizing **value for money**.
- Unitaid supports **equity** in addressing health disparities systemically associated with social and economic disadvantages related to access to health commodities in vulnerable populations, and based on current scientific evidence.
- Unitaid takes a pro-public health approach to **intellectual property**.[1]
- Unitaid subscribes to global "green procurement" efforts.

The procurement strategies and approaches employed by grantees are expected to improve access to Unitaid's priority health products by addressing the following market shortcomings that contribute to reduced access:[iii]

- **Availability**: The optimal medicine or technology to effectively prevent, diagnose or treat a particular disease or condition is not currently available;

- **Affordability**: The medicine or technology is offered at a price that imposes an unreasonable financial burden on governments, donors, individuals, or other payers;

- **Quality**: The medicine or technology is of sub-standard quality or reliable information on the quality of the product is not available. This includes not only the quality of the final product, but also the quality of starting and intermediary materials used to manufacture the final product;

- **Acceptability/adaptability:** The medicine or technology is not available or accessible in a format, formulation, or dose that is appropriate for use in a given population or setting;

- **Delivery:** Supply chain management systems (including product slection, quantification, procurement, storage, and distribution) are unable to equitably provide the right product or technology to the right person, in the right presentation, at the right dose, and at the right time with the least potential for error and at the lowest cost.

5. PROCUREMENT APPROACHES, RESPONSIBILITIES, STANDARDS, NORMS AND OBLIGATIONS

Procurement Strategy and Plan

5.1. For projects with a procurement component, Unitaid requests specific procurement-related information at the proof of concept (Intention to Submit) and proposal stages, prior to funding approval, and throughout the lifecycle of its approved projects. This is thoroughly documented in **Annex 1** to this document.

5.2. Each grantee is required to develop a procurement strategy for soliciting, selecting, and procuring products designed to achieve the market shaping and country-support goals of Unitaid-funded projects and to ensure a transparent and fair process that provides equal opportunity for all eligible products to be considered for inclusion in the project.

5.3. The development of the procurement strategy shall be informed by market information (including opportunities to pool procurement with other relevant funders/Unitaid grantees) and in-country intelligence.

5.4. The procurement strategy will establish, among other things, criteria for evaluating bids and a price negotiation strategy and will inform the development of requests for proposals and tenders under the project.

5.5. The procurement strategy will be designed to maximize competition among product manufacturers to support healthy and sustainable markets for priority products and to ensure affordable pricing, value for money, and optimal access.

5.6. **Unitaid's acceptance of a grantee's procurement strategy is a key prerequisite to signing a grant agreement and commencing project implementation.** The procurement approach set out in the procurement strategy should be in line with the international best-practices documented in WHO's *Operational Principles for Good Pharmaceutical Procurement,*[iv] and *Interagency Guidelines: A Model Quality Assurance System for Procurement Agencies* (referred to as MQAS).[v]

Unitaid's acceptance of a grantee's procurement strategy is a key prerequisite to signing a grant agreement.

5.7. Each grantee is also required to develop a procurement plan consistent with the procurement strategy. The procurement plan provides an overview of the tactical procurement approach (e.g., negotiations, tenders, and frequency thereof) and of the products to be procured in a defined period of time during the project (i.e., semiannual or annual period), based on the approved programmatic requirements of the project. The latter component of the procurement plan (products to be purchased) will include product cost and related cost estimates (freight, insurance, etc.) and will be provided to Unitaid at least on a semiannual basis, together with required procurement reporting and updates.

Procurement Capacity and Sub-Contracting

5.8. **Grantees may carry out procurement activities directly or sub-contract out this function to one or more procurement agents and/or sub-contractors. Either approach is subject to a satisfactory capacity assessment conducted by Unitaid.** Capacity considerations will include an assessment of resources (e.g., financial systems and human resources); documentation of policies and standards (e.g., quality manual, SOPs, code of conduct); procurement methods; product quality assurance in purchasing, organization, and responsibilities; and monitoring of supplier performance and storage and distribution practices, all in accordance with MQAS.[vi]

Grantees may carry out procurement activities directly or sub-contract it out. Either approach is subject to a satisfactory capacity assessment conducted by Unitaid.

