ACHIEVEMENT REPORT: SPECIAL EDITION

4 million treatments in 4 years

4,000,000

A message from the Executive Secretary of the Stop TB Partnership

The Global Drug Facility (GDF), a key initiative of the Stop TB Partnership, has had a major positive impact on the treatment of millions of TB patients globally since its establishment in 2001. By providing high-quality TB drugs to over 4.4 million people in some of the world's poorest countries, it has helped to save countless lives and significantly strengthened global TB control efforts.

In just four years, and through close collaboration with numerous partner organizations, the GDF has progressed from a concept to a successful mechanism for TB control in more than 58 countries worldwide. The GDF was established with initial funding from three core donors – the Canadian International Development Agency (CIDA), the government of the Netherlands and the United States Agency for International Development (USAID).

On behalf of the Stop TB Partnership, I am proud to present this report on achievements.

Dr Marcos Espinal,
Executive Secretary, Stop TB Partnership

4 in 4

WHO/HTM/STB/2005.32

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Anant Vijay
Hugo Vrakking

Report written by:
Sarah Weatherly

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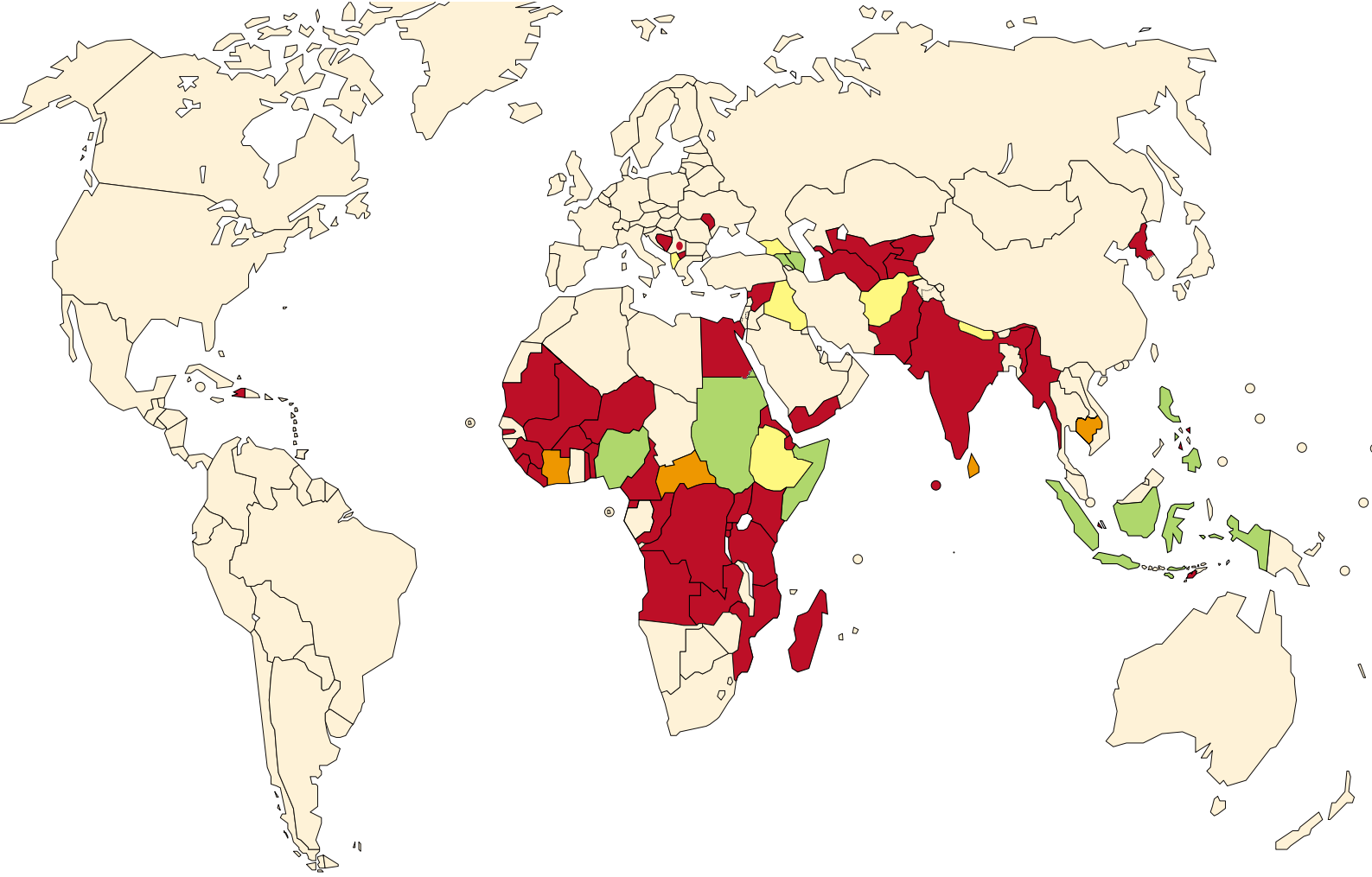
Who we are

