



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.

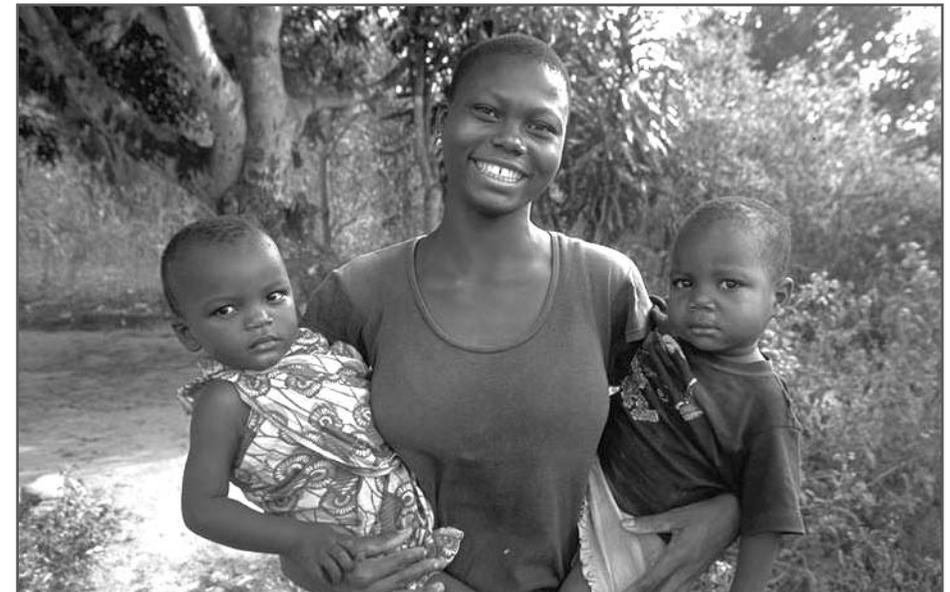
Therefore, the following guiding principles will apply:

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 donors to use the GDF DPS and/or PS to ensure that all the drugs used in the programme follow standardized specifications, are of good quality and competitively priced.
2. To facilitate the provision of drug management and quality assurance support, if required.
3. To encourage countries applying for a GFATM grant to include a budget for anti-TB drug procurement or re-programme budget lines to allow for such inclusion if the country is already receiving a grant. All GFATM approved countries will be encouraged to use the GDF DPS where outsourcing of procurement is required or preferred.

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

Country role
 A country may reapply for another term⁵ of GDF grant support. The GDF will observe the rules below in reviewing the application for a second-term grant.

Eligibility
 All countries on the "GDF eligible country list"⁶ where a GDF monitoring mission has established the need for external assistance, and where the GDF is considered the only source available to assist with provision of quality anti-TB drugs.



⁵ "another term" refers to a subsequent three-year GDF grant.
⁶ Gross National Product under US\$ 3000, DOTS accepted as NTP policy.

Priority

If GDF financial resources are limited at the time, priority will be given to countries where another term of GDF grant support will have a greater impact. The following criteria are used to determine the impact:

1. High-burden country⁷ as defined by WHO/Stop TB and DOTS Expansion Working Group.
2. Intensified Support & Action Countries⁸.
3. Countries with demonstrated adherence to GDF terms and conditions, and achievement of demonstrable progress (see below).
4. Countries where programme survival is at greater risk, and the GDF monitoring mission and TRC consider that there is a possibility that gains made through the GDF grant in the past will be lost if grant support ceases.

Terms and conditions

In order to receive the GDF grant on conclusion of the initial three-year grant, countries should agree to fulfill the terms and conditions below in addition to those during the first-term grant.

- Adherence to the GDF terms and conditions during the first-term grant, and compliance as well as demonstrated progress towards meeting the GDF TRC and monitoring mission recommendations.
- Proven sustained political commitment: government commitment to maintain or increase the TB Programme and anti-TB drug budget lines⁹ during the second-term grant period, as recommended by the GDF TRC.
- Progress made in DOTS expansion during the initial three years of the GDF grant. For countries with nationwide coverage this will mean sustaining the nationwide coverage and enhancing DOTS implementation as defined by the Stop TB Strategy.
- Achievement of an acceptable level of treatment success rates in DOTS implemented areas as determined by the GDF TRC. Consideration will be given to countries that have not achieved the desirable treatment success rates but have shown steady improvements in their results.

⁷ Group of 22 countries accounting for >80% of infective tuberculosis cases.

⁸ A special emergency initiative to accelerate DOTS expansion and reach the 2005 targets and the 2015 Millennium Development Goals, by the DOTS Expansion Working Group, the GFATM, other financial partners, and Stop TB.

⁹ Only for those countries that have established an anti-TB drug budget line.

- NTP agreement that drugs procured from non-GDF sources will be of proven quality (initially at least products manufactured at a site with Good Manufacturing Practice¹⁰ status and accompanied by WHO-type Certificate of Pharmaceutical Product and Analytical Batch Certificate). Demonstration to GDF of medium to longer term plans to assure proven quality will be required: procurement of anti-TB drugs pre-qualified under the TB prequalification project and implementation of quality control analyses.
- NTP agreement to move towards standardized formulations and presentation of anti-TB drugs, i.e. in line with those products in GDF catalogue.

Reapplication process

- Same as initial grant application
- Submit documents which were revised/updated since first application
- TRC follows the same principles in addition to the above criteria

Second-term grant period and grant value

The next second-term grant will be for a maximum of three years. However, each year the grant will be reassessed by the GDF monitoring mission and/or the TRC. Continuation of the grant will be subject to:

1. compliance with the GDF terms and conditions,
2. follow-up of the monitoring mission and TRC recommendations,
3. availability of funds.

