

Progress Report 10

Stop TB Partnership
Global Drug Facility

1 January 2006 – 31 December 2006



Stop TB Partnership Secretariat
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1. Summary

This report covers the activities of the Global TB Drug Facility (GDF) from 1 January to 31 December 2006, which are summarized below. Further details are given in sections 2–5 (and annexes 1-3).

Grants of free anti-TB drugs to countries

During this reporting period, GDF continued to provide grants of free adult, first-line anti-TB drugs for use in DOTS programmes worldwide to countries approved by the GDF Technical Review Committee (TRC). In addition, through support from UNITAID (an innovative new financing mechanism), GDF began offering grants of paediatric anti-TB drugs.

Sixty-six (66) applications for grants of adult and paediatric anti-TB drugs were reviewed by the GDF Technical Review Committee (TRC), of which fifty-three (53) were approved for a GDF grant of free anti-TB drugs. These grants represent treatments for 1.13 million patients, at an estimated total cost of 30.4 million US\$.

Furthermore, during this reporting period, GDF delivered 2 027 375 TB patient treatments to thirty-one (31) grant recipients. Including these figures, sixty-one (61) grant recipients have received a cumulative total of 6 862 485 anti-TB patient treatments through GDF from 2001 to 2006.

Direct Procurement of anti-TB drugs through GDF

During this reporting period, twenty-one (21) countries used the GDF Direct Procurement (DP) Service to place orders for first-line anti-TB drugs. These orders represented 369,000 anti-TB patient treatments, at an approximate cost of 6.2 million US\$.

The Global Fund to fight AIDS, Tuberculosis and Malaria continued to be a primary funder for drug orders placed with GDF: of the twenty-one (21) countries placing drug orders, nine (9) countries used grant monies from the Global Fund. The value of DP orders placed using Global Fund monies during 2006 was 4.2 million US\$ – or approximately 69% of the total value of all DP orders placed with GDF.

GDF delivered 527,976 anti-TB patient treatments to 19 DP customers in 2006. This raises the number of countries that have received anti-TB drugs through the GDF DP Service to 31, and the cumulative number of patient treatments supplied via GDF Direct Procurement (2001 to 2006) to 2 112 801.

During the reporting period, GDF expanded its product catalogue to include second-line anti-TB drugs – the drugs needed to treat multidrug-resistant TB (MDR-TB). This expansion was affected through the GDF convergence with the Green Light Committee (GLC). Twenty-two (22) countries received deliveries of second-line anti-TB drugs for use in twenty-five (25) MDR-TB Management Programmes that had been approved by the GLC. These deliveries reflected a total value of 3.69 million US\$ worth of second-line drugs.

GDF technical support for drug management

GDF organized 59 missions to National TB Control Programmes in all six (6) of the WHO regions, up from 51 in 2005. Of the fifty-nine (59) missions: five (5) were pre-delivery country visits, forty (40) monitoring missions, thirteen (13) technical support mission and one (1), a special mission to East Timor. To a complement the technical assistance provided during missions, GDF is very active in participating and hosting a range of drug management trainings and workshops. In 2006 GDF was involved in twelve (12) different capacity building activities.

GDF operations

In 2006, GDF continued changing to better meet the short and long-term needs of countries and the global movement to Stop TB. In particular, GDF grants began to slowly decrease as countries switched to Direct Procurement using other sources of funds. GDF expanded its catalogue of products to include more of the supplies required by programmes to treat patients, namely second-line anti-TB drugs (through convergence with the Green Light Committee) and paediatric anti-TB drugs. GDF structures evolved to deliver better support to countries, by placing staff in regions and creating portfolio officers in its secretariat.

2. Strategic developments

In 2006 GDF continued to evolve to better meet the short and long-term needs of countries and the global movement to Stop TB.

Key strategic developments in 2006 included:

- a gradual decrease in GDF grants of first-line anti-TB drugs for adults, as more countries transitioned to GDF Direct Procurement using funds from other sources, such as national budget lines or financing from the Global Fund to Fight AIDS, Tuberculosis and Malaria. Resources donated by the United Kingdom's Department for International Development (DFID) for use in supplying anti-Tuberculosis drugs in India make up a significant portion of all GDF grants provided in 2006;
- the introduction of GDF grants of first-line anti-TB drugs for children, with support from UNITAID, an innovative new financing initiative, which identified GDF as the Programmatic Partner to implement the procurement and supply of paediatric anti-TB drugs;
- the introduction of supply of second-line anti-TB drugs, the drugs needed to treat multidrug-resistant TB, through convergence with the Green Light Committee (GLC);
- the transformation of its country support team to a portfolio-based structure, in which GDF portfolio officers were assigned to support the specific needs of each region;
- the placement of regional support officers in the Eastern Mediterranean and South-East Asian regions to provide more direct support to countries receiving drugs from GDF and to identify needs for and broker technical support for drug management in the region;
- the placement of a procurement officer in the South-East Asian region to coordinate activities related to the procurement of anti-tuberculosis medicines for the Revised National Tuberculosis Programme, India;
- the creation of a GDF Business Advisory Committee, to consider and advise GDF on the complex set of business issues specifically relevant to procurement operations and strategy implementation, composed of experts in raw material manufacturing, pharmacy, product formulation for drugs and diagnostics, quality assurance, regulatory law, contract law, business development, competitive procurement processes, pricing and distribution.
- the endorsement of the Stop TB Partnership Coordinating Board, at its meeting in Jakarta in November 2006, of the following in relation to GDF Grants of first line anti-TB drugs: (i) Maintenance of the duration of a GDF grant to a 3 year cycle; (ii) Making all future GDF grants conditional on progressively increased budget lines for TB drugs; and (iii) Introduction by the GDF secretariat and its partners of a Financial Sustainability process for countries, to guide the creation and increase of budgets for TB drugs.
- the WHO Prequalification Programme for which the GDF has provided substantial financial and political support over the last 5 years received significant (multi-million \$ Grants) funding from two donors in 2006: the Gates Foundation and UNITAID. This funding is expected to enable the Prequalification Programme to catalyse a much more rapid prequalification of anti-TB drugs. GDF will use the funds it hitherto provided to the Prequalification Programme for normative TB prequalification activities, to finance activities that complement and enhance the work of the Prequalification Programme.