The Global Drug Facility (GDF) is one of the success stories in the fight against 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 drugs for a disease that is spiralling out of control in many parts of the world – fuelled by HIV/AIDS and the spread of multidrug-resistant TB. The GDF offers three services: (1) grants of first-line drugs to support DOTS expansion i.e. for countries that are donor-dependent for some or all of their drug supply and wish to expand their DOTS programmes; (2) a direct procurement service for countries, donors and non-governmental organizations (NGOs) to buy drugs for use in DOTS programmes i.e. for countries that have sufficient finances but which lack adequate procurement or quality assurance systems; and (3) a "White List" of prequalified manufacturers of quality TB drugs i.e. for countries that have sufficient finances and good procurement mechanisms but which lack a robust quality assurance system. Through its grant and direct procurement services, the GDF has procured TB drugs for over 4.4 million patients in the past four years. Assuming an 85% cure rate in those patients diagnosed and commencing treatment, this means that an additional 3.8 million patients are being cured through GDF support.[1]

"The GDF has had a profound impact on the ability of countries to access low-cost, high-quality life-saving medicines. The delivery of four million TB patient treatments in four years to 58 countries represents a unique accomplishment in the history of TB control."

LEE Jong-wook,
Director-General, World Health Organization

[1] *The figure is derived from the estimated cure rate of 85%, the official global target for TB control.*



GDF-supported countries: grants and direct procurement

	2001	2002	2003	2004
1	Congo (E)	Angola (E)	Afghanistan (DP)	Albania (DP)
2	Djibouti (G)	Armenia (E)	Armenia (DP)	Angola (G)
3	DPR Korea (G)	Azerbaijan (G)	Benin (G)	Azerbaijan (DP)
4	DR Congo (G)	Bangladesh (G)	Bosnia and Herzegovina (G)	Bangladesh (DP)
5	Kenya (G)	Burundi (G)	Cambodia (DP)	Burkina Faso (G)
6	Liberia (G)	Cameroon (E)	Central African Republic (E)	Cape Verde (G)
7	Myanmar (G)	Central African Republic (E)	Côte d'Ivoire (E)	Central African Republic (E)
8	Nigeria (G)	Congo (G)	Egypt (G)	Ethiopia (DP)
9	Pakistan (G)	Côte d'Ivoire (E)	Equatorial Guinea (G)	Georgia (DP)
10	Republic of Moldova (G)	Gambia (G)	Eritrea (G)	Guinea (G)
11	Somalia (G)	Haiti (G)	Iraq (DP)	India, Haryana State (DP)
12	Sudan (G)	India (G)	Madagascar (E)	Indonesia (DP)
13	Tajikistan (G)	India, Orissa State (G)	Madagascar (G)	Maldives (G)
14	Togo (G)	Indonesia (G)	Mali (E)	Mali (G)
15	Uganda (G)	Mauritania (G)	Nepal (DP)	Micronesia (Fed. States of) (DP)
16	Yemen (E)	Niger (E)	Niger (G)	Mozambique (G)
17		Philippines (E)	Nigeria (DP)	Republic of Moldova (DP)
18		Philippines (ppp) (G)	Somalia (G)	Sao Tome and Principe (DP)
19		Rwanda (G)	Sudan (South) (DP)	Somalia (DP)
20		Serbia & Montenegro, Kosovo (G)	Syrian Arab Republic (G)	Sri Lanka (E)
21		Sierra Leone (G)	TFYR Macedonia (G)	Timor-Leste (G)
22		Uzbekistan (G)	Timor-Leste (DP)	Turkmenistan (E)
23		Zambia (E)	Yemen (G)	UR Tanzania (G)
24			Zambia (G)	
25				
	16 (16 G)	23 (23 G)	24 (16 G; 8 DP)	23 (12 G; 11 DP)