The value of the grant will be proposed by the monitoring mission, endorsed by the desk audit and subject to the approval of the TRC.

Monitoring

The same monitoring conditions apply for the second-term grant. Each year, monitoring missions by TB and drug management experts will be conducted 6 months after the arrival of drugs in the country. Monitoring missions will also collect information in compliance with additional terms and conditions.

¹⁰ Based on WHO Guidelines for Group Inspections.

Group 2
Countries that are not in need of external financial assistance for anti-TB drug procurement

Subgroup 2.1
Countries that are financially sound but lacking procurement capacity including a robust quality assurance system.

GDF role
To encourage countries to use the GDF DPS to ensure that all drugs used in the programme follow standardized specifications, and are of assured quality and competitively priced.

All GDF missions to the country will brief the NTP, national drug regulatory authorities and other stakeholders on the GDF DPS.

Subgroup 2.2
Countries that are financially sound and have procurement capacity with the exception of a robust quality assurance system.

GDF role
GDF will encourage countries to use the GDF PS to ensure that all drugs used in the programme follow standardized specifications, and are of assured quality and competitively priced.

All GDF missions to the country will brief concerned authorities on the GDF PS. In addition, countries, potential donors and partners will periodically receive briefings on the PS.

IMPORTANT: Countries in an emergency¹¹ situation will be eligible to apply for an emergency grant (not exceeding one year and without buffer stock) regardless of whether they have received a three-year grant from GDF in the past or not.

¹¹ A country where imminent TB drug stock-out conditions exist and there is no other source of assistance to rectify this situation.

ANNEX 1

GDF TERMS AND CONDITIONS OF SUPPORT FOR FIRST-TERM GRANTS

The terms and conditions of GDF support are the following:

1. All drugs supplied by GDF will ONLY be used:
 - a. for treatment of TB patients,
 - b. free of charge to patients,
 - c. in treatment regimens following WHO guidelines,
 - d. in programmes following national guidelines for DOTS implementation,
 - e. in accordance with a multi-year plan for DOTS expansion and sustainability to reach global targets by 2005.

2. The applicant is responsible for the drugs beyond the agreed point of delivery. The applicant will make arrangements for the payment or waiver of any import duty or tax, storage fees or insurance levied on drugs supplied by the GDF in a timely fashion, so that the drugs are released from customs and supplied as required by the programme. The applicant is responsible for the in-country distribution and monitoring of drugs provided by the GDF.



3. Where registration is required, GDF drugs will be expeditiously registered and the applicant will facilitate this process, so that drugs are released from registration and supplied as required by the programme.
4. Regular assessments of the applicant's performance, including anti-TB drug management, will be carried out by an independent technical agency, and a complete assessment report will be provided to the GDF. The applicant will also submit the following reports to the Stop TB Secretariat:
 - a. a regular annual report on TB programme performance in accordance with WHO guidelines,
 - b. quarterly reports on case finding, smear conversion and treatment outcomes,
 - c. date of arrival of GDF drugs at port,
 - d. time taken to register drugs (if applicable),
 - e. date at drug reception in central drug store.
5. Public sector/donor funding for TB control activities will not be reduced as a consequence of, or during the period that GDF grants are received.
6. Co-financing and technical cooperation are available from other partners/donors for non-drug aspects of the multi-year plan (including DOTS expansion and sustainability).

LIST OF ABBREVIATIONS

DOTS: The internationally recommended strategy for TB control

DPS: Direct Procurement Service

GDF: Global Drug Facility

GFATM: Global Fund to fight AIDS, Tuberculosis and Malaria

NTP: National Tuberculosis Programme

PS: TB Prequalification Service

TB: Tuberculosis

TRC: Technical Review Committee

WHO: World Health Organization

GLOSSARY OF TERMS

Buffer stock (sometimes called safety or reserve stock): The stock that is kept on hand as a security measure against stock-outs caused by delayed deliveries, loss, expiry, damage of stock or markedly increased demand. In theory, the buffer stock is separate from the working stock, but in practice, there is no separation of the two.

Direct Procurement Service: A GDF Direct Procurement Service for countries, donors and NGOs to buy drugs for use in DOTS programmes, i.e. for countries that have sufficient finances but lack adequate procurement capacity including a robust quality assurance system.

Drug regulatory authority: A national body that administers the full spectrum of drug regulatory activities, including at least all of the following functions: marketing authorization of new products and variation of existing products; quality controlled laboratory testing; adverse drug reaction monitoring; provision of drug information and promotion of rational drug use; good manufacturing practice inspections and licensing of manufacturers, wholesalers and distribution channels; enforcement of operations; monitoring of drug utilization.

Formulation: The composition of a dosage form, including the characteristics of its raw materials and the operations required to process it.

Manufacture (manufacturing): All operations including purchase of materials and products, production, quality control, release, storage, shipment of finished products, and related controls.

Quality assurance: A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the objective of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality control: Concerned with sampling, specifications and testing, and with the organization, documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are actually carried out and that starting materials, intermediates and finished products are not accepted for use, sale or supply until their quality has been judged to be satisfactory.

Register: A list of all the pharmaceutical products authorized for marketing in a particular country. The register is maintained by the drug regulatory authority of the country in question.

TB Prequalification Service: A service funded by GDF and for which GDF identifies political support. The service is coordinated and implemented by WHO's Department of Medicines and Policy Standards and results in a list of prequalified quality TB products through a process that involves physical inspection of manufacturing sites and independent expert evaluation of product dossiers according to WHO Guidelines and Standards.