2. Grants of free anti-TB drugs to countries

During this reporting period, GDF continued to provide grants of free adult, first-line anti-TB drugs for use in DOTS programmes worldwide to countries approved by the GDF Technical Review Committee (TRC). In addition, through support from UNITAID (an innovative new financing mechanism), GDF began offering grants of paediatric anti-TB drugs in 2006.

In 2006, GDF completed its 13th and 14th rounds of grant applications. In addition, grant applications were reviewed outside of traditional TRC meetings during ad hoc technical reviews and delegated TRC reviews as part of annual monitoring of grant recipients.

Sixty-six (66) applications for grants of adult and paediatric anti-TB drugs were reviewed by the GDF TRC, of which forty (40) were new applications. Fifty-three (53) applications were approved for a GDF grant of free anti-TB drugs. These grants represent treatments for 1.13 million patients being treated under DOTS worldwide, at an estimated total cost of 30.4 million US\$.

This raises the cumulative number of new applications reviewed by GDF since 2001 to one hundred and fifty (149), with one hundred and eight (108) having been approved for a GDF grant.

13th round of applications

The 13th TRC met on 24-26 January, 2006 and reviewed eight (8) applications from programmes for grants of free anti-TB drugs:

- six (6) new applications (including three (3) new applications for 2nd term grants);
- one (1) application from a programme previously placed "under consideration"; and
- one (1) application for continuation of support for the third year of a grant.

Of the applications reviewed in round 13, the TRC approved four (4) new applications for support (Table 2.1). Two (2) of these approvals were for 2nd term grants.

One (1) "under consideration" application (*Kyrgyzstan*) was approved for a 3-year grant during TRC 13 after having been placed under consideration by TRC 3 (2002).

The TRC also reviewed the dossier from one (1) programme (*Equatorial Guinea*) for continuation of support (the third year of a 3-year grant). The application was not approved by the TRC for several reasons, including (but not limited to) a lack of compliance with recommendations previously made by the TRC, evidence of poor drug management in the country and a lack of government commitment to establish a national budget for TB control.

Table 2.1 Applications for grants of adult anti-TB drugs approved during the 13th Technical Review Committee

Country approved	Grant type	Patients*	Estimated cost (US\$)
Afghanistan	1 st term	21 700	546 288
Democratic People's Republic of Korea	2 nd term	53 300	991 992
Djibouti	2 nd term	3 250	146 666
Kyrgyzstan	1 st term	7 850	361 160
Lesotho	1 st term	23 100	552 344
Total (5)		109 200	2 598 450

* In principle, GDF includes 100% buffer stock with its grants. Patient numbers that appear here do not include patient treatments provided as buffer stock. The estimated cost (US\$) shown here does include the cost of buffer stocks.

Table 2.2 Applications for grants of adult anti-TB drugs approved during the 14th Technical Review Committee

Country approved	Grant type	Patients	Estimated cost (US\$)
Bangladesh	2 nd term	113 099	2 000 000
Democratic People's Republic of Korea	2 nd term, year 2	52 500	759 260
Iraq	1 st term	6 800	305 000
Malawi	1 st term	24 920	1 103 006
Myanmar	2 nd term, year 2	125 587	1 000 000
Niger	1 st term, year 3	9 046	203 413
Sierra Leone	2 nd term	8 988	299 490
The Gambia	2 nd term	2 100	64 860
Togo	2 nd term, year 2	1 828	140 824
Uganda	2 nd term	61 000	750 000
Vietnam	1 st term (1 year)	62 725	1 885 000
Total (11)		468 593	8 510 853

14th round of applications

The 14th TRC met on 13-16 November, 2006 to review thirty-five (35) applications from programmes for grants of free adult and (for the first time) paediatric anti-TB drugs:

- nine (9) new applications for grants of adult anti-TB drugs (including six (6) new applications for 2nd term grants);
- nineteen (19) new applications for grants of paediatric anti-TB drugs;
- four (4) applications for continuation of support for the second or third years of a grant;
- two (2) applications for approval to directly procure through GDF; and
- one (1) application for an emergency supply of GDF drugs.

Of the nine (9) applications for new grants of adult anti-TB drugs, seven (7) were approved (see table 2.2). Four (4) of these approvals were for new 2nd term grants.

Of the applications reviewed in round 14, the TRC approved fourteen (14) applications for new grants of paediatric anti-TB drugs (table 2.3).

The TRC also reviewed the dossiers from four (4) country programmes (*Democratic People's Republic of Korea, Myanmar, Niger* and *Togo*) for continuation of support (second and third years of a 3-year grant). All four (4) were approved, however, one was given (1) a cautionary approval¹ (*Niger*) and two (2) a conditional approval² (*Myanmar* and *Togo*).

Ad hoc³ technical reviews

In response to urgent country needs for anti-TB drugs, additional ad hoc technical reviews were held in June and August 2006. In total ten (10) country applications were reviewed:

- five (5) new applications (including three (3) new applications for 2nd term grants);
- four (4) applications for continuation of support for the second or third year of a grant;
- one (1) application for an emergency supply of GDF drugs.