5.9. When sub-contracted out, the selection of a procurement agent should follow transparent and competitive methods.

5.10. Grantees may also sub-contract with credible, experienced freight, insurance, customs clearance, and/or independent quality control agents for related services, ensuring always that sub-contractors are selected through a transparent, competitive process and in compliance with MQAS guidelines,[vii] and, where applicable, WHO's *Guide to Good Storage Practices*[viia] and *WHO Good Distribution Practices for Pharmaceutical Products.*[viib]

5.11. **Unitaid reserves the right to review and approve the selection process for any sub-contracted agents.** If, according to its capacity assessment, Unitaid determines the capacity of a grantee and/or its sub-contracted agent(s) to be insufficient, Unitaid may, at its sole discretion, require the grantee to use other established procurement and/or supply management agents or services acceptable to Unitaid.

Unitaid reserves the right to review and approve the selection process for any sub-contracted agents

Shipping and Insurance

5.12. In arranging for the shipment of products, grantees should endeavor to secure the most efficient and least costly means of delivery and insurance that meets the needs of beneficiary countries and ensures the safety and timely delivery of all products. INCOTERMS selected for each shipment must be dictated by the requirement of the specific procurement and be in conformity with the broader objectives of the procurement strategy.

5.13. Every effort to establish long-term agreements (LTAs) when outsourcing these services should be made by grantees.

Regional and Local Procurement

5.14. In an effort to expand the manufacturing base, grantees should use all reasonable efforts to ensure that eligible regional or local manufacturers are included in competitive selection processes and are favorably considered for awards of contracts, as long as the total cost of ownership is comparable to the lowest cost offered by a given international bidder and as long as the decision to procure locally or regionally results in more efficient (rapid, cost-effective) procurement.

5.15. Procurement-related negotiations should be conducted directly between the grantee and product manufacturer. However, grantees may choose to procure quality-assured products from local distributors and/or manufacturers' representatives as long as the total cost of ownership is comparable or lower than procurement through product manufacturers and access is enhanced. **The pre-approval of Unitaid is required to carry out such procurement, in advance and in writing.**

The pre-approval of Unitaid is required in advance and in writing, to carry out any procurement from local distributors and/or manufacturers' representatives.

Green Procurement

5.16. **Unitaid subscribes to a green procurement policy, which is as follows: Grantees will seek to procure goods and services that lessen the burden on the environment in their production, use, and final disposal, whenever possible and economical. To effect green procurement, Unitaid supports the 4 R's strategy to (i) re-think the requirements to reduce environmental impact, (ii) reduce material consumption, (iii) recycle materials/waste, and (iv) reduce energy consumption.** Before finalizing the procurement of goods and/or services, grantees should consider environmental concerns, including energy consumption, toxicity, ozone depletion, and radiation. The applicable eco-label ratings, including Energy Star, EU Eco-label, etc., should be evaluated to determine how environmentally friendly the goods and/or services are. The aim is to identify green goods and services, which have fewer harmful effects on human health and the environment than competing goods and services serving the same purpose. The project grantees will have to carefully consider the environmental impact of their work, especially on transportation and disposal of cartridges, machines, wastes, etc. Such considerations need to be presented in the project plan.

Grantees will seek to procure goods and services that lessen the burden on the environment.

Exceptions to Competitive Selection

5.17. A product may be contracted for quality-assured supply outside a competitive selection process in the following circumstances: where there is only one identified product that meets the criteria for supply to Unitaid grants, grantees will endeavor to negotiate the best prices, terms, and conditions for a term-limited procurement in order to supply that product prior to a competitive process being conducted, once a sufficient number of products are available. Grantees should strictly limit the quantities to be procured and the duration of the contract to the bare minimum and avoid offering market exclusivity or any fixed-term contract, during which selection of potential competitors through the tendering process could be hindered. **Such contracts should be subject to prior approval by Unitaid following receipt of a formal request.**

A product may be contracted for quality-assured supply outside a competitive selection process in the above-mentioned circumstances. Such contracts should be subject to prior approval by Unitaid following receipt of a formal request

5.18. Grantees may decide to exclude suppliers identified as eligible by WHO/Unitaid from the competitive selection process if there are sound ethical, commercial, and/or other reasons for doing so. **In such cases, the reasons for disqualification should be documented and agreed to in advance by the Unitaid Secretariat.**

Monitoring Performance

5.19. Grantees should monitor and evaluate the supply of all products under the project and work closely with suppliers, beneficiary countries, and Unitaid to ensure that the objectives of the project are being met in accordance with agreed performance metrics. The parameters to be monitored (product prices, delivery lead times, shipping costs, agent fees, etc.) will be defined in the logical framework that is developed as a part of the aforementioned grant agreement concluded by Unitaid directly with grantees.