E = emergency grant; G = grant; DP = direct procurement; ppp = public-private partnership

Map of GDF-supported countries

- **Countries approved for regular GDF support**
- **Countries approved for emergency GDF support**
- **Countries with direct procurement support**
- **Countries with both grant and direct procurement support**

> **"GDF support helped us strengthen our national TB policy and gave us the drugs our patients desperately needed. It also catalysed the provision of crucial training and drug management support from other partners. Quality drugs, an invigorated supply chain and a sound TB control plan have enabled us to overcome key obstacles to fighting this epidemic."**
>
> *Professor Emile Bongeli Yeikelo Ya Ato*
> *Minister of Health, Democratic Republic of the Congo*

STRENGTHENING HEALTH SYSTEMS

INDIA – Capacity building

The Revised National Tuberculosis Control Programme (RNTCP) in India is the largest and fastest expanding programme in the world. At present, approximately 110 000 patients are initiated on treatment every month. India was approved for a three-year grant from the GDF in 2002. GDF support has built capacity to enable India to expand DOTS coverage to a population of over 900 million. India is moving steadily towards its target of ensuring access to TB drugs for the entire population under the DOTS strategy within 2005. GDF has delivered approximately 300 000 patient treatments a year since 2002.

DEMOCRATIC REPUBLIC OF THE CONGO – Drug management support

In October 2001, three years after civil war had erupted in the Democratic Republic of the Congo (DR Congo), and three months after the Minister of Health had announced that the country faced an imminent stock-out of TB drugs, a team of experts from partner organizations brokered by the GDF, arrived in DR Congo to help accomplish what seemed to be an unlikely feat: develop a plan to move US$ 1.2 million worth of TB drugs down a supply chain that had yet to become fully operational, across a terrain ravaged by war, and into clinics in time to save some 50 000 lives from TB. The drugs were to arrive within the year, as the first delivery of the three-year GDF grant to a country that has the 11th highest TB burden in the world. As part of its bundled approach to drug management and supply, the GDF and partners organized a country visit prior to drug delivery. The purpose was to assist in ensuring that the necessary systems for distribution and good management were in place. The team issued five recommendations to improve drug management: develop a drug distribution schedule, increase warehouse capacity, increase training opportunities, establish a Drug Management Information System, and provide additional management support. Through the support of partners and the commitment of the NTP, all five recommendations were fulfilled within one year of beginning GDF support.

KENYA – Additionality

Within two years of receiving GDF drug support in 2001, Kenya – a country that was heavily dependent on donor support for TB drugs and that lacked a separate budget line for TB drugs – established a three-year budget plan specifically geared for TB drug procurement. This decision came after a team of GDF consultants from partner organizations met with the Ministry of Health and described the urgent need for government financial support. The Government of Kenya subsequently included a specific budget line for the procurement of TB drugs in its national budget. Additionality and sustainability are key GDF principles and the GDF works with countries on a case-by-case basis to ensure that they are upheld.

How we work

The GDF operates a unique “bundled” model of services that combines grant and direct procurement services for TB drugs with technical assistance for in-country management and TB drug monitoring. This holistic approach to TB control allows the GDF to maximize the impact of each patient treatment and strengthen global DOTS expansion efforts. The model is underpinned by the support and contributions of collaborative partners in the Global Partnership to Stop TB.

An emphasis on continuous monitoring and local accountability is at the core of GDF's operations, with the aim of enhancing drug management practices and ensuring commitment from recipients to reach the Millennium Development Goals’ target of reducing TB prevalence by half by 2015. The GDF business model prizes innovation and competition through international tenders for all procurement and key monitoring activities.

“The GDF is the most extraordinary innovation in TB control of the past decade. A pragmatic response to the call from many countries in need of drug support. A new way of guaranteeing low-cost, high-quality drugs to patients.”

Dr Mario Raviglione,
Director, Stop TB Department, World Health Organization

WHAT IS TUBERCULOSIS?

Tuberculosis has confounded attempts at control ever since the discovery of *Mycobacterium tuberculosis*, by Robert Koch 120 years ago. Today, control is seriously hampered by drug resistance and coinfection with HIV increases 10-fold the risk of developing TB. A resilient and persistent organism, *M. tuberculosis* can adapt to a wide variety of environmental conditions, making it an efficient modern human infectious disease.