Of the five (5) applications for new grants of adult anti-TB drugs, all were approved for at least one year of GDF support (see table 2.4).

The TRC also reviewed the dossiers from four (4) country programmes (*Egypt, Kenya, Uzbekistan, and Madagascar*) for continuation of

Table 2.3 Applications for grants of *paediatric* anti-TB drugs approved **during the 14th** Technical Review Committee

Country approved	Patients	Estimated cost (US\$)
Afghanistan	3 000	135 000
Bangladesh	14 000	630 000
Benin	100	4 500
Cambodia	1 800	60 750
Cote d'Ivoire	2 484	111 780
Djibouti	400	18 000
Indonesia	10 000	337 500
Iraq	870	39 150
Nepal	1 900	85 500
Pakistan	40 000	1 800 000
Rwanda	500	22 500
Somalia	1 300	58 500
Tajikistan	800	36 000
The Gambia	150	6 750
Total (14)	77 304	3 345 930

Table 2.4 Applications for grants of anti-TB drugs approved **during emergency technical reviews**

Country approved	Grant type	Patients	Estimated cost (US\$)
Bolivia	Emergency	10 004	112 570
Burundi	2 nd term (1 year)	6 850	122 996
Chad	1 st term (1 year)	5 270	98 253
Cote D'Ivoire	1 st term	24 250	1 074 278
Egypt	1 st term, year 3	5 500	92 737
Kenya	2 nd term, year 2	18 000	630 786
Madagascar	1 st term, year 2	20 000	851 298
Nigeria	2 nd term (1 year)	85 651	391 169
Tajikistan	2 nd term (1 year)	8 101	349 422
Uzbekistan	1 st term, year 3	12 000	420 195
Total (10)		195 626	4 143 704

¹ "Cautionary approval": serious attempts should be made to correct the problems identified.

² "Conditional approval": unless the deficiencies observed are corrected within the year, no further support should be expected.

³ An ad hoc review occurs when a sub-committee of the TRC physically meets to review applications that cannot wait until a regular full TRC meeting due to the urgency of the anti-TB drug needs of the countries in question. TRC sub-committee recommendations are circulated to the full TRC for final endorsement.

support (second and third years of a 3-year grant). One (1) was approved without reservations (*Kenya*), two were given (2) a conditional approval (*Madagascar* and *Egypt*), and one (1) was placed under consideration pending clarifications, which were later provided to the satisfaction of the reviewers (*Uzbekistan*).

One (1) country, *Bolivia*, was approved for a 1-year emergency supply of GDF drugs.

Delegated TRC reviews

Outside of traditional technical reviews, thirteen (13) applications were approved under delegated TRC assessments subsequent to an annual monitoring and evaluation assessment (table 2.5) i.e. If the GDF monitoring mission gives a green light for continuation of a first-term grant, and the independent GDF-contracted desk auditor confirms this decision, then the TRC is not required to review the dossier. All second-term dossiers, though, are reviewed by the TRC before a grant can be continued.

Six months after GDF grant drugs have arrived in the country, a GDF monitoring mission arrives composed of independent TB programme and drug management experts. The majority of these experts are affiliated with members of the STOP TB Partnership while some are independent consultants. The monitoring mission submits a report to the GDF Secretariat, together with information on GDF drug arrival, customs clearance, drug registration, quarterly reports on case findings and treatment outcomes and annual World Health Organization (WHO) TB data collection form. This information, known as a monitoring dossier, is then sent to external auditors.

The external auditor reviews the monitoring dossier for completeness, consistency and credibility. The auditor must also decide whether the information in the monitoring dossier is sufficient to enable the TRC to assess whether GDF terms and conditions of support as well as other monitoring requirements have been met.

Table 2.5 Applications for grants of anti-TB drugs approved **subsequent to annual monitoring and evaluation**

Country approved	Grant type	Patients	Estimated cost (US\$)
Burkina Faso	1 st term, year 3	4 187	202 794
Guinea	1 st term, year 2	6 893	212 458
Guinea	1 st term, year 3	6 826	189 000
Mali	1 st term, year 2	4 991	60 700
Pakistan	1 st term, year 3	112 126	5 410 314
Rwanda	1 st term, year 3	7 720	261 201
Syrian Arab Republic	1 st term, year 3	3 150	138 020
The former Yugoslav Republic of Macedonia	1 st term, year 3	715	57 784
Timor-Leste	1 st term, year 2	3 951	100 969
Turkmenistan	1 st term, year 2	714	16 733
United Republic of Tanzania	1 st term, year 2	66 000	3 305 363
Yemen	1 st term, year 3	6 644	201 485
Zambia	1 st term, year 3	60 000	1 626 895
Total (13)		283 917	11 783 716

Summary of GDF grants approved in 2006

Table 2.6 Summary of GDF Grants Approved in 2006

Source of Approval	Grants	Patients	Estimated cost (US\$)
13 th Round of Applications	5	109 200	2 598 450
14 th Round of Applications	25	545 897	11 856 783
Ad hoc technical reviews	10	195 626	4 143 704
Delegated TRC reviews	13	283 917	11 783 716
Total	53	1 134 640	30 382 653

Drug deliveries to GDF grant recipients

In total, from 1 January 2006 to 31 December 2006, GDF delivered 2 027 375 TB patient treatments to 31 grant recipients (table 2.7).

These figures raise the number of countries that have received free GDF anti-TB drugs to 61 and the cumulative number of patient treatments supplied via GDF grants (2001 to 2006) to 6 862 485.

