



**Pan American  
Health  
Organization**

Regional Office of the  
World Health Organization

**PAHO Policy in the Procurement of Pharmaceutical Products  
For Projects  
Financed by the Global Fund to Fight HIV/AIDS,  
Tuberculosis and Malaria**

**Context:**

The following policy has been elaborated by the Pan American Health Organization (PAHO) in support of Principal Recipients designated by the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GFATM) that wish to use the procurement services of PAHO for the purchase of pharmaceutical products required in the implementation of projects financed by the GFATM.

Specifically the policy applies to the procurement of ‘medicines’, ‘pharmaceutical products’ or ‘multisource pharmaceutical products’ as defined by the World Health Organization in the glossary, ‘Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A Manual for Drug Regulatory Authorities’. This information is found at <http://www.who.int/medicines/>.

### Policy Objective:

The procurement policy aims to ensure that any pharmaceutical product financed by a GFATM program grant is procured through PAHO applying ‘WHO Principles for Good Pharmaceutical Procurement’, in accordance with the ‘Global Fund Policy on Pharmaceutical and Other Health Products’, and following ‘PAHO Procurement Procedures and Regulations’. Specifically, it is expected that application of the policy will ensure that Principal Recipients receive the most cost-effective pharmaceutical products of quality, in correct quantities, procured on a timely basis, and at the lowest possible cost.

### Operational Elements of the Policy

#### 1. Selection of Pharmaceutical Products

In accordance with GFATM guidelines, Principal Recipients using PAHO procurement services for the purchase of pharmaceuticals must ensure that required products are included in national treatment guidelines, or the essential drug list of the WHO, the Member State, or the Principal Recipient as defined in the relevant grant agreement. Countries and recipients wishing to purchase products not included in one of the above lists should seek approval from the GFATM in writing before proceeding with procurement.

PAHO may provide technical assistance to the Principal Recipient on written request to ensure that drug selection conforms to the above criteria and needs of the country.

## 2. Estimation of Needs

Prior to requesting PAHO to solicit prices on its behalf, a Principal Recipient should ensure that product requirements are initially based on morbidity data, and thereafter on product consumption and estimated scale-up rates, and in accordance with the approved proposal. Stock management parameters within the supply chain must be taken into account to avoid stock outs. Upon written request, PAHO may provide technical assistance to countries to finalize the estimation of requirements, including supply chain management, product forecasting and evaluation of consumption patterns.

## 3. Selection of Suppliers

On official request by the Principal Recipient, PAHO will solicit prices from a list of pre-qualified suppliers of pharmaceutical product. Product quality is to be ensured through the rigorous application of criteria in the source selection of product:

- For single or limited-source pharmaceuticals including HIV/AIDS Antiretrovirals (ARVs):
  - A product listed in the most recent edition of the UN Pilot Procurement Quality and Sourcing Project (ref. <http://www.who.int/medicines/organization/qsm/activities/pilotproc/suppliers.doc>) **or**
  - A product authorized for use by the regulatory authority of a member of the Pharmaceutical Inspection Convention (ref. <http://www.picscheme.org/index.htm>) **or**
  - A product authorized by the regulatory authority of a member of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ref. <http://www.ich.org/>) **or**

- Until December 31, 2004, a product that has been registered by the National Drug Regulatory Authority. In the latter case, the Member State or Principal Recipient must provide in writing the Product Authorization Number of the product issued by the National Drug Regulatory Authority.
- For multisource pharmaceutical products:
  - Manufacturers and secondary suppliers that have been evaluated and prequalified by PAHO, providing evidence from the National Drug Regulatory Authority that they conform to current requirements of Good Manufacturing Practices, and apply appropriate standards in quality assurance and control to the products they are selling.
- For Second Line Drugs used in the Treatment of Multi-Resistant Tuberculosis
  - Products supplied through the Green Light Committee of the Global Stop TB Partnership.

#### 4. Price Solicitation and Procurement

At the request of the Principal Recipient, PAHO will solicit prices from pre-qualified suppliers in a manner that ensures effective competition, transparency and accountability in accordance with the 'Interagency Operating Principles for Good Manufacturing Practices', and following PAHO Procurement Rules and Regulations. The Principal Recipient will receive a consolidated price estimate indicating the lowest price per product consistent with quality criteria, and indicating the name of the product's manufacturer. Product prices normally are presented either on an FCA or CIP basis, freight and insurance at cost (ICC Incoterms 2000). The Price Estimate will include an administrative fee which is calculated by multiplying 3% times the cost of the product. Freight and insurance costs are not included in the calculation of the administrative fee.

PAHO does not solicit prices from suppliers unless there is firm intention to purchase: PAHO thus maintains the capacity to achieve best prices and conditions for those wishing to use PAHO procurement services.

It is the responsibility of the Principle Recipient to ensure that products selected comply with the Member State's patent protection regulations.

PAHO will proceed with procurement of a product upon receipt of a written request from the Principal Recipient, and upon receipt of funding adequate to cover the cost of the order plus PAHO's administrative fee.

#### 5. Shipment

All pharmaceuticals purchased through PAHO will be consigned to the Principal Recipient who is responsible for all customs clearance procedures and associated costs. Copies of purchase orders and shipping documents will be provided to the Principal Recipient institution prior to delivery. PAHO will coordinate delivery with the consignee, normally through the PAHO Country Office.

#### 6. Administrative and Technical Support

Principal Recipients wishing to avail of PAHO procurement services for the purchase of pharmaceutical products financed under a GFATM funded program must coordinate technical and administrative elements of the procurement process through the relevant PAHO Country Office. The Country Office, in turn, will coordinate with relevant technical program offices and the Procurement Services Unit at PAHO Headquarters, Washington DC. Similarly, PAHO communication and support to the Principal Recipient normally will be channeled through the PAHO Country Office.

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