

Progress Report 9

Stop TB Partnership
Global Drug Facility

1 July 2005 – 31 December 2005



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1. Summary

This report covers the activities of the Global TB Drug Facility (GDF) from 1 July to 31 December 2005, which are summarized below. Further details are given in sections 2–11 (and annexes 1-2).

Grant service and applications processed

During the reporting period, the GDF completed the 12th round of grant applications. The 12th Technical Review Committee (TRC) met on 15-18 August, 2005 and reviewed ten (10) applications from country programmes. Outside of the 12th TRC meeting in August, fourteen (14) applications were reviewed under special ad-hoc TRC assessments.

In total, from 1 July 2005 to 31 December 2005 approximately 680 222 patient treatments were approved and US\$ 11 332 700 committed, respectively.

Overall, these figures raise the number of beneficiaries approved for GDF grant support to 60 (including 1 state and 1 NGO) and the cumulative number of patient treatments, provided under grant support, to 4 689 164 million.

Direct procurement service

The growth in the GDF Direct Procurement (DP) service line is highlighted by the fact that during the reporting period, six (6) out of the twelve (12) countries using DP, used grant monies from the Global Fund to Fight Aids, TB and Malaria (GFATM) to purchase their anti-TB drugs.

The value of DP orders placed using GFATM funding during the reporting period was US\$ 1 362 454. Although only 14% of the value of all DP orders during this reporting period used GFATM funding, this trend is expected to increase with greater collaboration between the GDF and the GFATM and the faster disbursement of GFATM funds.

In total, DP drug orders for 803 665 patients at a value of US\$ 9 918 002 were placed during this reporting period.

Since the inception of the DP Service in 2002, DP drug orders for 2 001 205 patients at a total value of US\$ 24 911 002 have been placed with the GDF.

Technical support services

Technical support represents a critical aspect of the GDF as being a unique bundled mechanism. The technical support provided by the GDF reflects its mission to actively assist countries to become self-reliant and eventually capable of independently procuring and managing their TB drugs and commodities. Such technical support ranges from immediate technical assistance provided through GDF missions and monitoring systems to training workshops, the designing of a comprehensive technical assistance strategy and lastly, to supporting the TB prequalification project. During this reporting period, technical support services have significantly been scaled up.

Procurement of anti-TB drugs and related commodities

During this reporting period, the GDF delivered life-saving patient treatments to 55 countries (42 grant countries and 22 DP countries), worth approximately US\$ 26.8 million. 48 new drug orders (11 DP and 37 grant) were placed with the GDF procurement agent, UNDP/IAPSO, raising the total number of drug orders placed by the GDF since 2001 to 213.

In addition, the GDF and Green Light Committee Secretariat successfully completed a joint convergence plan that will improve efficiencies, finances and advocacy for both initiatives.

Also, in order to take forward the mandate to supply paediatric formulations, GDF issued an invitation for expressions of interest (EOI) in November to manufacturers already assessed as compliant with GMP under the prequalification project, to determine their interest in supplying paediatrics via GDF.

Lastly, in response to the earthquake (7.6 magnitude) that struck north-east of Islamabad, Pakistani Kashmir, on 8 October 2005, the GDF provided an emergency grant of much needed anti-TB drugs to Pakistan. The drugs helped replenish stocks lost and damaged during the earthquake.

Standardization of innovative, quality products

The GDF continued to evaluate and make available innovative new products for improving the quality of treatment received by TB patients.

Existing products, such as Stop TB Patient Kits, continued to be a popular product ordered by programmes during the reporting period. In the past several countries have wanted to use patient kits in their treatment programmes, but followed different treatment regimens than existing patient kits allowed. To support this need in the interim, until programmes are able to switch to the first choice regimens recommended by WHO, the GDF developed new Patient kits.

The GDF began work on a new product for its catalogue: an auto-disabling syringe with increased safety features (double-plunger movement). Such syringes allow for the reconstitution of streptomycin and injection of the patient using only one syringe before disabling itself.

As part of its ongoing effort to improve the supply of drugs at country level, the GDF has launched an innovative product packaging system. The new system codifies each different GDF drug formulation by a specific colour, and ensures that shipping cartons contain only one type of product, and that all products in a shipping carton have exactly the same shelf-life.

Advocacy and communications

While receiving unprecedented recognition from the international community for its efficient support to countries, GDF advocacy and communications focused its attention on the interests of partners, National TB Control Programmes, and donors:

The GDF completed its survey of the outcomes and perceptions of current GDF monitoring activities and gaps in national procurement systems that continue to challenge National TB Programmes. More than 30 NTP managers and partners participated in the survey. The results of this survey were openly shared with partners.

The GDF published its "Sustaining the gains" strategy. This strategy describes how the GDF encourages countries to take increasing responsibility to fund their TB control programmes while maintaining uninterrupted access to standardized, quality and competitively priced anti-TB drugs -- thus ensuring that any "gains" made through GDF grants are secured.

The GDF published its 4th GDF Newsletter in English and Spanish. The GDF Newsletter, an attractive and portable digest of noteworthy GDF activities worldwide, continues to function as an important advocacy tool.

The GDF made frequent updates to its public website. In addition to informing countries of how to apply for the 12th round of GDF grants and providing web-based access to all new GDF announcements and publications during the period, the website served as a tool for transparently sharing GDF technical and operational information with interested parties.

Strategic planning and operations

During this reporting period, GDF was pleased to welcome to its team four new staff, to replace departing staff: Mr. Homero Hernandez (Technical Officer, Country Applications and Review Processes), Mr. Edin Karahasanovic (Administrative Assistant), Ms. Desiree Kogevinas (Technical Officer, Monitoring and Evaluation Processes), and Ms. Sarah Schmitt (Procurement team leader).

Also during this reporting period GDF finalized the first draft of its 5-year Strategic Plan covering the period 2006-2010. The plan is derived from the broader longer-term strategy for the GDF as set out under Objective 3 of the Strategic Plan of the Stop TB Partnership Secretariat within the Global Plan to Stop TB: 2006-2015.

In addition, the GDF continued to pursue operational improvements so as to ensure the high quality and efficiency of GDF services. During the reporting period, GDF established an internal quality management system that was certified as ISO 9001:2000 compliant by the International Organization for Standardization for "Provision of quality assured anti-TB drugs and related services to eligible National TB Control Programmes." The certification of compliance with ISO recognizes that the policies, practices and procedures of the GDF ensure consistent quality in the services and products provided to GDF clients.

2. Grant service and applications processed

During the reporting period, the GDF completed the 12th round of grant applications. The 12th Technical Review Committee (TRC) met on 15-18 August, 2005 and reviewed ten (10) applications from country programmes: two (2) new applications (including one (1) new application for 2nd term grant), three (3) from country programmes previously placed "under consideration" and five (5) from country programmes seeking the continuation of support for the second and third years of their first term grant.

Of the applications reviewed in round 12, the TRC approved two (2) new applications for support (*Togo, Ukraine*), table 1.1. One (1) of these applications (*Togo*) was a new application for a 2nd term grant. Concerning "under consideration" countries, two (2) applications were approved (*Cameroon, Sri Lanka*), and one (1) was deferred for the second time (*Chad*). Although not approved for a 3-year grant during TRC 12, Chad was subsequently approved for an emergency 1-year grant (see table 1.2) so as to fill immediate gaps in national drug supply and avoid a stock-out in specific products.

The TRC also reviewed the dossiers from five (5) country programmes for continuation of support (second and third years of a 3-year grant). Two (2) of these countries were approved with caution¹ or conditions² (*Haiti, Rwanda*), one (1) was given a cautionary renewal (*Philippines*) and two (2) were given conditional renewal (*Cape Verde, Uganda*).

Outside of the 12th TRC meeting in August, fourteen (14) applications were reviewed under special ad-hoc TRC assessments (see table 1.2). Of these fourteen countries, eleven (11) (*Bangladesh, Bosnia-Herzegovina, Burkina Faso, Eritrea, Gambia, India [Orissa State], Mali, Mozambique, Niger, Syrian Arab Republic and Uganda*) were countries that had undergone an annual monitoring and evaluation assessment, two (2) were countries that had applied for emergency support (*Guinea and Pakistan*) and one (1) applied for a 3-year grant but was approved for a 1-year emergency grant (*Chad*).

