

Technical Guidance Note for Global Fund HIV Proposals



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Access to medicines and health technologies and Strengthening the pharmaceutical sector component of health systems strengthening funding requests

Rationale for including this activity in the proposal

Within the Global Fund financing portfolio, more than 40% of grants are invested in procuring and managing pharmaceuticals and health products. Ineffective and inefficient pharmaceutical systems are one of the major obstacles to scaling-up HIV, tuberculosis and malaria programmes. This affects the health outcomes for these and other diseases, and wastes resources when supplies expire and cannot be used. Strengthening procurement and supply management systems is a key health systems priority for the Global Fund.

Health service delivery is critically dependent on access to medicines and health technologies – this access is one of the World Health Organization's (WHO) six building blocks of health systems.¹

In resource-limited settings, health systems are often weak in their pharmaceutical and health technology supply services. The attention and priority given to specific health programmes – such as HIV, tuberculosis (TB), family planning and immunization – has in many countries led to the development of “vertical” procurement and supply management of related medicines and health technologies. These vertical systems have often been successful in securing access to the programme-specific supplies – as the relatively low stock-out and inventory loss rates for HIV medicines shows – but are not 100% successful. Some define the range of supplies in their purview too narrowly (e.g. no oral morphine or co-trimoxazole in HIV supply chains). This shows that even managing supply systems with a relatively small scope remains challenging in the absence of a significant human resource base and flexible infrastructure. In addition, indefinitely managing programme supplies vertically hampers adequate resourcing of critical functions of the national pharmaceutical sector, such as the effective regulatory control of medicines and medical devices, and it makes it difficult to realize economies of scale in warehousing, distribution and the development of logistic management information systems.

To secure long-term, sustainable supply of medicines and health technologies for HIV, TB and malaria, the Global Fund and WHO collaborate to develop and implement a more comprehensive approach to the pharmaceutical sector and health technology supply chains.

Situation analysis

The Global Fund and WHO suggest that the pharmaceutical sector is assessed to identify areas that need strengthening using the Global Fund–WHO Harmonized Country Pharmaceutical Profile (attached). This tool has nine sections:

1. health and demographic data
2. health personnel and infrastructure
3. health and pharmaceutical policy
4. pharmaceutical manufacturers
5. pharmaceutical regulations including pharmacovigilance

¹ *Everybody's business: strengthening health systems to improve health outcomes – WHO's framework for action.*, Geneva, World Health Organization, 2007.

6. medicine financing, pricing, affordability and availability
7. pharmaceutical procurement and distribution
8. selection and rational use
9. household data on access.

These areas facilitate assessment of the whole pharmaceutical sector and raise issues that are likely to be relevant for all disease programmes, including HIV, TB and malaria. Disease-specific PSM programmatic issues can be addressed using the Pharmaceutical and Health Product Management Country Profile (Part II) and the Procurement Plan, which cover the following sections:

- ◆ overview of existing Global Fund and pharmaceutical and health product management (PHPM) arrangements;
- ◆ overview of current PHPM technical assistance;
- ◆ key stakeholders in PHPM and their coordination;
- ◆ product selection for specific diseases (HIV, TB, malaria);
- ◆ procurement;
- ◆ management information and reporting systems;
- ◆ forecasting and quantification;
- ◆ receipt, storage and inventory management;
- ◆ distribution.

Details of these sections are in the attached Country Profile Part 2. The Procurement Plan details a list of pharmaceutical, health and non-health products; their compliance to WHO and national standards and to Global Fund quality assurance policies; and their estimated quantities, cost and procurement schedules. For details, the Procurement Plan tool is attached.

Objectives for this area

- ◆ To secure an uninterrupted supply of the medicines and health technologies needed for the response to HIV, TB and malaria.
- ◆ To strengthen the national medicines and health technologies supply systems through various mechanisms (particularly capacity building activities) to develop and maintain long-term sustainable supply chain management systems for HIV, TB and malaria medicines and health technologies.

Focus populations

The beneficiaries of improved supply chains management systems for HIV, TB and malaria commodities are primarily the clients of programmes, but they benefit the entire population of partner countries beneficiaries of Global Fund money. It may be advisable to coordinate the medicines and health technology flows for HIV, TB and malaria with those of other health concerns, and adopt a systemic approach to developing the capacity for both.

