PHARMACEUTICAL SYSTEMS STRENGTHENING AND PHARMACOVIGILANCE INFORMATION NOTE

Introduction

A well-functioning system for providing equitable access to quality essential pharmaceuticals, health products and technologies is one of the seven essential functions of a health system. A pharmaceutical system consists of functions and activities to select, quantify, procure, store, distribute, use and monitor quality-assured health products.

Pharmaceutical systems can be strengthened through technical support and other capacity building efforts that cover processes by which individuals, groups, organizations, institutions and countries increase their abilities to perform core functions, address challenges, define and achieve objectives in a sustainable manner.

Why is pharmaceutical systems strengthening critical within the context of Global Fund investment?

Within the Global Fund financing portfolio, increasing access to critical health products is a core element of its mandate as it is estimated that between 20 and 45 percent of grants are invested at country level for the procurement and management of pharmaceuticals and health products. Ineffective and inefficient pharmaceutical systems are a major obstacle to achieving scale-up of HIV/AIDS, tuberculosis and malaria interventions, and better health outcomes for these and other diseases.

Why is pharmaceutical systems strengthening important?

a) General

The Global Fund recognizes the importance of supporting the strengthening of public, private and community health systems where weaknesses and gaps in those systems constrain the achievement of improved outcomes in reducing the burden of HIV, tuberculosis and malaria (Global Fund Fact Sheet: Health Systems Strengthening).

Inadequacies in various areas of the pharmaceutical sector often translate to weaknesses and/or challenges in procurement, management, delivery and use of safe and effective pharmaceuticals and health products. These challenges generally become the main obstacles faced by countries during grant signing and implementation, and often negatively impact grant performance. Key outcomes of inefficient pharmaceutical systems are stock-
outs and/or disruption of treatments and in some cases, overstocking and expiry of health products.

b) Pharmacovigilance

Pharmacovigilance (PV) is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem”. It is therefore essential for the review and update of international and national treatment guidelines and its wider implementation can help alert in-country and global health communities to previously unrecognized drug-related problems. An effective PV system can also reveal problems of irrational use of medicines, medication errors and drug quality issues.

A 2001 World Health Assembly Resolution recommends providing “support for implementation of drug monitoring systems in order to better identify development of resistance, adverse reactions and misuse of drugs within health systems, thus promoting rational use of drugs” in Member States. However, according to the WHO, few countries are currently benefiting from a functioning pharmacovigilance system.

What type of support is currently available to strengthen pharmaceutical systems?

The important role of pharmaceuticals and other health products within the Global Fund investment portfolio is underscored by the proportion of grant funds allocated to procurement and delivery of life-saving health products. Through its policies, guidelines and assessment tools, the Global Fund has established the standards required for the procurement and overall management of the health products, based on recognized international norms and standards.

Applicants are referred to the various initiatives or technical support provided through the Global Fund and its partners for the development and/or strengthening of their pharmaceutical system. Key initiatives include the following:

**Strengthening Procurement and Supply Chain Management Systems**

The Global Fund Secretariat established the Procurement Support Service within the Pharmaceutical Management Unit to facilitate the provision of Voluntary Pooled Procurement (VPP) and Capacity Building Services / Supply Chain Management Assistance (CBS / SCMA) for grant recipients. The procurement support service is a coordinated approach in providing support to countries to address procurement bottlenecks and supply chain management challenges, and to facilitate the timely access to pharmaceuticals and health products.

The Capacity Building Service (CBS) / Supply Chain Management Assistance (SCMA) component focus on both short and long term interventions aimed at ensuring improvement and sustainability of in-country pharmaceutical management systems through the collaborative efforts with partners. Priority areas for strengthening pharmaceutical systems:

- Quantification / forecasting;
- Procurement planning;
- Logistics management (storage, inventory control, transportation, distribution and management information systems);
• Quality assurance activities;
• National / Central Medical Stores and its affiliates.

For additional information on the procurement support service.

**Developing / Strengthening Pharmacovigilance systems**

The Global Fund, in collaboration with WHO and other key technical partners such as the Uppsala Monitoring Centre (Sweden), the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance (Ghana) and the USAID-funded Strengthening Pharmaceutical Systems Program implemented by Management Sciences for Health (USA), is currently working on providing guidance on PV to countries. WHO is developing standardized definitions and tools with the objective of building national capacity for the collection of pharmacovigilance data in priority diseases such as HIV, tuberculosis and malaria.

The following resources are available:

• Safety monitoring of medicinal products: guidelines for setting up and running a pharmacovigilance centre, the WHO Collaborating Centre for International Drug Monitoring, Uppsala, 2000


Focus areas for strengthening Pharmacovigilance systems include:

• National regulatory authorities (NRA) strengthening
• Strengthening of resistance monitoring and containment

**Investing in Pharmaceutical System Strengthening using Global Fund Grants**

The Global Fund recognizes that effective pharmaceutical systems to ensure universal, regular, and timely access to quality medicines and health products at community level starts by ensuring that the necessary investments required to strengthen the pharmaceutical sector are planned, requested, and made available. It also notes that strengthening pharmaceutical systems in a sustainable manner is a long-term investment and commitment requiring the efforts of all.

The Global Fund supports the strengthening of pharmaceutical systems within the framework of health systems strengthening. Applicants are strongly encouraged to identify challenges within their pharmaceutical systems and include activities for pharmaceutical systems strengthening, including pharmacovigilance, in grant proposals.