



SUSTAINING THE GAINS

NATIONAL SELF-SUFFICIENCY FOR TB DRUG ACCESS
A GLOBAL DRUG FACILITY STRATEGY

The GDF is committed to continuously improve the quality of its services so as to provide quality-assured anti-TB drugs and commodities to countries at affordable prices in a timely manner and to meet all agreed legal and regulatory requirements as they relate to WHO and relevant international standards. While providing support the GDF actively assists countries to become self-reliant and eventually capable of independently procuring and managing its TB drugs and commodities.

The GDF will hereby meet the needs and expectations of the customers it services and contribute to the fulfilment of broader health objectives as embodied in the strategic goals of the global Partnership to Stop TB and the United Nations Millennium Development Goals.

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INTRODUCTION

The Global Drug Facility (GDF) is one of the success stories in the fight against tuberculosis (TB). Formally established at the Stop TB Partners' Forum in Washington in October 2001, the GDF has developed a radically new approach to providing access to TB drugs for a disease that is spiraling out of control in many parts of the world – fuelled by HIV/AIDS and the spread of multidrug-resistant TB.

The GDF regular grant is in principle for a three-year period and subject to satisfactory compliance with GDF terms and conditions of support, annual independent monitoring and availability of resources. However, the funding situation for anti-TB drug procurement in many countries remains such that continuous external assistance is still required. For many of these countries, GDF is the only source to support such assistance. In addition, there are concerns that GDF grant cessation will result in a loss of the gains achieved by the country during the grant period, including expansion or maintenance of the internationally recommended strategy for TB control (DOTS), availability of quality drugs and advances made in drug management.

For these reasons, the GDF “Sustaining the gains” strategy was developed, in close consultation with the Technical Review Committee (TRC), Stop TB Partnership Secretariat, Coordinating Board and the Stop TB Department of the World Health Organization (WHO).

The objectives of the GDF second-term grant strategy are: (a) to encourage countries to take increasing responsibility to fund their TB control programmes; (b) to ensure uninterrupted access to standardized, quality and competitively priced anti-TB drugs; and (c) to ensure that any "gains" made through the GDF grant are secured.

In close collaboration with the Stop TB partners, GDF will ensure monitoring, evaluation and problem solving for effective drug delivery and deployment, through capacity building and assistance in drug management, as well as through direct technical feedback to countries, partners and others concerned. The GDF will also encourage the local production of quality anti-TB drugs by identifying political and financial support for the WHO TB Prequalification Project.





BACKGROUND: the initial grant

The GDF, an initiative of the global Stop TB Partnership, was established in 2001 following the Amsterdam Declaration from the Ministerial Conference on "Tuberculosis and Sustainable Development" in March 2000. During this conference, a call was made for the establishment of a global drug facility for TB to support new international approaches towards ensuring universal access to, and efficient national systems of, procurement and distribution of tuberculosis drugs.

The GDF was established in order to respond to the four key drug-related impediments to countries in achieving the global targets¹ for TB control:

1. lack of resources to purchase first line anti-TB drugs;
2. inadequate in-country procurement mechanisms to purchase quality anti-TB drugs;
3. lack of standardization of anti-TB drugs used internationally (variety of products, packaging and regimens); and
4. inadequate management and monitoring of anti-TB drugs.

In response to these problems, the GDF provides a mechanism to expand access to and availability of quality anti-TB drugs and to facilitate DOTS maintenance and expansion, through the following three core services:

1. **Grant Service (GS)** whereby first-line anti-TB drugs are granted to approved countries and nongovernmental organizations (NGOs) to support DOTS expansion and sustainability of nationwide coverage in countries that are donor-dependent for their drug needs.

¹ The global targets for TB control, adopted by the World Health Assembly, are to cure 85% of newly detected cases of sputum smear-positive TB and to detect 70% of the estimated incidence of sputum smear-positive TB. (Resolution WHA44.8 of the Forty-fourth World Health Assembly, Geneva, World Health Organization, 1991 (WHA44/1991/REC/1), and Resolution WHA46.36 of the Forty-sixth World Health Assembly, Geneva, World Health Organization, 1993 (WHA46/1993).

2. **Direct Procurement Service (DPS)** for countries, donors and NGOs to purchase drugs for use in DOTS programmes in countries that have sufficient finances but lack adequate procurement capacity including a robust quality assurance system.
3. **TB Prequalification Service (PS)** which results in a list of prequalified quality anti-TB drugs, for countries that have sufficient finances and good procurement mechanisms with the exception of a robust quality assurance system. GDF is a principal contributor of funds for this service and identifies political support for it. The service is coordinated by WHO's Department of Medicines Policy and Standards².

As part of the grant, technical assistance is provided for TB control and drug management in related areas through the pre-drug delivery and annual monitoring missions conducted.

Due to the importance of financial sustainability in national TB programmes (NTPs), the GDF GS was always envisaged to be time limited so as not to create long-term dependency on grants. The objective of the GDF GS is to overcome problems of drug shortage and dubious quality drugs for DOTS sustainability and national coverage of quality anti-TB drugs in the short to medium term³. To achieve this, one of the key conditions to receive a GDF grant is that it should be an "additional" resource for the NTP, i.e. that government TB budget lines⁴ should not be reduced or removed as a consequence of a GDF grant during the grant period (Annex 1).

The DPS and PS are, in part, GDF's approaches to reduce the dependency on grants. In addition, the GDF encourages grant receiving countries to use the DPS as a cost-sharing exercise. The GDF works closely with partners and technical agencies including WHO, which houses the GDF, to strengthen sustainable national procurement, drug management capacity and national quality assurance mechanisms.