Globally, 20 000 people develop TB and 5000 die of it every day. Each year, there are 8.8 million new cases and 1.7 million deaths. Without treatment, 50–70% of people with infectious TB will die. If left untreated, a single person with infectious TB can infect between 10 and 15 people a year. The global TB epidemic is increasing by 1% every year, largely because of the TB/HIV co-epidemic. In areas where the WHO-recommended DOTS strategy is not yet being implemented, there is an increased prevalence of multidrug-resistant TB, which is expensive and difficult to treat.

In 2000, following a previous resolution of 1991, the World Health Assembly set global targets for 2005 of detecting at least 70% of all TB cases and curing at least 85% of those detected.

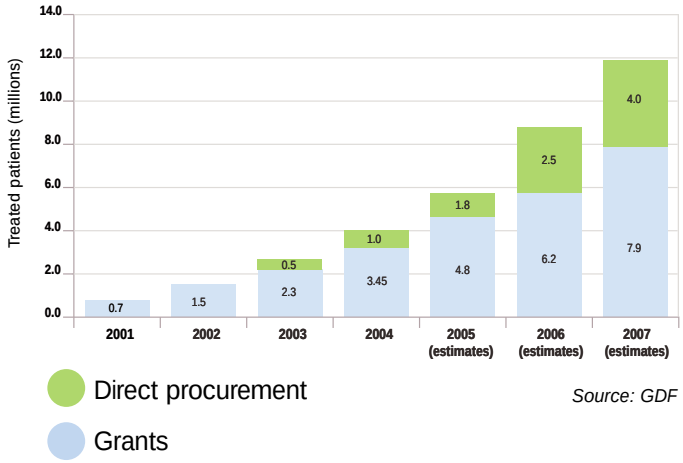
What we have achieved

The GDF has procured 4.4 million life-saving TB drug treatments and made deliveries to 58 countries in four years

By guaranteeing a regular, uninterrupted supply of TB drugs to some of the 8 million people who contract TB every year, the GDF is helping to save lives. In many parts of the world, insecure financing and shortages of TB drugs are frequent and serious, and while poor drug supply is not unique to TB control, the impact can be especially severe. In addition to allowing the disease to spread uncontrolled, inadequate and erratic supply contributes to the emergence of multidrug-resistant TB, which is costly and difficult to treat. Grants of free TB drugs are at the core of the GDF mission and build a strong foundation for sustainable global TB control and the eventual elimination of the disease. By the end of 2004, 58 countries, NGOs and states had received GDF support. Of the 4.4 million patient treatments ordered by GDF, 3.45 million are for GDF grants and 1.028 million procured through the Direct Procurement Service using recipient country funds.

Dramatic growth in grant and direct procurement service lines

Patient treatments provided through the GDF (cumulative, millions of patients)