Table 2.7 Deliveries of anti-TB drugs to GDF Grant Recipients in 2006

Country	Grant Type	Patient Treatments Supplied by GDF
Afghanistan	1 st term, year 1	24,530
Bangladesh	1 st term, year 3	52,159
Benin	1 st term, year 2	6,865
Bolivia	Emergency	6,690
Bosnia and Herzegovina	1 st term, year 3	5,899
Burkina Faso	1 st term, year 2	1,063
Cameroon	1 st term, year 1	60,882
Democratic People's Republic of Korea (the)	2 nd term, year 1	67,569
Democratic Republic of the Congo (the)	2 nd term, year 1	113,597
Egypt	1 st term, year 2	8,983
Eritrea	1 st term, year 3	824
Guinea	1 st term, year 2	11,934
Haiti	1 st term, year 3	29,865
India	DFID/INDIA Grant	892,820
Kenya	2 nd term, year 2	27,000
Lao People's Democratic Republic (the)	1 st term, year 1	4,145
Maldives	1 st term, year 2	355
Mali	1 st term, year 2	1,997
Mozambique	1 st term, year 2	91,518
Myanmar	2 nd term, year 1	46,539
Niger (the)	1 st term, year 2	8,655
Pakistan	1 st term, year 3 / Emergency	252,407
Philippines (the)	1 st term, year 2	10,000
Syrian Arab Republic (the)	1 st term, year 2	497
The former Yugoslav Republic of Macedonia	1 st term, year 3	1,959
Togo	2 nd term, year 1	2,378
Turkmenistan	1 st term, year 2	714
Uganda	1 st term, year 3	81,918
United Republic of Tanzania (the)	1 st term, year 2	113,516
Yemen	1 st term, year 3	10,097
Zambia	1 st term, year 3	90,000
Total (31)		2 027 375

3. Direct Procurement of anti-TB drugs through GDF

The GDF Direct Procurement (DP) Service is intended for governments, donors and non-governmental organizations that wish to purchase drugs for use in programmes in countries that have sufficient finances but lack adequate procurement capacity, including a robust quality assurance system. The DP Service, begun in 2003, is flexible enough to support a variety of country and donor needs, resulting in a solid base of regular users of this Service while appealing to new customers.

During 2006, twenty-two (22) orders for anti-TB drugs were placed through the GDF DP Service (see Table 3.1). These orders represented 369,014 anti-TB patient treatments, at an approximate cost of 6.2 million US\$. Of the orders placed in 2006:

- eight (8) were placed by countries using the DP Service for the first time in 2006, bringing the total number of countries using the DP Service to thirty-eight (38).
- fourteen (14) were placed by countries that had previously used the DP Service.

Table 3.1 Orders placed for anti-TB drugs through the GDF Direct Procurement Service in 2006

Country (Funding Source)	Patient Treatments	Estimated drug costs (US\$)
Afghanistan (Kuwait Fund)	1000	21,890
Albania (Government)	1400	27,330
Armenia (KFW)	4360	80,318
Azerbaijan (KFW)	16,846	401,372
Bangladesh (Global Fund)	57,190	839,593
Congo, the Democratic Republic of the (Global Fund)*	67,828	1,018,320
Dominican Republic (Government)*	3468	60,439
Gabon (Government)*	2882	32,196
Georgia (KFW)	9000	200,893
Georgia (KFW)	1050	23,743
Ghana (Global Fund)*	25,400	524,592
Guyana (Global Fund)*	600	15,037
Indonesia (Global Fund)	100,000	1,427,000
Lebanon (WHO)*	400	7,409
Malawi (DFID, KNCV, Norway)*	18,898	484,405
Republic of Moldova (Global Fund)	10,500	203,000
Mongolia (Global Fund)	7200	136,895
Nepal (DFID)	28,000	427,041
Nigeria (WHO)	4,500	36,197
Papua New Guinea (WHO)*	6,000	134,046
Serbia (and Kosovo) (Global Fund)	1,300	36,388
Tajikistan (Global Fund)	1,200	27,173
Total (22)	369,014	6,165,277

* Indicates a country that in 2006 used GDF Direct Procurement for the first time.

As well as meeting country needs, in 2006 the DP Service continued to serve a variety of donors:

- Nine (9) countries placed drug orders using grant monies from the Global Fund to Fight AIDS, Tuberculosis and Malaria. Five (5) of these countries used Global Fund monies to order through GDF DP for the first time, increasing the cumulative number of countries doing so to seventeen (17). The value of DP orders placed using Global Fund monies during 2006 was 4.2 million US\$ – or approximately 69% of the total value of all DP orders placed.
- Six (6) countries placed drug orders using monies from a variety of other donors, including DFID, KNCV, KFW and the Kuwait Fund.
- Three (3) countries placed drug orders using monies provided by the WHO.
- Three (3) countries placed drug orders using their own Government's funds.

Drug deliveries to GDF Direct Procurement customers

In total, from 1 January 2006 to 31 December 2006, GDF delivered 527,976 TB patient treatments to 19 DP customers (table 3.2). The drugs delivered represented an approximate value of 8.76 million US\$. Of the orders delivered in 2006:

- Eight (8) orders were paid for using grant monies from the Global Fund. The value of DP orders paid for using Global Fund monies during 2006 was 3.6 million US\$ – or approximately 42% of the total value of all DP orders delivered.
- Five (5) orders were paid for using monies from a variety of other donors, including DFID, KNCV, KFW, the Norwegian Government and the World Bank.
- Four (4) orders were paid for using monies provided by the WHO.
- Two (2) orders were paid for using Government funds.

These figures raise the number of countries that have received anti-TB drugs through the GDF DP Service to 31 and the cumulative number of patient treatments supplied via GDF Direct Procurement (2001 to 2006) to 2 112 801.