In total, from 1 July 2005 to 31 December 2005 approximately 680 222 patient treatments were approved and US\$ 11 332 700 committed, respectively.

Table 2.1 Applications reviewed **during** the twelfth GDF Technical Review Committee

Country	Total no. patients, with buffer	Total cost US\$
Cameroon	30 000	510 000
Cape Verde	620	10 540
Chad	Deferred (see below)	
Haiti	16 320	277 440
Philippines	20 000	320 000
Rwanda	13 334	226 678
Sri Lanka	23 700	402 900
Togo	2 276	38 692
Uganda	118 360	1 893 760
Ukraine	150 000	2 550 000
Total (10)	374 610	6 230 010

Table 2.2 Applications reviewed **outside** of GDF Technical Review Committee meetings

Country	Total no. patients, with buffer	Total cost US\$
Bangladesh	113 099	376 718
Bosnia-Herzegovina	2 998	108 542
Burkina Faso	1635	22 711
Chad *	6 500	21 143
Eritrea	4 220	86 942
Gambia	1963	62 816
Guinea *	6 893	7 840
India (Orissa State)	52 651	695 683
Mali	4 991	187 677
Mozambique	37 817	1 285 778
Niger	8 165	163 024
Pakistan	5 000	88 194
Syrian Arab Republic	500	14 944
Uganda	59 180	1 980 678
Total (14)	305 612	5 102 690

* Emergency grant only covered specific products that were in short supply, so as to avoid a national stock-out.

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.

Overall, these figures raise the number of beneficiaries approved for GDF grant support to 60 (including 1 state and 1 NGO) and the cumulative number of patient treatments, provided under grant support, to 4 689 164 million.

The main beneficiaries of GDF grants continue to be low-income countries (per capita gross national product below US\$ 1000) that fulfil GDF conditions of support. Lower middle-income countries with a per-capita gross national product below US\$ 3000 are also eligible. The GDF is working with non-GDF countries in need to encourage future grant applications. Furthermore, we are working with countries that are approaching the end of 3-year GDF grants to transition into other GDF services, namely Direct Procurement, and to ultimately graduate altogether from dependence on GDF support.

3. Direct procurement service

The growth in the GDF Direct Procurement (DP) service line is highlighted by the fact that during the reporting period, six (6) out of the twelve (12) countries using DP, used grant monies from the Global Fund to Fight Aids, TB and Malaria (GFATM) to purchase their anti-TB drugs.

A memorandum of understanding signed in May 2005 by the Stop TB Partnership and the GFATM, as well as a concerted effort on the part of the GDF secretariat to strengthen collaboration and communication with the Portfolio Managers of the GFATM, have contributed to increasing the number of countries using GFATM funds to procure drugs through the GDF to twelve (12).

During this reporting period, twelve (12) countries used the DP service to place orders for anti-TB drugs (see Table 3.1). Of these:

- six (6) countries signed on to the DP service for the first time, bringing the total number of countries using the DP service to 27.
- six (6) countries that had previously used the DP service placed new orders during this reporting period, of which three (*Afghanistan, India and Republic of Moldova*) used different funding sources than in previous orders.

Country (Funding Source)	Patient Treatments	Value (US\$)
Afghanistan (GFATM)	7000	135 830
Azerbaijan (KFW)*	14 600	328 866
Cote d'Ivoire (GFATM)	41 400	476 857
Ethiopia (WHO)*	n/a**	9600
India (World Bank)	598 300	6 643 710
Liberia (GFATM)*	10 400	108 972
Micronesia, Federated States of (WHO)	192	6039
Moldova, Republic of (GFATM)	5900	101 901
Namibia (GFATM)*	30 000	489 623
Nepal (WHO)	61 873	1 316 363
Serbia and Montenegro (GFATM)*	6000	49 271
Sudan (LHL)*	28 000	250 970
TOTAL (12 countries)	803 665	9 918 002

* First time using the GDF Direct Procurement service.
 ** Includes only some of the products required to treat a patient.

The value of DP orders placed using GFATM funding during the reporting period was US\$ 1 362 454. Although only 14% of the value of all DP orders during this reporting period used GFATM funding, this trend is expected to increase with greater collaboration between the GDF and the GFATM and the faster disbursement of GFATM funds.

In total, DP drug orders for 803 665 patients at a value of US\$ 9 918 002 were placed during this reporting period.

Since the inception of the DP Service in 2002, DP drug orders for 2 001 205 patients at a total value of US\$ 24 911 002 have been placed with the GDF.

DFID helps provide treatment for 750,000 DOTS patients in India

The United Kingdom's Department for International Development (DFID) agreed to donate US\$ 72 million to GDF over the next five years to provide treatment for a population of 500 million under DOTS in India – the country with the world's highest burden of TB. The 5 year grant is estimated to treat on average 750 000 patients per year, with a total of US\$ 60 million to be spent on procuring TB drugs and US\$ 12 million on related technical assistance.

GDF has provided support to India for three years, via both Grant and DP agreements. DFID's commitment, over five years, will allow GDF to further collaborate with India's Revised National TB Control Programme on an effective long-term procurement policy. The 20% of the donation to be used for technical assistance will also enable GDF to work with partners, such as the World Health Organization (WHO), on in-country support.

4. Technical support services

Efficient drug management systems are an essential component of effective national TB control programmes. As stated in the GDF Quality Policy, "while providing support, the GDF actively assists countries to become self-reliant and eventually capable of independently procuring and managing their TB drugs and commodities". The technical support services of the GDF reflect this mandate.

Assessments of the TB drug distribution system continue to be carried out as part of all GDF country and monitoring visits. These assessments include on-the-spot technical assistance and recommendations to improve good drug management practices for consideration by national tuberculosis programmes (NTPs), key in-country partners and WHO's Department for Medicines and Policy Standards (PSM).

In addition to this direct technical assistance to individual country programmes, the GDF has been involved in the planning and implementation of several drug management training workshops and has continued to support, financially and politically, the WHO/PSM coordinated TB Prequalification project.

Looking ahead the GDF plans to bring all this technical support under a more robust and coherent Technical Assistance (TA) Service line which will also see a strengthening of GDF's TA mandate through a more proactive and direct involvement in TA for drug management and increased coordination/collaboration with other TA providers. During this reporting period GDF starting drafting a start-up plan that will underpin the creation and launch of a TA Service line. The draft plan was presented to GDF's TRC in August and enriched with the Committee's input. The final start-up plan will be presented to the Stop TB Coordinating Board in April 2006 for endorsement.

4.1 Monitoring and technical support

The monitoring system of the GDF includes the provision of technical support through missions organized to countries that are either receiving GDF grant support or using its Direct Procurement service, or both. The consultants carrying out these missions are drawn from Stop TB partners and independent consultants on the basis of their expertise in TB control and drug management. Three types of missions are conducted:

- (1) All countries that are approved or placed "under consideration" for grant support undergo country visits prior to receipt of drugs in order to brief the country on the GDF terms and conditions of support; to provide an overview of the country's drug distribution system; and to confirm drug needs for the year to come.
- (2) Annual monitoring missions are conducted to grant countries about four to six months after the bulk of the drugs arrive. These missions assess programme management, financial management and drug management, and verify that all GDF terms and conditions of support are being met. Calculations of drug needs are verified for potential continuation of GDF support. They provide on-the-spot technical assistance and help address immediate matters of concern. In consultation with the National TB Programme and in-country partners, they issue recommendations, including on the continuation of GDF support.
- (3) Annual technical support missions are carried out in Direct Procurement countries. In addition to providing assistance in TB drug management, these missions assess the adherence to GDF terms of supply and help finalizing the drug request for the next year of supply, if relevant.