Focus populations to improve medicines and health technology supply systems include the people working in and preparing to work in institutions and companies who manage and support the availability of health supplies, and the decision-makers who define their priorities and performance.

Suggested activities

The activities that need resourcing would be identified by the situation analysis of the pharmaceutical sector and the state of the HIV, TB and malaria supply chains. Several Principal Recipients have indicated the following priority areas for strengthening their pharmaceutical systems:

- ◆ quantification and forecasting;
- ◆ procurement planning;
- ◆ logistics management (storage, inventory control, transportation, distribution and management information systems);
- ◆ quality assurance activities;
- ◆ national or central medical stores and affiliates.

Controlled substances should also be made available, such as oral morphine for use in opioid substitution therapy (if this is part of the grant request) and palliative care.²

Suggested key indicators

The 12 “Harmonized monitoring and evaluation indicators for the PSM systems” help prevent stock-outs and overstocking of antiretroviral, anti-tuberculosis and antimalarial medicines. The indicators marked with a star (*) are considered as early warning indicators to prevent stock-outs and overstocking.

1. Percentage of medicine items received (procured plus donated) or planned to be received that are in the national standard treatment guidelines.
- 2a. Percentage of patients receiving antiretroviral drugs and tuberculosis treatment in line with national standard treatment guidelines.
- 2b. Percentage of patients initiating antiretroviral treatment on regimens in line with first-line treatments in national standard treatment guidelines. (This is also an early-warning indicator for HIV drug resistance.)
- 3*. Proportion of quantities of products actually received (procured plus donated) during a defined period out of total quantities planned for the same period.
- 4*. Percentage of quantities used out of total quantities available for consumption after deduction of buffer stock (opening balance plus quantities procured plus quantities donated minus buffer stock) during a defined period.
5. Ratio between median price of products procured and the international median reference value.
- 6*. Percentage of orders delivered in full and on time (as stated in the procurement agreement) per supplier in a defined period.
- 6b1. Percentage of orders to be cleared from port that were cleared before the deadline.
- 6b1. Average number of days between arrival at port and date of clearance from port.
7. Percentage of the product batches tested in the past year that met national and international quality control standards.
- 8*. Percentage of treatment sites that received all orders in full and on time during a defined period.
- 9*. Percentage of treatment sites that submitted complete inventory control reports on time, according to an established schedule, during a defined period.

² See A ‘step-by-step’ algorithm for the procurement of controlled substances for drug substitution treatment. Geneva, United Nations Office on Drugs and Crime, World Health Organization and the Joint United Nations Programme on HIV/AIDS, 2007 (http://www.who.int/hiv/amds/step_by_step_procure_subs_treat.pdf, accessed 2 August 2011).

10. Percentage of quantities of each product lost per total quantities available for use (opening stock plus quantities procured plus total quantities donated) in a defined period.
- 11*. Percentage of treatment sites that placed orders during a defined period while the stock in hand of one or more items was below the minimum stock level.
12. Percentage of treatment sites that had a stock-out of one or more required medicines during a defined period. (This is also a universal access indicator and early-warning indicator for HIV drug resistance.)

Further information can be found at http://www.who.int/hiv/pub/amds/monitoring_evaluation/en/index.html

Linkages with other activities

Access to medicines and health technology links to all forms of health service delivery, and is critical for the availability of selected commodities (such as condoms and rapid diagnostic tests), service delivery in other sectors and community-level programmes. Strengthening access to medicines and health technology is part of efforts to strengthen health systems.

Approach to costing

With increasing demand and constrained resources, it is very important to procure health supplies in the most cost-effective way. To inform decisions about competitive prices for medicines and diagnostics for HIV, TB and malaria, several databases benchmark prices for various commodities and medicines:

- ◆ The Global Price Reporting Mechanism collects procurement transactions from all the AIDS Medicines and Diagnostic Services' (AMDS) collaborating partners, including the Global Fund, the US President's Emergency Plan for AIDS Relief (PEPFAR), and national procurement agents. It currently captures over 90% of HIV medicines procurement in low and low–middle-income countries; a large proportion of sales of medicines for opportunistic disease, TB and malaria; and an increasing number of transactions of diagnostics used in HIV, TB and malaria. The database is searchable by medicine and formulation, diagnostic test, country, group of countries and country income category. See <http://www.who.int/hiv/amds/gprm/en/index.html>
- ◆ The Global Fund's Price and Quality Reporting (PQR) collects all procurement data of medicines and diagnostics, bed nets and equipment that is paid for with Global Fund proceeds. See <http://www.theglobalfund.org/en/procurement/pqr/>
- ◆ Médecins sans Frontières maintains a database on prices quoted by suppliers of antiretroviral drugs and their price policies; this has more information on upper-middle-income countries than the Global Price Reporting Mechanism or PQR. See <http://utw.msfacecess.org/>
- ◆ Management Sciences for Health (MSH) maintains the International Essential Drug Price Indicator, which samples procurement of essential medicines and is useful to benchmark procurement prices of medicines not included in the Global Price Reporting Mechanism or PQR databases. See <http://erc.msh.org/mainpage.cfm?file=1.1.htm&module=dmp&language=english>

Price information on condoms can be found from the United Nations Population Fund, or from the Global Price Reporting Mechanism at <http://www.who.int/hiv/amds/condoms/en/index.html>

Information on sources and prices of medicines used for opioid substitution therapy and oral morphine can be found in the controlled substances database maintained by AMDS at <http://www.who.int/hiv/amds/controlmedicine/en/index.html>

Beyond costing the procurement of the commodities, it is important to also budget for their transport to the country, clearance through customs (which might require paying tariffs, taxes and handling fees), transport to warehouses and distribution from warehouses to the facilities where they will be dispensed. To avoid stock-outs and overstocking, quantification and forecasting need to be resourced, and procurement needs to be planned. Logistics management (storage, inventory control, transportation, distribution and management information systems) needs to be resourced and budgeted, and quality assurance activities paid for. Technical assistance and capacity building activities to strengthen quality assurance services and quality control tests also need to be costed.

Sources of technical assistance for implementation

WHO and other partners in the AMDS network coordinate to provide technical support to PRs. This support includes PSM workshops that strengthen the capacity of PSM managers, linking the PR to emergency supplier to mitigate the risk of stock-outs and direct country technical support to tackle specific PSM areas at the request of the PRs.

AMDS partners can be contacted directly or via the AMDS web site.

The Global Fund Secretariat established the Procurement Support Service within the Pharmaceutical Management Unit, to facilitate the provision of Voluntary Pooled Procurement and Capacity Building Services / Supply Chain Management Assistance for grant recipients. It provides support to address procurement bottlenecks and supply chain management challenges, and facilitate timely access to pharmaceuticals and health products, with a focus on improvement and sustainability of in-country pharmaceutical management systems. Applicants are referred to the Global Fund web site for additional information on the procurement support service at <http://www.theglobalfund.org/en/procurement/vpp/?lang=en>

Links to key reference materials

AMDS web site: <http://www.who.int/hiv/amds/en/>, with links to:

- ◆ Global Price Reporting Mechanism <http://www.who.int/hiv/amds/gprm/en/index.html>
- ◆ Regulatory database http://www.who.int/hiv/amds/patents_registration/en/index.html
- ◆ Controlled substances database <http://www.who.int/hiv/amds/controlmedicine/en/index.html>

Benchmarks for procurement prices for medicines and diagnostics

- ◆ Global Fund: <http://www.theglobalfund.org/en/procurement/pqr/>
- ◆ Médecins sans Frontières: <http://utw.msfaccess.org/>
- ◆ Management Sciences for Health: <http://erc.msh.org/mainpage.cfm?file=1.1.htm&module=dmp&language=english>

PSM toolbox

WHO and AMDS partners maintain a database of approximately 300 tools developed by various institutions working in supply chain management and pharmaceutical sector, which can be used for capacity building. The database and links to the tools, searchable by PSM area, disease, type of commodity or organization is available at <http://www.psmtoolbox.org/en/>

Selecting high-quality medicines

Lists of prequalified medicines and their suppliers can be found on the WHO prequalification programme website at <http://apps.who.int/prequal/> and on the United States Food and Drug Administration website at <http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/AsiaandAfrica/ucm119231.htm>

Global Fund standards for procurement

Link to GFATM standards required for procurement and overall management of health products, based on recognized international norms and standards.

- ◆ PQR: <http://www.theglobalfund.org/en/procurement/pqr/>
- ◆ Quality assurance policy: <http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/>
- ◆ Country Profiles (1 and 2) and the procurement plan (attached)