Table 3.2 Deliveries of anti-TB drugs to GDF Direct Procurement Customers in 2006

Country (Funding Source)	Patient Treatments	Estimated drug costs (US\$)
Afghanistan (Global Fund)	7000	112,440
Albania (Government)	1400	27,329
Armenia (KFW)	4360	80,317
Azerbaijan (KFW)	15,840	341,949
Bangladesh (Global Fund)	20,000	438,069
Dominican Republic (Government)	1,332	25,528
Georgia (KFW)	9,000	200,892
Indonesia (Global Fund)	162,181	2,025,932
Liberia (Global Fund)	10,400	168,399
Malawi (DFID, KNCV, Norway)	18,898	447,971
Mongolia (Global Fund)	7200	182,111
Namibia (Global Fund)	27,110	508,805
Nepal (WHO)	44,455	905,174
Nigeria (WHO)	4,500	39,196
Papua New Guinea (WHO)	6,000	135,239
Philippines (World Bank)	170,800	2,835,714
Republic of Moldova (Global Fund)	10,500	204,858
Tajikistan (Global Fund)	1,200	27,172
Uganda (WHO)	5,800	61,619
Total (19)	527,976	8,768,714

Procurement of anti-TB drugs for MDR-TB management programmes

During the reporting period, GDF expanded its product catalogue to include second-line anti-TB drugs – the drugs needed to treat multidrug-resistant TB (MDR-TB). This expansion was affected through the GDF convergence with the Green Light Committee (GLC).

In 2006, twenty-two (22) countries received deliveries of second-line anti-TB drugs for use in twenty-five (25) MDR-TB Management Programmes that had been approved by the GLC. These deliveries reflected a total value of 3.69 million US\$ worth of second-line drugs – approximately 40% more than the value of deliveries made in 2005 (2.64 million US\$).

4. GDF technical support for drug management

Shortages of anti-TB drugs frequently result from an insufficient capacity within a country to plan, fund, procure or manage its drug supply. GDF has successfully used a holistic approach to address immediate gaps in drug supply while helping countries to overcome systemic problems in drug management and establish the long-term capacity needed by national TB control programmes in the management of their drug supplies.

Technical assistance in drug management to support National TB Programmes (NTPs) continues to be carried out as part of all GDF in-country missions. GDF experts provide on-the-spot support and provide achievable recommendations to improve good drug management practices. In addition to the direct technical assistance provided to individual country programmes, GDF builds capacity by conducting a variety of regionally-based drug management trainings and has continued to support, financially and politically, the WHO coordinated Prequalification Programme.

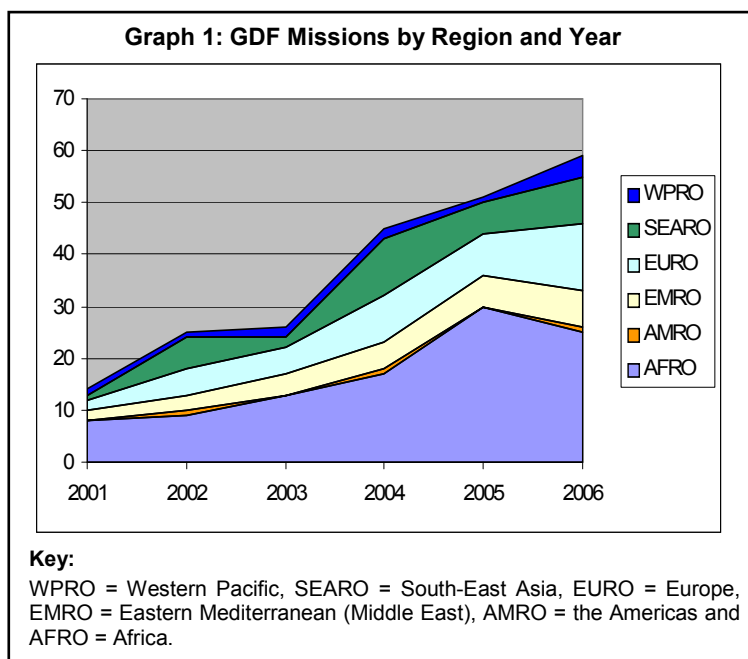
Technical Assistance through Missions

GDF missions are pillars in the provision of technical support to NTPs. Mission teams monitor the use of existing drug supplies while working with national programmes to address bottlenecks and weaknesses in their supply chain and help programmes plan for their future drug needs. Visits are organized in countries that are either receiving GDF grant support or using its Direct Procurement service, or both. Drawing from Stop TB partners and independent consultants, individuals are selected based on their expertise in TB control and drug management. Three types of GDF missions are conducted: *country visits* for countries that are approved or placed "under consideration" for grant support; *monitoring missions* which are annual visits conducted to all grant supported countries; and *technical support missions* for countries utilizing the GDF Direct Procurement service. In addition to these standard missions, GDF, in collaboration with its Partners, does, on occasion, arrange for ad-hoc, targeted missions in particular circumstances where urgent, specific drug management support is crucial.

Since 2001, GDF has sent more than 200 teams of drug management and TB experts to GDF supported countries. Graph 1, "GDF Missions by Region and Year", shows the cumulative number of missions organized per WHO region and per year since GDF founding.

In 2006 alone, GDF organized 59 missions to NTPs in all six (6) of the WHO regions, up from 51 in 2005. Of the fifty-nine (59) missions: five (5) were pre-delivery country visits, forty (40) monitoring missions, thirteen (13) technical support mission and one (1), a special mission to East Timor.

The placement of GDF Regional Support Officers with drug management expertise and experience in the WHO Eastern Mediterranean and South-East Asian regions, has served to enhance GDF's capacity to provide and/or broker timely and relevant technical assistance.



Training workshops

To complement the technical assistance provided during missions, GDF is very active in participating and hosting a range of drug management trainings and workshops. In 2006 GDF was involved in twelve (12) different capacity building activities.