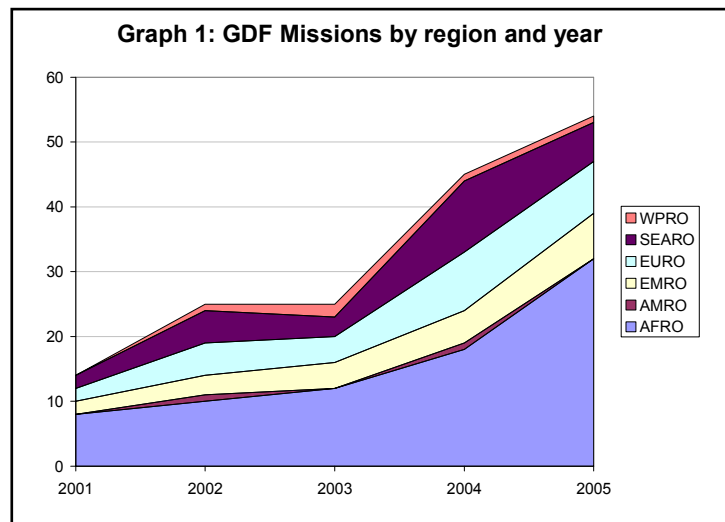
Up until the end of 2005, the GDF secretariat has organized a total of one hundred and sixty (160) missions. Graph 1, "GDF Missions by region and year", shows the cumulative number of missions organized per WHO region and per year since GDF founding.

During this reporting period, GDF completed twenty-five (25) missions: four (4) pre-delivery country visits, twenty (20) monitoring missions, and one (1) technical support mission. Over the next six months (January-June 2006), thirty-seven (37) missions are expected: three (3) pre-delivery visits, twenty-two (22) monitoring missions and twelve (12) technical missions.

Seventeen (17) monitoring dossiers were reviewed by GDF desk auditors for repeat support, and five (5) grant countries have been reviewed by the 12th Technical Review Committee for final review on GDF continuation of support.

During this reporting period, three (3) countries received a cautionary approval for the next year of grant support, with clear recommendations to be followed up on if the countries are to be granted any further support.

Specific terms and conditions for 2nd term grants, based on the Sustaining the Gains strategy, were presented and finalized at the 12th TRC meeting in August 2005. A 2nd term checklist was developed by the GDF Secretariat, and subsequently reviewed and endorsed by the TRC. An *Additionality* section (see below) was included in all the GDF monitoring checklists with a scope to routinely collect, monitor and report detailed financial information from client countries, where possible.



Country visit and monitoring checklist report forms were revised to ensure the harmonization of indicators and refine the data collection methodology. These revised checklists also provide more detailed information on drug management. During this reporting period, these checklists were field tested, then adopted and used routinely.

GDF currently has three desk audit agencies³, German Leprosy and TB Relief Association (GLRA), Swiss Tropical Institute (STI), and Management Sciences for Health (MSH). In response to the increasing demand for desk audits, additional auditors may be selected in GLRA and STI, following GDF Secretariat's internal review and the evaluation of the desk auditor's capabilities.

All monitoring processes and procedures are computerized and part of the overall GDF information management system. The GDF Secretariat therefore works on a regular basis with an automated monitoring of all the functions and lead times.

4.2 Additionality

Due to the importance of financial sustainability in national TB programmes (NTPs), the GDF Grant Service has always been regarded as a time-limited mechanism of support. This is an important concept, as the GDF does not want to create long-term dependency on grants. The objective of the GDF Grant Service 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 term.

As part of GDF's effort to contribute towards the very arduous task of long term self-sufficiency, GDF operates under the concept of "additionality." One of the key conditions to receive a GDF grant is that it should be an *additional* resource for the NTP. More specifically, this means that government TB budget-lines should not be reduced or removed as a consequence of a GDF grant during the grant period. This includes a budget-line for drugs for all second-term grantees and first-term grantees accorded a grant from April 2005 onwards (following the December 2004 revision of the Grant Agreement between WHO and the Canadian International Development Agency (CIDA) for funding of the GDF).

The terms and conditions of GDF support for its grantees have been updated to reflect this requirement of additionality. Countries applying for GDF grants must clearly demonstrate that the potential GDF supplies of free first-line anti-TB drugs would not displace funding for TB control and

³ The agencies are responsible for reviewing reports from GDF monitoring missions to ensure that they are credible, consistent and complete, such that the GDF secretariat and the Technical Review Committee can make informed decisions/recommendations on continuation of support.

more specifically, funding for anti-TB drugs. Ministry of Health - national TB programme budgets as well as donors funds are therefore monitored to ensure that existing budget lines are not being reduced or removed as a result of GDF.

As indicated in Annex 2, 93% of the countries monitored during this reporting period (for which information was available, i.e. 14/15 countries), have either maintained or increased their TB Programme budget.

4.3 Training workshops

The GDF, in close collaboration with Management Sciences for Health (MSH), held two TB drug management workshops during this reporting period. On 19 October 2005, at the 36th annual International Union Against TB and Lung Disease (IUATLD) World Lung Health Conference in Paris, approximately 50 participants attended a full day workshop entitled "Strengthening Medicine Supply in National TB Programmes: Practical Guidelines and Tools." The purpose of this workshop was to provide practical solutions used by other countries in strengthening TB pharmaceutical management; to allow participants the opportunity to learn how to use tools for quantifying and monitoring TB medicines procured through the GDF; and to share information concerning the access to technical assistance for pharmaceutical management. The target audience for the IUATLD Conference workshop included NTP managers, managers of essential medicines and procurement departments, medicines policy makers, and TB donors/partners.

During this MSH-GDF workshop, the GDF profited from the opportunity to conduct a special meeting for GDF consultants who conduct country missions. The objectives of the consultant's session were to update consultants on the GDF, to review the purpose and objectives of GDF missions, to review the roles and responsibilities of the consultants, and to allow the GDF secretariat to directly receive feedback and discuss mission procedures with its consultants.

In addition to the IUATLD meeting activities, a 5 day workshop for GDF TB drug management consultants was held in Hanoi, Vietnam from 7-11 November 2005. The event, which was a collaborative effort between the GDF and MSH, aimed to increase the number of TB drug management experts in the South East Asia and Western Pacific regions which the GDF and other partners may draw upon in their activities. In the first half of 2006, involvement of Vietnam workshop participants in GDF monitoring missions as drug management consultants is expected.

In light of the success of this activity, two further drug management workshops for other regions are being organized for the first half of 2006. The workshops will train consultants from or working in the Central Asian Republics (CAR) and francophone Africa. The first workshop is planned for 30 January - 3 February for the CARs in Almaty, Kazakhstan. It is being co-organized by GDF, Project Hope, MSH and John Snow Inc. The second workshop, targeting French speaking consultants working in francophone Africa, is being co-hosted by GDF and MSH. It is tentatively scheduled for August 2006 in Cotonou, Benin. For GDF consultant's workshops, the cooperation and assistance from the National Tuberculosis Programmes in the host country, WHO and other Stop TB partners significantly facilitates the planning and execution of the events.

Lastly, GDF has already begun the discussions on participation in the 2007 IUATLD World Conference on Lung Health to be held in Paris in November 2006. As in previous years the GDF will be working closely with MSH to hold a workshop on a to-be-determined aspect of the drug management of anti-TB medicines.

4.4 Technical assistance

After almost 5 years of focus on providing quality, affordable anti-TB drugs to countries, the GDF is taking concrete steps towards strengthening its role in the provision of technical assistance to beneficiary countries. To this end, as previously reported, the GDF commissioned a stakeholder analysis in early 2005. Findings clearly indicated that many countries continue to have an unmet need for technical assistance in drug management. At the 12th meeting of the GDF Technical Review Committee (TRC) in August 2005, a subgroup was formed to examine the GDF's role in technical assistance. The subgroup examined the issue and later facilitated a discussion with the

entire committee. By the conclusion of the meeting there was a unanimous recommendation that the GDF develop a strategy for a more robust approach in the provision of technical assistance.

Following TRC 12, various strategic options, proposed by both an external consultant and the TRC subgroup, were examined, reviewed and synthesized into a comprehensive document. At the 13th meeting of the TRC (January 2006), the subgroup was presented this document and put to task to further refine a focused path forward.