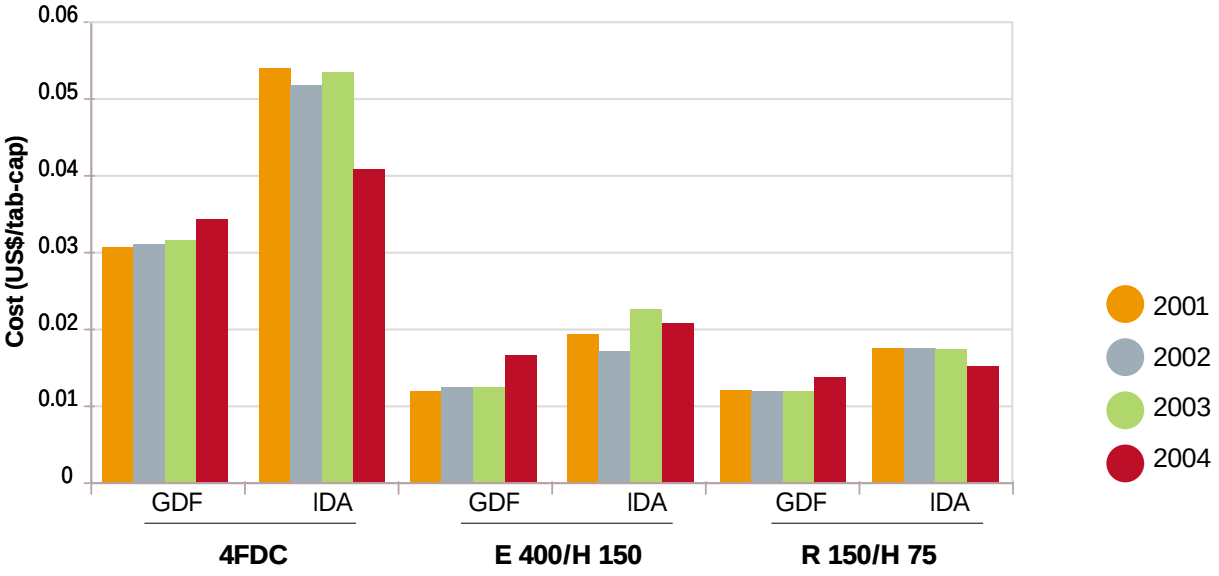
Source: GDF

> **"Over the past four years, we have seen how the facility has become one of the most cost-effective and efficient channels to control TB, and to improve the supply, distribution and monitoring of TB drugs."**
>
> *The Honorable Aileen Carroll*
> *Minister of International Cooperation,*
> *Canadian International Development Agency*

The GDF guarantees access to low-cost, high-quality TB drugs

Poor-quality TB drugs severely increase the risk of treatment failure and the development of multidrug-resistant TB, which is expensive and difficult to treat. For this reason, the GDF has developed a series of mechanisms that guarantee the quality of TB drugs. The GDF buys only from manufacturers that have been pre-qualified because they have passed stringent manufacturing criteria set by WHO. International tenders during 2001– 2003 were managed by GDF's procurement agent (UNDP/ IAPSO) and resulted in three manufacturers being selected to supply first-line TB drugs through the GDF. In addition to prequalification the GDF ensures quality control of all batches of manufactured drugs at an independent, competitively contracted laboratory and requires pre-shipment inspection of all orders prior to delivery. Supplying quality-assured, low-cost drugs helps to maximize the impact of donor and government funding. Through bulk procurement, competitive bidding, prompt payment policies and standardization of products, the GDF paid, from 2001 to 2003, US$ 10–12 for a standard six-month course of treatment, a 30% reduction on average global pricing. Increasing raw material prices for TB drugs have meant an increase in overall prices, but the current price range of US$ 12– 14 for the standard six-month course of treatment is still the most competitive on the global market, for TB drugs of the highest quality.

Product costs: GDF costs compared with those from other international sources



Notes

- *Tab = tablet; cap = capsule*
- *IDA = "International Dispensary Association" (http://www.ida.nl)*
- *Sources of prices: for years 2001–2003, MSH Drug Price Indicator Guide (http://erc.msh.org); and for year 2004, GDF Catalogue and IDA Catalogue, Dec. 2004.*
- *4FDC = Four fixed-dose combination tablets (rifampicin 150 mg; isoniazid 75 mg; pyrazinamide 400 mg; ethambutol 275 mg)*
- *R: rifampicin; H: isoniazid; E: ethambutol*
- *IDA price not next closest for E400/H150 in 2003; price of Missionpharma A/S (http://www.missionpharma.com) was the next closest for E400/H150 in 2003.*

The GDF mobilizes a wide network of partners

As a product of partnership, the GDF understands why partners are key to its success. The GDF benefits from the Stop TB Partnership's broad alliance of national governments, funding agencies, foundations, national and international NGOs, and the private sector for invaluable technical assistance, monitoring support, staff secondment and funding. Partners provide invaluable support to its "bundled" approach to TB control in the areas of technical assistance and drug performance monitoring. Partner involvement is also fundamental in building capacity for effective drug management and distribution at the country level.

Contractual partners

- Procurement services *UNDP/IAPSO*
- Manufacture *Svizera Europe, Lupin Ltd., Cadila Ltd.*
- Quality control/PSI *SGS*
- Freight forwarding *Kuehne Nagel and Mahe*
- Quality assurance *NIPER, MRC, SGS, WHO*

Collaborating partners

- Donors: CIDA, DFID, Government of the Netherlands (Ministry for Development and Cooperation), Government of Norway (Royal Ministry of Foreign Affairs), Novartis Foundation, OSI, Rockefeller Foundation, USAID, World Bank
- Technical assistance: Caritas, CHD, Damien Foundation, GLRA, IUATLD, JSI, KNCV, LHL, MSF, MSH, Project Hope, TRC, WHO, World Bank, World Vision