Conflict of Interest and Confidentiality

5.20. Grantees should have conflict of interest and confidentiality policies and mechanisms for the disclosure and management of conflicts of interest and confidential information. They should ensure that all personnel involved in the selection of products are not bound by any real, potential, or apparent conflicts of interest or any practices infringing confidentiality agreements between all parties to procurement at all times and throughout the life of the project.

Avoidance of Fraud, Waste and Diversion

5.21. Grantees should have in place adequate procedures, systems, and measures in accordance with the provisions of the grant agreement to ensure the quality and security of supplied items and avoid any fraud, diversion, and/or waste (e.g., drug expiries, product damage, improper storage) throughout the supply chain. **Grantees are required to report to Unitaid all cases of suspected fraud and loss during the project, including after closure of a suspected case.**

Grantees are required to report to Unitaid all cases of suspected fraud and loss during the project.

5.22. Unitaid may conduct or commission financial audits, reviews, and operational or programmatic evaluations of any or all of a grantee's procurement activities, documents, and/or records relating to a Unitaid- funded project.

6. COMPLIANCE WITH APPLICABLE INTERNATIONAL & NATIONAL POLICIES AND LAWS

Compliance with WHO and National Treatment Guidelines

6.1. When defining the products' technical specifications, grantees should ensure that they are in accordance with WHO and beneficiary country treatment guidelines for medicines, diagnostics, and preventives. National preferences for a given brand are not acceptable to Unitaid.

Applicable International and National laws

6.2. The manufacture, procurement, and delivery of Unitaid-funded health products and all related contracts associated with Unitaid-funded projects should be consistent with applicable national and international laws, including applicable intellectual property (IP) laws. Where IP barriers hamper competition, affordability, and/or development of appropriate formulations (e.g., fixed-dose combinations), Unitaid will support countries' use of compulsory licensing or other flexibilities under the guidelines of the 2001 World Trade Organization Declaration on the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) and Public Health ('Doha Declaration'), when applicable.[vii]

National Regulatory and Importation Requirements

6.3. Grantees should ensure that the products are registered with the National Drug Regulatory Authority (NDRA) of each beneficiary country or granted waivers of registration, if necessary, prior to the delivery of goods.

Specifically, grantees should:

- Expedite all authorizations necessary for the importation of products into project countries, including clearance, storage, and distribution of all;

- Ensure exemption of the products from any duties, taxes, charges, licenses, or fees associated with the importation of the products into the project countries.

Unitaid reserves the right to request evidence from the grantee on fulfillment of the above obligations.