The GDF has declared the strengthening of its technical assistance mandate as one of its priorities in 2006 and will request endorsement of the plan to achieve this by the Stop TB Partnership Coordinating Board at their first biannual meeting in April 2006. Recruitment of an additional technical officer who will lead the development of the technical assistance programme is under discussion. It is hoped that this position will take effect in March 2006. In addition, the terms of reference for the regional focal points being established in AFRO, SEARO and India, along with the existing regional focal point in EMRO, will be adapted to reflect their increased role in the provision of technical assistance in the area of drug management.

4.5 Prequalification of anti-TB products

The GDF encourages the local production of quality anti-TB drugs by identifying political and financial support for the WHO TB Prequalification Project. This project 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. All activities related to prequalification of TB products are coordinated by WHO's Department of Medicines Policy and Standards.

The GDF and WHO/PSM lists of: (a) prequalified TB products and (b) manufacturers complying with Good Manufacturing Practices (GMP) as assessed under the ongoing WHO/PSM coordinated TB Prequalification Project, are as follows:

- Prequalified TB products: four (4) adult product formulations with at least one supplier out of the nine (9) requiring prequalification (no change from previous reporting period). Of the four products two (2) have at least two (2) suppliers, which is the GDF goal for every product in its catalogue (no change from previous reporting period).
- Manufacturers complying with GMP: Seven (7) manufacturing sites are deemed to be complying with WHO GMP as assessed under the prequalification project (one less than the previous reporting period).

Table 3: List of pre-qualified anti-TB products as assessed under the TB Prequalification Project

Ref. No	International Non-proprietary Name (INN)	Strength	Dosage form	Supplier	Manufacturing site		Packaging material and pack	
008	Ethambutol	400mg	Tablet	Cadila Pharmaceuticals Ltd. Ahmedabad	Cadila Pharmaceuticals Ltd. Dholka, Ahmedabad	India	HDPE bottle Blister	1000 10
015	Pyrazinamide	400mg	Tablet	Cadila Pharmaceuticals Ltd. Ahmedabad	Cadila Pharmaceuticals Ltd. Dholka, Ahmedabad	India	HDPE bottle Blister	1000 10
024	Rifampicin/ Isoniazid/ Pyrazinamide/ Ethambutol	150/ 75/ 400/ 275mg	Tablet	Wyeth Pakistan Limited, Karachi	Wyeth Pakistan Ltd, Karachi	Pakistan	Blister	80
068	Rifampicin/ Isoniazid	150/ 75mg	Tablet	Lupin Ltd, Mumbai	Lupin Ltd, Aurangabad	India	PVC/PVDC blister HDPE bottle	6 x 15 100, 500, 1000
070	Rifampicin/ Isoniazid/ Pyrazinamide/ Ethambutol	150/ 75/ 400/ 275mg	Tablet	Lupin Ltd, Mumbai	Lupin Ltd, Aurangabad	India	Blister HDPE bottle	4 100, 500, 1000
084	Rifampicin/ Isoniazid	300/ 150mg	Tablet	Sandoz Pty Ltd, Isando	Novartis SA (Pty) Ltd, Kempton Park	South Africa	PVC/PE/PVDC foil (Blisters) Polypropylene containers	20, 40, 60, 500
085	Rifampicin/ Isoniazid	150/75 mg	Tablet	Sandoz Pty Ltd	Novartis SA (Pty) Ltd Kempton Park Strides Arcolab Ltd, Bangalore	South Africa India	Blister Polypropylene containers	10 30-100 1000
090	Rifampicin/ Isoniazid/ Pyrazinamide/ Ethambutol	150/75/ 400/275 mg	Tablet	Sandoz Pty Ltd	Novartis SA (Pty) Ltd, Kempton Park Strides Arcolab Ltd Bangalore	South Africa India	Blister Polypropylene containers	10 30-100 1000

List of manufacturing sites meeting WHO GMP as assessed under the TB Prequalification Project:

- Cadila Pharmaceuticals Limited, 1389 Dholka Road, Bhat, Ahmedabad, Gujarat State, India (non Rifampicin containing products only)
- MacLeods Pharmaceuticals Ltd Address Plot N° 25-27, Survey N° 366 Premier industrial estate Kachigam Daman – 396 210 (UT), India
- Lupin Laboratories Limited, A-28/1, MIDC Industrial Area, Chikalthana, Aurangabad 431 210, India (Rifampicin containing products only)
- Sandoz Pty Limited, a sector of Novartis South Africa (Pty), 72 Steel Road, Spartan, Kempton Park, South Africa
- Strides Arcolab Limited, KRS Gardens, Suragajakanahalli, Indhawadi Cross, Annekal, Taluk, Bangalore 562, India
- Svizera Private Labs Limited, Plot No D16/6, TTC Industrial Area, MIDC, Turbhe, Navi, Mumbai - 400 703, India
- Wyeth Pakistan Limited, S-33, Hawks Bay Road, SITE, Karachi, Pakistan

Paediatric anti-TB drug formulations

During the last reporting period GDF agreed in principle to add additional paediatric products (i.e. in addition to three (3) paediatric fixed dose combinations (FDCs) already eligible for dossier review under the TB Prequalification Project) and specific mono-substances (for the management of patients experiencing side effects from treatment with fixed dose combinations), to the list of products for which manufacturers are invited to submit dossiers for review under the TB Prequalification Project. During this reporting period one (1) additional product was added for the treatment of children: Isoniazid 100mg. No products were added for the management of side-effects as this is planned for the next WHO/PSM invitation for EOs to manufacturers who wish to participate in the TB prequalification project, which is scheduled to be issued in early 2006.

5. Procurement of anti-TB drugs and commodities

During this reporting period, the GDF delivered life-saving patient treatments to 55 countries (42 grant countries and 22 DP countries), worth approximately US\$ 26.8 million. 48 new drug orders (11 DP and 37 grant) were placed with the GDF procurement agent, UNDP/IAPSO, raising the total number of drug orders placed by the GDF since 2001 to 213.

As of 31 December 2005, a cumulative total of 67 countries (60 grant countries and 29 DP countries)⁴ have received shipments of life-saving TB drugs through the GDF since its inception.

Key GDF procurement and supply highlights during this reporting period were as follows:

- The **GDF and Green Light Committee Secretariat** successfully completed a joint convergence plan that will improve efficiencies, finances and advocacy for both initiatives; the plan was formally endorsed by the Director of the WHO Stop TB Department in December 2005 and will be implemented in 2 phases starting in 2006. The first phase will comprise the convergence of procurement functionalities of first and second line drugs. During this reporting period preliminary steps were taken to allow for the initiation of procurement of second line drugs under a converged GDF/GLC in 2006 i.e. a competitive selection process for a procurement agent of second line TB drugs which involved:
 - issuance of an international invitation for EOIs in September;
 - issuance of Requests for Proposals to the agents deemed eligible to submit Proposals via the EOI screening process in November;
 - adjudication of Proposals in December.

A Contract Award is expected to be made to the successful agent in Q1 2006 following clearance of the selection process by WHO's Contracts Review Committee.

➤ **Paediatric TB Drugs:**

During this reporting period, in order to take forward the mandate to supply paediatric formulations, GDF issued an invitation for EOIs in November to manufacturers already assessed as compliant with GMP under the prequalification project, to determine their interest in supplying paediatrics via GDF. As a part of this process the manufacturers invited were required to submit product dossiers based on a Pharmaceutical Product Questionnaire (based on a standard template developed by GDF, WHO and other UN agencies) for an **ad hoc assessment** by WHO/PSM to determine whether the products could be conditionally procured by GDF pending full prequalification.

In relation to this exercise, the GDF procurement sub-team was temporally strengthened by an interning pharmacist from the International Federation of Pharmaceutical Students to do a literature review on all aspects of TB treatment for children including demand and supply dynamics, with a special focus on dosaging and the possible use of adult formulations for treatment of TB in children. The pharmacist was responsible for compiling and organizing the ad hoc WHO/PSM evaluations on the product dossiers received in December, as a part of the aforementioned EOI process.