Coordination with countries

- WHO regional and country offices
- GFATM

CHD = Consultants for Health and Development
CIDA = Canadian International Development Agency
DFID = United Kingdom Department for International Development
GFATM = Global Fund to Fight AIDS, TB and Malaria
GLRA = German Leprosy and TB Relief Association
IUALTD = International Union Against TB and Lung Disease
JSI = John Snow Inc.
KNCV = Royal Netherlands TB Association
LHL = Norwegian Association of Heart and Lung Patients
MRC = Medical Research Council, South Africa
MSF = Médecins Sans Frontières
MSH = Management Sciences for Health
NIPER = National Institute for Pharmaceutical Education and Research
OSI = Open Society Institute
RIT = Research Institute of TB, Japan
SGS = Société Générale de Surveillance
TRC = GDF Technical Review Committee
UNDP/IAPSO = UNDP Interagency Procurement Services Office
USAID = United States Agency for International Development
WHO = World Health Organization

The GDF is building the capacity of procurement systems

Efficient procurement systems are key to helping countries quickly access a regular supply of high-quality TB drugs. With a dedicated team at the Stop TB Partnership secretariat coordinating procurement activities and several contractual agents managing supply, logistics and freight, the GDF is able to deliver life-saving drugs on time and on budget. The GDF works hard to ensure that agreed lead times are met. Moreover, GDF procurement services include a web-based mechanism that enables countries and organizations to place order requests for TB drugs and trace their progress through the manufacturing, quality control and delivery stages. UNDP/IAPSO manages the web-based mechanism. By the end of 2004, 19 countries had purchased TB drugs through the GDF Direct Procurement Service worth over US$ 12 million. Indonesia, a high-burden TB country, placed one of the largest orders in 2004 using a US$ 3.4 million grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria.

"Thanks to the excellence with which the Stop TB Partnership Secretariat and the partners have implemented the GDF's work, this facility has played a key role in the dramatic increase in the spread of modern TB treatment and thus in the global reduction in TB prevalence."

Ernest Loevinsohn
Director General, Program Against Hunger, Malnutrition and Disease, Multilateral Programs Branch, Canadian International Development Agency and Chairman of the Stop TB Partnership Coordinating Board

"The GDF has brought a sense of healthy competition for local industry to produce high-quality drugs. It has also created a demand at the district level for GDF-supplied drugs."

Dr Syed Karam Shah,
Programme Manager, National TB Control Program, Ministry of Health, Pakistan and Chairman of the Stop TB Partnership Working Group on DOTS Expansion

The GDF promotes standardization and innovation in TB drug products

One of the biggest barriers to effective TB treatment has been the large numbers of products and regimens available to national TB control programmes as well as conflicting international recommendations on treatment. For this reason, the GDF is promoting standardized WHO-recommended regimens underpinned by the use of fixed-dose combination (FDC) products, which allow for an average of 3 tablets to be taken daily and dispensed from blister sheets. FDCs have several advantages over conventional formulations. For instance, with FDCs, it is easier for patients as fewer tablets are taken and better for health workers as there are fewer tablets to manage and dispense. The GDF has also developed "Patient kits" that contain all the drugs needed to treat one, middle-weight patient for six months.

The GDF monitors grant performance to ensure real impact

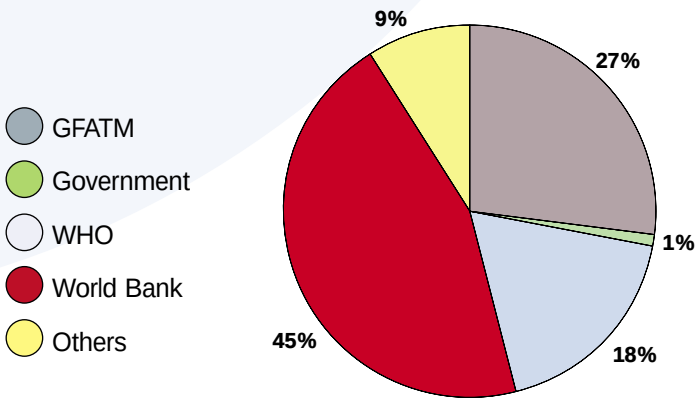
Providing grants without monitoring their impact damages global chances of TB control. The GDF monitors country performance at every step of the grant and procurement process to ensure that the "bundled approach" achieves results. All countries that are approved or placed under consideration for a grant undergo country visits prior to receipt of drugs. The visits are used to brief the country on the GDF and to provide a rapid assessment of the drug distribution system. Four to six months after drugs arrive, a monitoring visit assesses TB programme, financial and drug management aspects and verifies that all the GDF terms and conditions of support have been met. In order to be approved for second- and third-year grants, the GDF must be satisfied with performance and impact. For each grant, recipients are accountable for the resources committed. This performance-based system of grant making is fundamental to the GDF's focus on tangible results.