In close collaboration with its key partner Management Sciences for Health (MSH), GDF co-hosted four (4) workshops. Two (2) workshops, held in Kazakhstan and Benin, aimed to increase the number of drug management experts that will serve as technical assistance providers during GDF missions in Central Asia, Eastern Europe and Francophone Africa. A third workshop, also held in Benin, targeted National TB Programme staff in Francophone Africa and aimed to respond to an urgent call from the Region to strengthen the TB drug

management capacity in those countries. The fourth joint workshop entitled "Building capacity in pharmaceutical management for TB, MDR-TB and TB/HIV" was held at the annual IUATLD⁴ conference in Paris, November 2006. Targeting National Programme staff and other partners, the seminar drew over 50 participants and received positive feedback. Along the same theme, two (2) workshops were conducted in Tanzania and Russia focusing on specific drug management issues related to MDR-TB and 2nd line drugs.

Furthermore, GDF involved in two (2) workshops in Ghana and Senegal, training national stakeholders to prepare procurement plans for submission to international financing mechanisms, such as the Global Fund.

Lastly, since GDF believes that technical support is not only critical in the effective management of drug supplies, but also equally important to ensuring quality-assured medicines reach the market, GDF participated and supported three (3) workshops in 2006. The workshops -- two (2) in Russia and (1) one in China -- were targeted at anti-TB drug manufacturers with the objective of improving their understanding of the WHO Prequalification Programme, including how to achieve WHO's Good Manufacturing Practice (GMP) standards and how to submit strong product dossiers for 1st and 2nd line anti-TB drugs into the Prequalification pipeline.

⁴ International Union Against TB and Lung Disease

5. GDF operations

In 2006, the following key developments characterized GDF's functions at the management and operational levels:

- GDF transformed its country support team to a portfolio-based structure, in which GDF portfolio officers were assigned to support the specific needs of each region. The expected benefits are: (i) the development of a personal relationship between the GDF Secretariat Portfolio Officers and NTPs of all GDF supported countries, GDF region-based staff, WHO regional and national offices, Stop TB HQ regional focal points and regional pools of consultants (ii) an increased knowledge of country issues and backgrounds, leading to a better responsiveness and pro-activity from the GDF Secretariat, including engaging new countries to use GDF services; (iii) closer relations forged with Global Fund portfolio managers; (iv) allowing the work of the country support team staff to become more diverse, country focused and invested with a sense of ownership of country activities.
- A new procurement team leader was hired and took office in February 2006.
- Regional Support Officers were placed in the Eastern Mediterranean and South-East Asian regions to provide more direct support to countries receiving drugs from GDF and to identify needs for and broker technical support for drug management in the region. A procurement officer was also placed in Delhi, India to coordinate activities related to the procurement of anti-tuberculosis medicines for the Revised National Tuberculosis Programme, India funded by DFID. It is expected that Regional Support Officers will be placed in the Africa Region (one Anglophone and one Francophone) in 2007.
- GDF successfully concluded the first year of its five-year MOU with DFID to provide TB drugs and technical support (via WHO and other partners) to India's TB Control Programme. Approximately US\$ 10 million worth of TB drugs were delivered to the TB Programme. Some supply bottlenecks were experienced with the newly introduced paediatric patient kits, which were addressed by a GDF mission to India in October, to deal decisively with the non-compliant supply partner.
- GDF successfully concluded a Long Term Agreement (2006 to 2008) with GTZ for procurement of first-line anti-TB drugs and diagnostics from 2006 to 2008, following a transparent, competitive selection process. The selection saw a significant revision of the conditions of service for the role of the agent designed to optimize costs, improve efficiency and better service GDF's client countries in terms of timely access to critical anti-TB drugs.
- The GDF five-year strategic plan was strengthened in collaboration with the development consulting firm, Apt Associates (financial support was secured via USAID to pay for the consultancy). The Plan will be published in Q1 2007.
- GDF successfully retained its ISO 9001:2000 Certification following an independent audit in Dec. 2006. A few corrective actions were recommended particularly with regards to documentation management, which will be addressed in Q1 2007.

Challenges for 2007

While 2006 has seen some impressive successes and milestones for GDF, 2007 will present some important challenges:

- More intensive efforts will need to be made in 2007 to further diversify the GDF funding base for Grants and also further; but gradually; scale down the Grant Service as required by the GDF Strategic Plan so as to ensure greater complementarity with the Global Fund and increased use of GDF's DP service. That said, GDF will continue to maximize its efforts to ensure that Grants are maintained for core beneficiaries i.e. those countries where GDF services offer a comparative advantage e.g. weak programmes and emergency grantees.
- Pursuing the Stop TB Partnership Coordinating Board Mandate to (i) make all future GDF grants conditional on the creation of budget lines/earmarked funds for anti-TB drugs (where absent in government financial programming) and the progressive annual increase in budget lines/ear-marked

funds for anti-TB drugs and (ii) as a corollary, introduce a Financial Sustainability process for countries, to guide the creation and increase of budgets/earmarked funds for anti-TB drugs, will be a challenging but worthwhile endeavour.

- Ensuring timely placement of GDF Regional Support Officers in the Africa Region could be a challenge given the difficult experience of other Stop TB units in 2006 in placing staff at the WHO regional or country offices in the Africa Region.
- Prequalification of anti-TB drugs, especially second line and paediatric anti-TB drugs where no products/supply sources have yet been prequalified will remain a challenge. While the unprecedented multi-million dollar funding received by the WHO Prequalification Programme for 2007 provides vast opportunity for acceleration of the prequalification effort GDF will need to work proactively to ensure that TB remains a priority among other competing disease areas (HIV, Malaria, Reproductive Health and soon Chronic diseases). Moreover, GDF will need to work to ensure that the funds are spent on priority TB products and according to a schedule that meets Stop TB and programme priorities.
- The recently created GDF Business Advisory Committee will need to be given very clear direction and carefully prioritize which areas of GDF business operations to target with their expertise in order to ensure that it adds value and that its advice and recommendations are transformed into tangible results.