The ad hoc assessment revealed that the dossiers received for almost all products were lacking significant data, such that GDF was unable to issue an LICB by the end of December 2005 as planned. It was decided to contact the responding manufacturers in Q1 2006 to obtain the missing data and/or obtain clarifications on both the information submitted and that which was lacking. Based on this follow-up it is hoped that an LICB and/or direct negotiations with manufacturers (in the event there is only one qualified supplier for a product) can be initiated to allow GDF to begin supplying paediatric formulations no later than mid 2006.

⁴ Note that the same country can be a recipient of TB drugs via a Grant and via Direct Procurement.

Emergency response to Pakistan earthquake

In response to the earthquake (7.6 magnitude) that struck north-east of Islamabad, Pakistani Kashmir, on 8 October 2005, the GDF provided an emergency grant of much needed anti-TB drugs to Pakistan. The drugs will help replenish stocks lost and damaged during the earthquake.

The GDF responded to the crisis and the ensuing shortage of drugs by working with the Pakistani NTP to identify their immediate needs for anti-TB drugs and calling for an emergency grant review by the GDF Technical Review Committee. The approved GDF grant for anti-TB drugs, which should be sufficient to treat 5000 TB patients, was completed less than a month after the earthquake struck. At the time of the earthquake, Pakistan had a buffer stock designed to cover drug shortages in exceptional situations. However, as this would have entailed re-shuffling drug stocks, a costly and logistically difficult effort, the emergency supply of GDF drugs was set in motion. The emergency grant is in addition to existing GDF grant support for Pakistan, which has delivered approximately 210 000 patient treatments since 2001



Anti-TB drugs dispensed from makeshift drug store in Pakistan

Challenges for 2006

While 2005 has seen impressive progress for GDF in procurement, the second half of the year presented some important challenges:

- GDF relations with its procurement agent were strained in the latter part of 2005 due to disagreement over payment terms and procedures; the new competitive process planned by GDF in 2006 for procurement agents of first line TB drugs will need to be designed to prevent such problems under any new contracts as well as optimize the services a procurement agent provides by ensuring that lessons learned during the last 2 years of the contract with UNDP/IAPSO positively influence any new contract that results from the competitive selection process for procurement agents planned for early 2006.
- GDF needs to revise its interim quality assurance process to ensure that it better complements the formal prequalification process implemented by WHO while minimizing risk and ensuring reliable supply for countries. Dialogue was held with WHO/PSM and Medcin Sans Frontiere's (MSF) Campaign for Access to Essential Medicines in August and September to exchange views on how this could best be achieved. GDF ultimately decided to pursue a multi-pronged approach to promote the WHO TB Prequalification Project to suppliers and to assist the GDF in making evidence based awards for supply in the cases where prequalification has not been obtained. It was decided that the approach, once finalized in early 2006 pursuant to approval of the Stop TB Partnership Coordinating Board, would be incorporated in GDF's Strategic Plan: 2006-2010.
- In 2005 GDF TB drug delivery lead times were not optimal and were hampered by an unpredictable market for TB drug raw materials and supplier concentration in this market. The expected benefits of the GDF competitive tender process in April 2005 (As documented in Progress Report 8) were not fully realized: the risk of drug supply chain bottlenecks stemming from raw material shortages was certainly reduced for the key drug Rifampicin but not for Isoniazid nor Ethambutol. Moreover, the buffer stocks that were supposed to be built by manufacturers under the resultant Long Term Agreements were not built up to the required levels due to a combination of manufacturer capacity constraints, lack of incentive on the part of the

suppliers and a sub-optimal system in place for monitoring/managing the stocks which relied heavily on manufacturer cooperation and compliance.

In 2006 GDF will have to ensure that it has a better understanding of the market through updated strategic analyzes and work proactively with its partners to reduce the risks of supplier concentration in the supply of raw materials. Moreover, buffer stocks of key TB drugs will need to be built up under a revised system that puts greater control in the hands of GDF and its procurement agents and less in the hands of the manufacturers; an additional funding source to finance the development of these stocks and related management systems would certainly be welcome as it would ensure that existing resources are dedicated to regular drug supply and also mitigate the risks involved in stockpiling.

6. Standardization of innovative, quality products

The GDF continued to evaluate and make available innovative new products for improving the quality of treatment received by TB patients.

6.1 GDF/Stop TB Patient Kits

Stop TB Patient kits continued to be a popular product ordered by programmes during the reporting period.

In the past, several countries have wanted to use patient kits in their treatment programmes, but followed different treatment regimens than existing Stop TB Patient Kits allowed. To support this need in the interim, until programmes are able to switch to the first choice regimens recommended by WHO, the GDF developed new patient kits.

As a result, the GDF can now supply patient kits to support the following treatment regimens:

- 2(RHZE)/4(RH),⁵ 2(RHZE)/4(RH)₃ and 2(RHZE)/6(EH) (*Category I+III patients*)
- 2S(RHZE)/1(RHZE)/5(RHE)⁶ and 2S(RHZE)/1(RHZE)/5(RH)E (*Category II patients*)

The GDF initiated a study in June to assess the experiences of countries using Stop TB Patient Kits, with extensive data received from Kenya and the Philippines during the reporting period. Data was analysed and presented at the Drug Management Workshop held during the 36th Congress of the IUALTD in October 2005. The most striking finding was that health workers reported that the use of Stop TB Patient Kits had considerably reduced the number of patients who defaulted and did not finish their treatment. The Final report of this study is expected to be ready during Q1 2006 for further in depth analysis and subsequent dissemination and potential publication.

6.2 Auto-disabling syringes

In line with the Safe Injection policies of WHO, GDF requested Beckton and Dickinson (BD), one of GDF's suppliers of syringes, whether they could develop an auto-disabling (AD) syringe which would allow for the reconstitution of streptomycin and injection of the patient using only one syringe before disabling itself. BD took up this request and managed to produce such a device that GDF will introduce in 2006 as part of all of its Grant orders that include Streptomycin and as a standard feature of its Category II patient kits. Moreover, starting in the first half of 2006 GDF will facilitate training at the central level for programmes receiving these special AD syringes so as to build capacity for the NTP to carry out training in clinics using these syringes and thereby ensure appropriate use.

6.3 New GDF packaging

As part of its ongoing effort to improve the supply of drugs at country level, the GDF has launched an innovative product packaging system. The new system codifies each different GDF drug formulation by a specific colour, and ensures that shipping cartons contain only one type of product, and that all products in a shipping carton have exactly the same shelf-life.

The concept for the design emerged after GDF clients expressed concerns that the delivery of non-standardized packaging from an increasing number of suppliers could needlessly complicate the storing and monitoring of drug stocks. The new designs, developed in collaboration with GDF clients, are part of the first initiative from outside the TB pharmaceutical industry to design a standard packaging system in order to improve drug management.

Under this new packaging system, all GDF products, regardless of manufacturer, will be contained in high-quality containers and tagged with a product-specific coloured ribbon. The introduction of colour coding will facilitate cartons of drugs to be loaded, off-loaded and stored even when staff are unable to read text on labels.

⁵ First Choice WHO regimen for Category I and III patients

⁶ First Choice WHO regimen for Category II patients



Also under this system, shipping cartons used to deliver GDF products to clients will no longer contain a mix of products, or different batches of the same products. Shipping cartons will be clearly marked with the colour code of the product it contains, while retaining all WHO recommended and legally required labeling information, such as product name, batch number, manufacturing and expiry dates.

By ensuring that each shipping carton only contains a single type of product, with exactly the same shelf-life, this system will streamline storage practices. Grouping products in known quantities is expected to improve the efficiency of stock monitoring. These advances will ultimately benefit the patient, by ensuring a constant supply of drugs in helpful packaging.

The new packaging system is expected to become fully operational by January 2006, following the phasing-out of the previous packaging system.