Source: Stop TB Image Library

“My father died of TB; I had TB as did both of my children. I was very scared but, thanks to the free treatment, my children are TB free as is all my family.”

Viorica, former TB patient
Chisinau, Republic of Moldova,
the first GDF recipient country

Sources for direct procurement funding	Contribution (US$)
GFATM	3 446 991
Government	7 861
WHO	2 198 827
World Bank	5 654 437
Others	1 091 323
Total	12 399 439



- Includes all GDF direct procurement orders through the end of 2004
- 100% = 12 399 439 US$ – all orders placed before end 2004
- “Others” are agencies/governments providing financial support to governments procuring drugs through the GDF Direct Procurement Service, including the following: Caritas, Government of Albania, Government of Japan, GLRA, KFW, and NLRA

The GDF has put TB control back on the global public health agenda

As part of the Stop TB Partnership, the GDF has been able to raise awareness of TB as a public health risk. It has succeeded in this not only through marketing of the GDF's core business and products but also with strong advocacy work carried out by its partners. While the direct effects of the GDF's grant activities in terms of political and social awareness-raising are not easy to measure, greater focus has been placed on the issues surrounding drug procurement and management in many countries. This has created a number of advantages, ranging from helping countries to ask the right questions regarding drug costs and quality, to making sure countries reflect TB control in their national health budgets.

The GDF has catalysed global DOTS expansion

The GDF is widely regarded as an innovative and effective tool for supporting global DOTS expansion and is credited with playing a significant role in improving global TB treatment rates. In stimulating DOTS expansion in countries by making the strategy a condition for grants, the GDF has helped to strengthen national TB control programmes and will, in the long term, improve the sustainability of country programmes. Only governments and NGOs that adhere to proven effective, diagnostic, treatment and disease monitoring practices encompassed in DOTS are eligible for GDF grants. DOTS expansion leads to significantly fewer TB patients, lower health care costs and the social and economic benefits of improved public health.

The GDF always looks to the future

The GDF initially provides grants only for a period of three years. It works with countries to ensure that once the grant period ends, a recipient country can "secure the gains" made in drug management, procurement and quality control. A phase-out strategy designed to secure the gains is currently being introduced in countries coming to the end of the three-year grant programme. Activities include helping countries to leverage funding from alternative sources such as the GFATM and encouraging them to take advantage of the GDF Direct Procurement Service and the White List of approved manufacturers which guarantee low-cost, high-quality TB drugs.

Direct Procurement Service at a glance*

Country	Funding source	US$	Patient treatments
Afghanistan	WHO	405 632	38 190
Albania	Government of Albania	7 861	700
Armenia	KFW[a]	34 364	4 200
Bangladesh	WHO	202 922	22 500
Cambodia	Government of Japan	34 811	N/A
Ethiopia	WHO	2 651	N/A
Georgia	KFW	89 154	10 100
India, Haryana State	WHO	644 064	49 920
Indonesia	GFATM[b]	3 446 991	311 904
Iraq	WHO	316 982	18 000
Micronesia (Fed. States of)	WHO	1 409	220
Nepal	WHO	504 365	43 316
Nigeria (1)	NLRA[c]	219 059	18 250
Nigeria (2)	GLRA[d]	700 906	58 410
Philippines	World Bank	5 654 437	440 800
Republic of Moldova	Caritas Luxembourg	4 362	400
Sao Tome and Principe	WHO	3 075	150
Somalia	WHO	63 072	5 260
Sudan	WHO	19 844	2 500
Timor-Leste	Caritas Norway	43 478	3 150
	Totals	12 399 439	1 027 970

[a] KFW = German Bank for Reconstruction

[b] GFATM = Global Fund to Fight AIDS, Tuberculosis and Malaria

[c] NLRA = Netherlands Leprosy Relief Association

[d] GLRA = German Leprosy and TB Relief Association

* As of end 2004

Notes

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Stop TB Partnership is housed by the World Health Organization

20, avenue Appia • CH-1211 Geneva 27
Switzerland

Telephone (+41) 22 791 2111
Fax (+41) 22 791 4886
Web site: http://www.stoptb.org/gdf/