Annex I. Select GDF performance, process and impact indicators

Table 1: Select GDF Performance, Process and Impact Indicators

GDF core functions	Activity	Results		
		Current reporting period (2006)	Previous year (2005)	Cumulative (2001-2006)
Funding	Funds raised for GDF operations, in US\$ '000	54 220 (2006)		137 590
	Total funds raised for GDF grants, in US\$ '000 ⁵	40 723 (2006)		106 819
Grants	No. of patient treatments supplied via grants ⁶	2 027 375	1 537 905	6 862 485
	Value of grants approved, in US\$ '000	30 383	19 502	105 009
Direct Procurement	No. of new countries placing Direct Procurement orders ⁷	8	9	38
	Value of Direct Procurement orders placed, in US\$ '000 ⁸	6 165	12 512	31 076
	No. of patient treatments supplied via Direct Procurement ⁹	527 976	1 009 418	2 112 801
Grants and Direct Procurement	No. of patient treatments supplied via GDF Grants and the Direct Procurement Service	2 555 351	2 547 323	8 975 286
Grant applications and review	No. of High Burden Countries ¹⁰ receiving GDF drugs through a GDF Grant or GDF Direct Procurement	13	12	15
	No. of rounds of grant application and review	2	2	14
	No. of new applications for a grant ¹¹	39	12	149
	No. of new applications approved for a 1 st term grant ¹²	9	6	82
	No. of new applications approved for a 2 nd term grant	9	4	13
	No. of new applications approved for a paediatrics grant	14	0	14
	No. of countries approved for a GDF grant	25	5	65
	No. of applications for new or continued support not approved or placed "under consideration"	13	6	59
Monitoring and evaluation	No. of pre-delivery country visits to GDF countries	5	7	62
	No. of monitoring missions to GDF Grant countries	40	38	127
	No. of technical assistance missions to countries using the Direct Procurement Service	13	5	21
	No. of countries that completed their 1 st term 3-year grant	13	13	28
First line anti-TB Drug Prequalification & GMP Compliance¹³	No. of manufacturers that are WHO GMP compliant	1	5	6
	No. of prequalified products from those listed in the GDF catalogue (out of 9)	1	4	5
	No. of prequalified products from those listed in the GDF catalogue (out of 9) that have 2 or more suppliers	2	2	4
Procurement	No. of grant countries that received drug deliveries	31	36	61
	No. of countries using the Direct Procurement Service that received drug deliveries	19	18	31
	Total no. of countries that received drug deliveries (Grant and Direct Procurement Services)	46	47	71

⁵ Includes both cash contributions and drugs donated in-kind.

⁶ The number of patient treatments delivered to grant recipients during the reporting period (table 2.7).

⁷ Countries that are already Direct Procurement clients who place new orders are not counted again.

⁸ Based on Purchase Orders.

⁹ The number of patient treatments delivered to countries via the Direct Procurement Service during the reporting period (table 3.2).

¹⁰ The Stop TB Partnership defines as "High Burden" those countries accounting for 80% of global infective cases of tuberculosis.

¹¹ Includes only new applications for a 3-year first-term or second-term GDF grant of adult or paediatric medicines. Annual renewal of GDF support for years 2 and 3 of a Grant is not considered a new application. An "under consideration" country that re-applies is not considered a new application. Applications for emergency deliveries of drugs to avoid humanitarian crises are not included.

¹² Includes new applications for a grant as well as "under consideration" applicants that were approved during the reporting period.

¹³ As assessed under the Procurement, Quality and Sourcing Project: Access to Anti-Tuberculosis Drugs of Acceptable Quality, which is coordinated and implemented by the WHO Department Medicines Policy and Standards/Quality Assurance and Safety of Medicines and for which GDF is a principal contributor of funds and political support.

Area	Indicator	GDF price per tablet / vial	Lowest other price per tablet / vial
Direct Procurement (Affordability)	GDF drug price (US\$) compared to the lowest price offered by a competitive selection of international suppliers ¹⁴		
	RHZE 150/75/400/275	0.0481	No other sources listed ¹⁵
	EH 400/150	0.0229 (-)	0.0254
	H300	0.0038 (-)	0.0051
	RH 150/75	0.0207	0.0172 (-)
		Current reporting period (2006)	Previous year (2005)
Cure Rates	Estimated number of TB patients that will be cured with drugs supplied via GDF Grants ¹⁶	1 723 269	1 307 219
	Estimated number of TB patients that will be cured with drugs supplied via GDF Direct Procurement ¹⁷	448 780	858 005
	Total estimated number of TB patients that will be cured (Grants and Direct Procurement)	2 172 048	2 165 225
	Average cost per additional cure in US dollars (including product costs, insurance and delivery fees) ¹⁸	26.45 US\$	

¹⁴ Source: International Drug Price Indicator Guide 2006, <http://erc.msh.org/>.

¹⁵ No other sources of RHZE 150/74/400/275 were listed in the International Drug Price Indicator Guide for 2006

¹⁶ 85% of patient treatments delivered via GDF grants during this reporting period

¹⁷ 85% of patient treatments delivered via the Direct Procurement Service during this reporting period

¹⁸ Cost per estimated patient cured, excluding buffer. Figure comes from the Secretariat estimation of \$23 per patient (includes average drug cost, insurance and freight) and based on an 85% cure rate.