7. Advocacy and communications

In 2005, the GDF received unprecedented recognition from the international community for its cost-effective, efficient and sustained impact in developing nations. Advocacy and communications (A&C) helped make this possible by building relationships with partners, informing national TB programmes of the availability of GDF grants and services, and raising the GDF's profile among the donor community:

- A Memorandum of Understanding signed in May 2005 by the Stop TB Partnership and the GFATM contributed to the dramatic increase in the number of countries using GFATM funds to procure drugs through the GDF.
- The GDF grant service approved support for its 60th beneficiary. Six (6) new countries began using the Direct Procurement (DP) service. Five (5) countries that had previously used the DP service demonstrated their satisfaction by placing new orders.
- In a landmark effort to provide treatment for a population of 500 million under DOTS in India – the country with the world's highest burden of TB – the United Kingdom's Department for International Development (DFID) agreed to donate US\$ 72 million to GDF over the next five years. Continued support from existing donors, such as Canadian CIDA, has made it possible for the GDF to approve grants of anti-TB drugs for more than 4.6 million patients worldwide since 2001.

During this reporting period, GDF A&C efforts continued to pursue the interests of these three audiences:

- The GDF completed its survey of the outcomes and perceptions of current GDF monitoring activities and gaps in national procurement systems that continue to challenge National TB Programmes. More than 30 NTP managers and partners participated in the survey. The results of this survey were openly shared with partners.
- The GDF published its "Sustaining the gains" strategy in English and French. This strategy describes how the GDF encourages countries to take increasing responsibility to fund their TB control programmes while maintaining uninterrupted access to standardized, quality and competitively priced anti-TB drugs -- thus ensuring that any "gains" made through GDF grants are secured.
- The GDF published its 4th GDF Newsletter in English and Spanish. The GDF Newsletter, an attractive and portable digest of noteworthy GDF activities worldwide, continues to function as an important advocacy tool. Useful when introducing the GDF during workshops, conferences and missions, the GDF Newsletter also results in well-prepared content that can be broadcast via other communication channels (such as the GDF's public website or through Stop TB Partnership email lists).
- The GDF made frequent updates to its public website. In addition to informing countries of how to apply for the 12th round of GDF grants and providing web-based access to all new GDF announcements and publications during the period, the website served as a tool for transparently sharing GDF technical and operational information with interested parties.



During this reporting period the GDF began work on several A&C projects, including:

- An advertisement highlighting the importance of quality assurance in anti-TB drug procurement will appear in the Commonwealth Health Ministers Reference Book in early 2006.
- A tri-fold brochure for the GDF DP Service, in English and Spanish, will be delivered in the first half of 2006.
- The GDF public website will be enhanced to provide access to a rich set of procurement and financial data gathered by (or resulting from) GDF work with countries in mid-2006. Key portions of the GDF website will be routinely made available in English, French and Spanish.

8. Strategic planning and operations

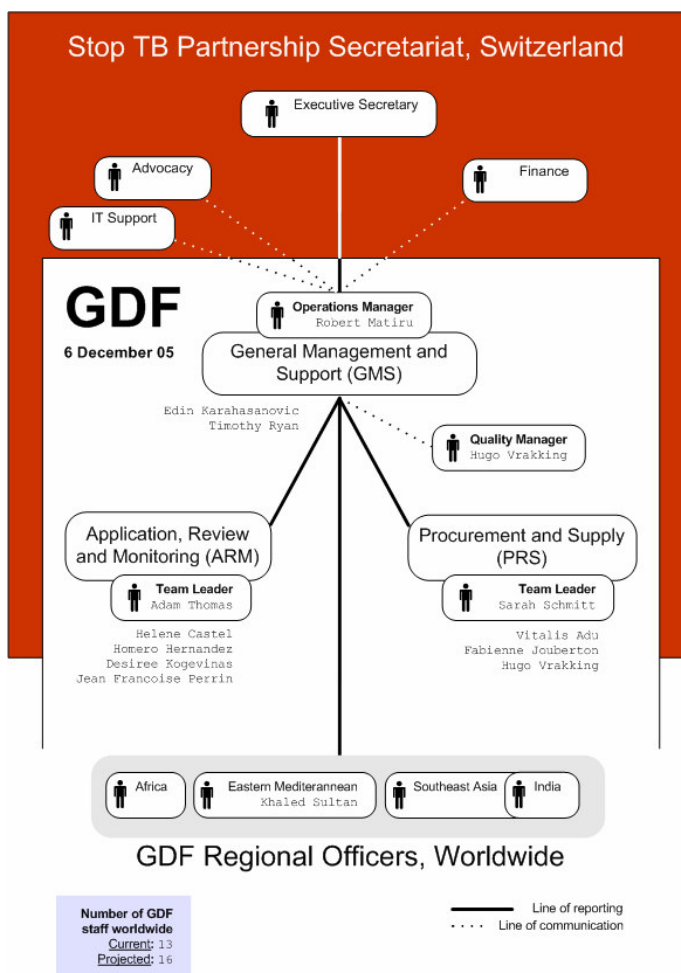
8.1 Staff

During this reporting period, GDF was pleased to welcome to its team Mr. Homero Hernandez (Technical Officer, Country Applications and Review Processes), Ms. Desiree Kogevinas (Technical Officer, Monitoring and Evaluation Processes) and Mr. Edin Karahasanovic (Administrative support Officer, General Management and Support sub-team). The new staff were hired as replacements of departing staff.

Mr. Hernandez, of the Dominican Republic, comes to the GDF after working with the World Intellectual Property Organization (WIPO) since 1999. Prior to joining the GDF, Ms. Kogevinas, of Greece and Sweden, worked with the WHO's Department of Injuries and Violence Prevention (VIP) for three years. Mr. Karahasanovic joined the GDF after 4 years of accomplished service working in WHO's Department for Communicable Diseases.

A hiring process was also concluded (in December) to fill the vacant position of team leader of the GDF Procurement sub-team. Ms. Sarah Schmitt, who hails from New Zealand and brings with her several years of experience with the Pharmaceutical Management Agency of New Zealand (PHARMAC), is expected to join the GDF in early 2006.

The plan, reported in Progress Report 8, to hire two (2) additional professional staff as Regional Support Officers for the Africa and South East Asia regions, was postponed until 2006.



8.2 GDF Strategic Plan: 2006-2010

During this reporting period GDF finalized the first draft of its 5-year Strategic Plan covering the period 2006-2010. The plan is derived from the broader longer-term strategy for the GDF as set out under Objective 3 of the Strategic Plan of the Stop TB Partnership Secretariat within the Global Plan to Stop TB: 2006-2015. This objective is to: Ensure the effective functioning, growth, dynamism and catalysing effect of the GDF in global TB control.

Drug supply is a critical partnership resource underpinning the assumptions of the Global Plan to Stop TB (2006-2015), which will be launched at the World Economic Forum in Davos in January 2006. An important part of the Secretariat's strategic vision is therefore the evolution of the GDF to ensure access to quality, affordable TB drugs in all countries where there is need.

Summary of Strategic Plan

By 2007, the supply of TB drugs through the GDF will meet the biennial target of patient treatments to be delivered globally, as identified by DOTS Expansion Working Group. Though the focus of the GDF within the Secretariat will remain on the provision of 1st line TB treatment, the GDF will expand the availability of products in the GDF catalogue, to introduce diagnostic kits, paediatric TB drugs,

single TB drug formulations for patients experiencing the side effects of currently available fixed dose combination formulations and 2nd line TB drugs (following a merger by 2007 with the Green Light Committee - the supply mechanism for 2nd line TB drugs). Moreover, in view of the close relationship between TB and HIV infection, the GDF will be prepared for the harmonized supply of TB-HIV preventative therapies by 2007 and possibly other TB-HIV treatment therapies by 2009.

Beyond this, the GDF will become more actively involved in the process of supporting the development and diversification of competition in national and global TB drug markets - by facilitating the prequalification process of TB drugs and rapidly scaling up its direct procurement service (where the development and impact of the GFATM will be a critical determining factor). The longer term aim is to support self-sufficiency in drug management at national and regional level through the implementation of the GDF Sustaining the Gains Strategy and the establishment of a technical assistance service line to broker support from partners for countries in need. The strengthening of the GDF at regional level, to be completed by 2007, will facilitate the process.