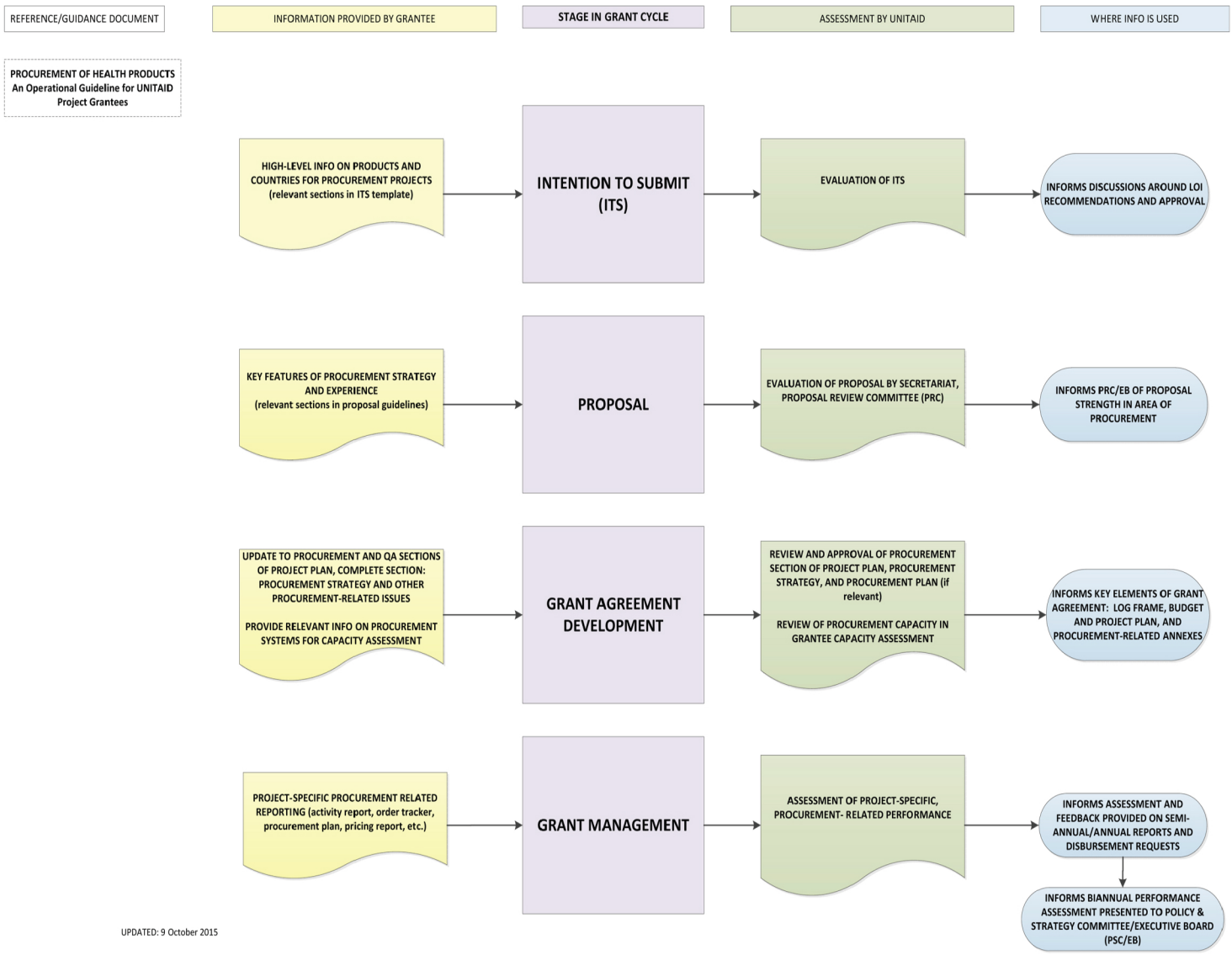
7. PRODUCT QUALITY ASSURANCE

7.1. Unitaid requires that its grantees procure all health products funded by it, in accordance with *Unitaid Quality Assurance Policy for HIV/AIDS, HCV, Tuberculosis and Malaria Health Products.*[viii]

7.2. The Unitaid QA guideline is intended to guide Unitaid's grantees on the specific quality requirements that pharmaceuticals and diagnostic products purchased with Unitaid resources must meet to ensure the quality, safety, and efficacy of products throughout the supply chain to the point of use, for adequate prevention, diagnosis, treatment, and monitoring in HIV, TB, and malaria programs. The guideline is a product of extensive stakeholder consultation and buy-in and is founded on the quality assurance standards set forth by WHO's Medicines and Diagnostics Prequalification Programmes[ix] and Stringent Regulatory Authorities.[x]

ANNEX 1: PROVISION AND USAGE OF PROCUREMENT-RELATED INFORMATION FOR UNITAID-FUNDED GRANTS

PROVISION AND USAGE OF PROCUREMENT-RELATED INFORMATION FOR UNITAID-FUNDED GRANTS



UPDATED: 9 October 2015

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[viii] *Unitaid Quality Assurance Policy for HIV/AIDS, HCV, Tuberculosis and Malaria Health Products*, October 2013

[ix] WHO Prequalification of Diagnostics Programme available at http://www.who.int/diagnostics_laboratory/evaluations/en

[x] *Unitaid Quality Assurance Policy for HIV/AIDS, HCV, Tuberculosis and Malaria Health Products,* October 2013

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