² Please visit: <http://mednet3.who.int/prequal/>.

³ The minimum required time horizon for the GDF is expected to be 10-15 years.

⁴ Including a budget line for drugs for all second-term grantees and first-term grantees accorded a grant from April 2005 onwards.



SECOND-TERM GRANT: guiding principles

While financial self-sufficiency is the ultimate goal, considering the realities of the funding situation in resource limited countries, "sustainable financing" for TB control is considered a more realistic goal in the short term.

The GDF definition of sustainability is:

Financial self-sufficiency must be the ultimate goal. However, in the nearer term, sustainable financing for TB control is defined as a country's ability to mobilize and efficiently use governmental and supplementary external resources to achieve TB control targets and the Millennium Development Goals. Sustainable National TB Programme financing must be a shared concern and is the responsibility of both governments and their partners.

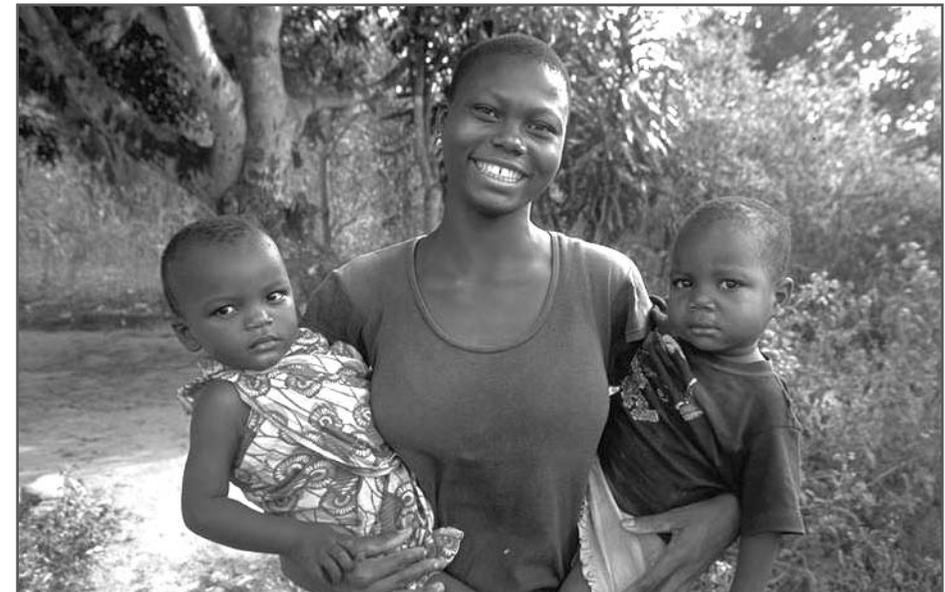
Therefore, the following guiding principles will apply:

1. GDF grant termination must not hamper DOTS coverage.
2. GDF grant termination should not have negative effects on advances made in access, standardization, quality and cost for anti-TB drugs.
3. The GDF should continue to facilitate strengthening of national TB drug management systems (procurement, distribution, and quality assurance, including quality control) by advocating technical assistance for capacity building and by engaging donors.
4. The GDF should ensure, where needed, uninterrupted supply of anti-TB drugs through the DPS when GDF grants are no longer required.



OBJECTIVES

1. To ensure that any "gains" made through GDF grants related to DOTS sustainability, drug quality, cost and improved drug management are secured.
2. To encourage countries to take an increasing responsibility to fund their TB control programmes including sufficient funds for anti-TB drugs.
3. To ensure uninterrupted access to standardized, quality and competitively priced anti-TB drugs for DOTS expansion and/or sustaining nationwide coverage.





IMPLEMENTATION PROCESS

During the second year of the GDF grant, the monitoring mission and the TRC will confirm whether the country will need financial assistance for anti-TB drugs on conclusion of the initial three years of the GDF grant. They will verify the funding situation of the NTP, in particular the availability and adequacy of funds for anti-TB drug procurement from the government. The monitoring mission will also assess whether a termination of the grant will result in adverse effects on gains made through the initial first-term GDF grant. Furthermore, the mission will collect information about the availability of funds for anti-TB drug procurement from other potential donors including the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM).

The following are the two main groups of GDF grant-receiving countries with their respective subgroups:

Group 1 Countries that will continue to depend on external financial assistance for the procurement of anti-TB drugs

Subgroup 1.1
Countries dependent on external financial assistance for anti-TB drugs after the initial three years of the GDF grant and for which there are other donors available to fill in the funding gap

Country role

The NTP mobilizes interested donors/agencies to provide a financial or in kind donation of anti-TB drugs. The donor "adopts" the country by providing financial or in kind assistance for anti-TB drugs and may consider using the GDF DPS. Simultaneously, the country aims to establish national budget lines for anti-TB drugs.

GDF role

1. To encourage countries and GDF DPS and/or PS to ensure drugs used in the program standardized specifications, quality and competitively price
2. To facilitate the provision of cost and quality assurance support
3. To encourage countries apply grant to include a budget for procurement or re-programm allow for such inclusion if the country receiving a grant. All GFA countries will be encouraged DPS where outsourcing of procurement required or preferred.

Subgroup 1.2
Countries dependent on external assistance for anti-TB drugs three years of a GDF grant and for which no donors available to fill in the funding gap

Country role

A country may reapply for another grant support. The GDF will observe below in reviewing the application for second-term grant.

Eligibility

All countries on the "GDF eligible" list where a GDF monitoring mission identifies the need for external assistance. GDF is considered the only source to assist with provision of quality assurance



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⁵ "another term" refers to a subsequent three

⁶ Gross National Product under US\$ 3000, L