As new technologies and tools for TB control come on-line towards the middle of this strategic plan timeframe, the GDF plans to incorporate them into the overall package of services it offers. The GDF will need to position itself to negotiate concessional pricing for new technologies and tools as well as promote quality assurance of the same, thereby sustaining the reputation of the Partnership and Secretariat for supporting the provision of quality, low cost TB control interventions. By 2010, GDF systems will be prepared for the introduction of new drugs and new diagnostics. By 2015, plans and service lines for new vaccines will be fully developed.

The draft plan was presented to the Stop TB Partnership Coordinating Board meeting in November in Assisi, Italy. Though the Board endorsed the Strategic Plan in principle, Board Members requested that they and our various partners be given additional time to provide feedback on the GDF Strategic Plan. The GDF initiated a process to solicit feedback after Assisi and will arrange for a consultative meeting with key partners to review, discuss and finalize the GDF Strategic Plan in Q1 2006.

8.3 Information management

The GDF continued to seek improvements in how it manages information for operational efficiency and customer satisfaction.

Two critical information tools were established within the GDF secretariat during the period. The first tool will help GDF staff efficiently plan, coordinate and report on the increasing number of GDF missions that take place each year. The second tool will help track requests for drug orders and the financial oversight of commitments made with agents and suppliers.

In addition to these tools, the GDF instituted an internal quality management system that was certified as ISO 9001:2000 compliant by the International Organization for Standardization for "Provision of quality assured anti-TB drugs and related services to eligible National TB Control Programmes." To become certified as ISO compliant, the GDF underwent an one-year evaluation process that included quality management system development, a management system documentation review, pre-audit, and finally the inspection for certification. The certification of compliance with ISO recognizes that the policies, practices and procedures of the GDF ensure consistent quality in the services and products provided to GDF clients.



Annex 1: Statement of income and expenditure

Statement of GDF Income and Expenditures including Direct Procurement For the year ending 31 December 2005 (All figures in US\$'000)		
	Notes	2005
Income		
Governments and their Agencies – Specified		26,085
In-kind Contribution for Drugs from Novartis Foundation		2,605
Contributions for Direct Procurement	1	13,433
Other Income		188
Total Income		42,311
Expenditures		
Grant Procurement of Anti-TB Drugs		28,367
Direct Procurement		13,433
Quality Assurance and Pre-qualification		123
Technical Assistance, Monitoring and Salaries		1,649
Advocacy and Communications		57
Indirect Costs		1,151
Total Expenditures		44,780
Surplus/(Deficit) of Income over Expenditures	2	<u>(2,469)</u>

Notes:

- 1 Contributions for Direct Procurement were received from Afghanistan, Albania, Armenia, Azerbaijan, Bangladesh, Cote d'Ivoire, Djibouti, Ethiopia, Georgia, India, Indonesia, Kenya, Liberia, Micronesia, Moldova, Mongolia, Namibia, Nepal, Nigeria, Philippines, Sudan and Tajikistan.
- 2 Deficit of income over expenditures in 2005 arose due to late remittance of pledged money. The deficit was covered by the surplus brought forward from 2004.

Annex 2. GDF performance, process and impact indicators

Table 1: GDF Performance & Process Indicators

GDF core functions	Activity	Results		
		Current reporting period (1 July – 31 Dec 2005)	Previous reporting period (1 January – 30 June 2005)	Cumulative (up to 31 Dec 2005)
Funding	Funds raised for GDF operations, in US\$ '000	28 691 (2005)		83 370
	Total funds raised for GDF grants, in US\$ '000 ⁷	23 474 (2005)		66 096
Grants	Total no. of patient treatments approved via grants ⁸	680 222	554 653	4 689 164
	Value of grant commitments in US\$ '000	11 333	8 169	74 626
Direct Procurement	No. of new countries concluding direct procurement agreements ⁹	6	3	27
	Value of direct procurement orders, in US\$ '000 ¹⁰	9 918	2 594	24 911
	No. of patient treatments approved (including buffer) via direct procurement	803 665	169 570	2 001 205
Grants & Direct Procurement	No. of patient treatments approved via grants and direct procurement	1 483 887	724 223	6 690 369
Grant applications and review	No. of High Burden Countries ¹¹ receiving GDF support (grant or DP)	5	15	15
	No. of rounds of applications and review	1	1	12
	No. of new applications for GDF support ¹²	4	8	110
	No of countries approved for 2 nd term grant	1	3	4
	Total no. of applications approved for support ¹³	2	4	77
	Corresponding no. of countries approved for support	2	3	61
	No. of applications not approved	0	2	9
	No. of applications approved that were previously not approved or placed "under consideration"	0	0	19
	Average time from receipt of application to grant agreement ¹⁴	49 days	47 days	N/A
	No. of pre-delivery country visits to GDF countries ¹⁵	3	4	57
% of countries that have received formal feedback from GDF at review stage ¹⁶	100%	100%	100%	

⁷ Includes both cash contributions and drugs donated in-kind.

⁸ Covers patients treatments approved by the Technical Review Committee and Stop TB Coordinating Board (new applications and 2nd and 3rd year grant commitments). Patient numbers are from Table 3, Annex 2, and are derived from grant agreements or GDF application forms.

⁹ Countries that are already Direct Procurement Clients who conclude new/additional agreements are not counted again.

¹⁰ Based on Purchase Orders.

¹¹ The Stop TB Partnership defines as "High Burden" those countries accounting for 80% of global infective cases of tuberculosis.

¹² A country that applies, is not approved and reapplies is considered as one country but two applications. A country that applies for emergency support and regular support is also considered as one country, but two applications. A second or third year of support for a country [i.e. monitored] is not considered as a new application. An "under consideration" country is not considered a new application.

¹³ Total number of approved applications refers to new applications plus applications that were "under consideration" but were subsequently approved during the reporting period.

¹⁴ Does not include countries that were "under consideration" and for which a decision was pending from the previous TRC

¹⁵ All countries which are accepted or placed "under consideration" for a 3-year grant receives a GDF country visit. Emergency countries receive country visits at the discretion of the Technical Review Committee. Direct procurement countries receive country visits at the discretion of the GDF Secretariat.

¹⁶ All countries which have undergone a country visit receive formal feedback in the form of a letter and e-mail detailing the recommendations of the Technical Review Committee. All countries that receive a country visit are sent a copy of the GDF country visit report.

GDF core functions	Activity	Results		
		Current reporting period (1 July – 31 Dec 2005)	Previous reporting period (1 January – 30 June 2005)	Cumulative (up to 31 Dec 2005)
Monitoring and evaluation	No. of monitoring missions to GDF Grant countries ¹⁷	20	18	87
	Technical assistance missions to Direct Procurement clients ¹⁸	1	4	8
	No. of applications evaluated for repeat support ¹⁹	18	20	79
	% of countries that have received formal feedback from GDF following monitoring missions	100%	100%	100%
	No. of applications approved for repeat support (following Desk Audit Review)	17	19	82
	No. of grant countries not approved for continued support	1	1	2
	% of GDF countries evaluated on drug management and technical issues as part of GDF monitoring missions	100%	100%	100%
	No of countries that completed their 1 st term 3-year grant	3	3	7
	No of countries approved for 2 nd term grant	1	3	4
	% monitoring visits on time ²⁰	90%	75%	N/A
TB Drug Prequalification & GMP Compliancy²¹	No. of manufacturers that are WHO GMP compliant	0	1	7
	No. of pre qualified products from those listed in the GDF catalogue (out of 9)	0	4	4
	No. of pre qualified products from those listed in the GDF catalogue (out of 9) that have 2 of more suppliers	0	2	2
Procurement	No. of grant countries that received drug deliveries ²²	42	28	60
	No. of direct procurement countries that received drug deliveries ²³	22	9	29
	Total no. of countries that received drug deliveries (Grant and Direct Procurement Services)	55	34	67
	Average lead time from placing order to receipt of drugs in country, excluding countries which asked for delayed deliveries, in days	145	154	N/A
	% of countries receiving drugs within agreed lead time ²⁴	31%	40%	N/A
	No. of drug orders placed ²⁵	48 ²⁶	39	213
	% of orders delivered within 120 calendar days of Purchase Order	34%	33%	N/A

N/A = Not Available

¹⁷ All countries receiving three-year grants receive monitoring missions.