Annex II. The additionality of GDF support to countries

Introduction

The Global Drug Facility (GDF) has supplied anti-TB drugs to X countries between 2001-2006. Drugs are paid for from several sources, including bilateral donors (such as DFID to India), national budget lines (such as Albania), international financing mechanisms (such as the Global Fund), governments and non-governmental organizations, and through grants of free drugs from the GDF.

An important consideration when providing grants of free drugs is the potential impact of GDF support on other, existing funding for TB control and, in particular, impact on national budget lines for first-line anti-TB drugs. A goal of GDF is to build strong, sustainable and independent national TB control programmes by ensuring its support is additional to existing funding and by catalysing the creation of national budget lines for TB control and TB drugs.

In 2006 GDF reviewed its previous support to countries, with the intention of:

1. Gathering the data required to perform an in-depth, comprehensive study of GDF additionality and impact on national budget lines for TB control and for TB drugs;
2. Performing an initial assessment of GDF's support to countries vis-à-vis national budgets for TB control and TB drugs;
3. Developing ideas for improved monitoring and reporting on GDF additionality.

This report includes the data gathered during step 1 above: including the history of GDF support to countries from 2001 to 2006. The data included in this report covers two key indicators of GDF support: a) patient treatments supplied by GDF and b) the US\$ value of drugs supplied freely to countries through GDF grants. For each country supported by GDF, this report also includes data on annual national budget lines for TB control and for 1st line anti-TB drugs.

Data on national government budgets was supplied by the World Health Organization's Stop TB Department unit responsible for annual reporting on global surveillance, planning and financing in TB control for the period 2001-2006, where reported. Where data was not reported or reported data was unequivocally questionable, data from GDF monitoring reports were used to estimate government funding.

Data Collected

Data collected by GDF for analysis is contained within an annexed spreadsheet (GDF_Support_to_Countries_2001_2006.XLS).

Analysis of Results

To date GDF has been active in 78 countries in all of the WHO Regions.

Cross country comparison is difficult as alternative data sources were used where data was not available. Even where data is available, comparison of countries is complicated by their varying income levels, and by the varying scope of the epidemic and trends in TB Prevalence among them.

Table A1. Patient treatments supplied to countries via GDF Grants and the Direct Procurement Service

	2001	2002	2003	2004	2005	2006
GDF Grants	96,274	552,171	1,181,401	1,467,359	1,537,905	2,027,375
GDF Direct Procurement	0	0	81,506	493,901	1,009,418	527 976
Total	96,274	552,171	1,262,907	1,961,260	2,547,323	2 555 351

Table A2. Countries receiving anti-TB drugs via GDF Grants and the Direct Procurement Service

	2001	2002	2003	2004	2005	2006
Countries receiving drugs	6	16	30	42	47	46

Despite this diversity in country comparison, some key conclusions can be drawn from the analysis:

1. In most instances, countries have tried to increase their overall budgets for TB; few countries have yet to prioritize the financing of TB drugs in their budget allocations.
2. GDF support has indeed been additional to most previously planned budgets from international agencies, programs and government financing.
3. Where political commitment is combined with existing financial resources, TB financing is constant.
4. While national budgets for TB control are increasing in some countries, in other countries they are decreasing
5. Where Sector Wide Approaches (SWAs) exist or where countries are moving towards the Swamps it is difficult to disaggregate funding for TB control (drugs and non-drugs).
6. Many countries are unable to/lack the capacity to finance their TB programs and are heavily donor dependent.
7. Some countries have diverted funding from TB drugs to support other TB related activities.
8. There is a challenge to deal with the co-infection of HIV and TB which has put a strain on health systems in countries with already an unfunded and weak health sector.
9. The co-existence of TB and HIV in countries has resulted in some instances that external funders provide funding for both diseases further confounding efforts at precisely measuring funding for one disease or the other.

Challenges ahead

To ensure that countries are provided with the tools needed to control TB, resources must be made available and put to good use in a timely manner. Variable drug supply remains an issue to be addressed. Also, timely in-country distribution of drugs once received is a factor that impedes optimal effectiveness in using resources. Countries require technical assistance to ensure that their TB programs are effectively maintained. Other issues which need to be considered are absorptive capacity and allocative efficiency in countries with weak health system infrastructure. Institutionalizing strong monitoring systems can help detect such problems and provide possible solutions to these challenges.

Annex III. Statement of income and expenditure

Statement of GDF Income and Expenditures including Direct Procurement for the year ending 31 December 2006 (All figures in US\$'000)		
	Notes	2006
Income		
Governments and their Agencies – Specified	1	40,723
In-kind Contribution for Drugs from Novartis Foundation	2	3,226
Contributions for Direct Procurement	3	6,165
Other Income	4	125
Total Income		50,239
Expenditures		
Grant Procurement of Anti-TB Drugs		41,344
Direct Procurement		6,165
Quality Assurance and Prequalification		84
Technical Assistance, Monitoring and Salaries		1,875
Advocacy and Communications		43
Indirect Costs	5	1,366
Total Expenditures		50,877
Surplus/(Deficit) of Income over Expenditures		- 638

Notes		
1. Contributions from Governments and their Agencies		
	CIDA	22,862
	USAID	5,000
	Norway	899
	DFID	11,962
	Sub-total	40,723
2. Novartis Foundation contribution to procure anti-TB drugs for the United Republic of Tanzania		
		3,226
3. Contributions for GDF Direct Procurement		
	For list of countries from which funds for direct procurement orders were received in 2006 see Table 3.1, p.9 of this report.	6,165
4. In-kind contribution (staff secondment)		
	Staff secondment by Management Sciences for Health	125
	Total Income	50,239
5. Indirect costs		
	WHO Program Support and General Administration Costs	1,366