¹⁸ All Direct Procurement clients receive an annual technical support/assessment visit

¹⁹ Represents the number of applicants that have had a monitoring mission for which a monitoring checklist has been submitted to independent review by a GDF desk auditor.

²⁰ On time means that the monitoring mission happened 4–6 months after drug delivery, as per GDF standard operating procedures.

²¹ 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.

²² One country can have more than one order. A split order is considered as one delivery for this indicator.

²³ Ibid.

²⁴ This is where the expected delivery date set originally is equal to or less than the actual delivery date.

²⁵ Split orders are NOT considered separately for this indicator. Even where an overall order has more than one sub-order, only the overall order for the country is counted. Figures for previous reporting period and cumulative total have thus been revised.

²⁶ Includes 11 Direct Procurement orders and 37 Grant orders.

Table 2: GDF Impact Indicators

Area	Indicator	Current Reporting period (1 July – 31 Dec 2005)	Previous reporting period (1 January – 30 June 2005)
Procurement	No. countries which stocked out because GDF drugs did not arrive on time ²⁷	0	0
Direct Procurement (Affordability)²⁸	Direct procurement price as a percentage of prices offered by other international agencies ²⁹		
	RH 150+75 (Cost per tablet)	GDF price is 10% lower	
	RHZE 150+75+400+275 (Cost per tablet)	GDF price is 19% higher	
Quality³⁰	% GDF drugs of known good quality ³¹	100%	100%
	% GDF batches that were rejected by pre shipment quality control	0%	0%
	Number of GDF batches that have failed in-country quality control ³²	0	0
Drug management³³	% of GDF countries with stock out at national, intermediate or peripheral levels	25%	42%
	% GDF countries with out of date drugs	0%	16%
	% GDF countries where NTP partially or fully followed-up on drug management recommendations ³⁴	100%	75%
Standardization³⁵	% of countries adhering to 1 st choice WHO recommended treatment regimens ³⁶	40%	N/A
	% of Grant and Direct Procurement countries using 4FDCs through GDF support. ³⁷	74%	N/A
	% Grant and Direct Procurement countries using blistered products with GDF support ³⁸	94%	N/A
	% Grant and Direct Procurement countries using Patient Kits with GDF support ³⁹	6%	N/A
DOTS Expansion	No. of countries which introduced DOTS or developed a DOTS Expansion Plan due to GDF support ⁴⁰	0	2

²⁷ Data gathered from monitoring check list and desk audit reports.

²⁸ The two key products promoted and supplied by GDF have been selected for the drug price comparison.

²⁹ Source: International Dispensary Association, Price Indicator Guide, August 2005 (www.ida.nl)

³⁰ Data from the monitoring checklist.

³¹ Drugs assessed and prequalified via the WHO/PSM coordinated TB Prequalification project and/or assessed and approved for supply by an independent ad hoc committee of experts on quality assurance of anti-TB drugs convened by GDF.

³² As reported by recipient country

³³ Data from monitoring checklist and concern only those countries monitored during the reporting period.

³⁴ NTP are required to address recommendations from the Technical Review Committee and previous missions in the year before the next monitoring mission occurs.

³⁵ Based on the countries that were reviewed by TRC and approved by CB during this report period.

³⁶ REVISED INDICATOR: First choice WHO recommended treatment regimen for Category I & III is: 2(RHZE)/4(RH) and for Category II is: 2S(RHZE)/1(RHZE)/5(RHE) or (RH)E

³⁷ NEW INDICATOR

³⁸ Ibid

³⁹ Ibid

⁴⁰ Some countries apply to the GDF in order to start DOTS. This data is derived from the application form.

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Area	Indicator	Current Reporting period (1 July – 31 Dec 2005)	Previous reporting period (1 January – 30 June 2005)
Cure Rates	Estimated number of TB patients that will be cured with GDF drugs through grants ⁴¹	293 074	471 455
	Estimated number of TB patients that will be cured with GDF drugs through direct procurement ⁴²	191 560	144 135
	Total estimated number of TB patients that will be cured (Grants + Direct Procurement)	484 634	615 590
Drug Prices ⁴³	GDF prices in comparison to International price (per product) ⁴⁴	GDF prices / international price	
	RH 150+75 (Cost per tablet)	0.02086/0.023	
	RHZE 150+75+400+275 (Cost per tablet)	0.0468/0.03794	
	Average cost per additional cure in US dollars (including insurance and freight) ⁴⁵	\$21.20	\$21.20
	Price as a percentage of prices offered by other international agencies ⁴⁶	GDF prices compared to international price	
	RH 150+75	GDF is 10% lower	
	RHZE 150+75+400+275	GDF is 19% higher	
Political commitment/ additionally/ GDF Terms and Conditions ⁴⁷	% countries which have complied with all GDF terms and conditions of support ⁴⁸	80%	68%
	% of countries which implemented recommendations from country visits or Technical Review Committee	80%	69%
	% of countries which maintained or increased Govt. expenditure on NTP post GDF support ⁴⁹	93% ⁵⁰	81% ⁵¹

⁴¹ Covers patients approved by the TRC and STB Coordinating Board during the report period [new applications and monitoring applications] but no forward projection of patient numbers for 2nd or 3rd year. Patient numbers are taken from Column G, Table 3, Appendix 2, and are derived from grant agreements or GDF application forms. The figure assumes that 85% of total patients to be treated with GDF drugs will be cured. The figure is derived from the estimated cure rate of 85% - the official global target for TB control.

⁴² 85% of patient treatments covered by the Direct Procurement Agreements concluded during this reporting period (see Section 7)

⁴³ The two key products promoted and supplied by GDF have been selected for the drug price comparison.

⁴⁴ Source: International Dispensary Association, Price Indicator Guide, August 2005 (www.ida.nl)

⁴⁵ Cost per estimated patient cured, excluding buffer figure comes from the Secretariat estimation of \$21.2 per patient (includes average drug cost, insurance and freight) and based on a 85% cure rate.

⁴⁶ Source: International Dispensary Association, Price Indicator Guide, January 2005 (www.ida.nl)

⁴⁷ Data is from monitoring checklist

⁴⁸ See Table 5, Appendix 2 for more information.

⁴⁹ Ibid.

⁵⁰ Out of 24 countries this indicator only applicable to 20. Data only available for 15 out of 20. Of the 15 countries for which we have data, 14 countries have maintained or increased budget-lines.

⁵¹ Based on information for those countries for which financial information was available (13/16 countries).

Table 3 – Details of GDF Country Support: 1July - 31 December 2005. TB cases and patient numbers in GDF supported countries and demand indicators⁵²

A	B	C	D	E	F	G	H	I	J	K	L
Country	Estimated TB cases ⁵³	Total patients to be treated with GDF drugs (not including buffer) ⁵⁴	Total patients to be treated with GDF drugs (including buffer) ⁵⁵	Estimated Total Value of grant including buffer (D*18) ⁵⁶	Estimated value of grant not including buffer (C*18)	Estimated TB Cases to Cure (C*0.85) ⁵⁷	Cost per additional cure in US dollars (F/G) ⁵⁸	Indicator 1 APPLY TO REVIEW in days ⁵⁹	Indicator 2 REVIEW TO APPROVAL in days ⁶⁰	Indicator 3 APPROVAL TO GRANT in days ⁶¹	Indicator 4 GRANT TO ORDER in days ⁶²
<i>New applications</i>											
Cameroon	28725	32044	64088	1153584	576792	27237	21.2	41	20	12	30
Sri Lanka	12445	11850	23700	426600	213300	10072	21.2	83	15	84	27
Ukraine	47227	17470	34940	628920	314460	14849	21.2	22	20	184	
<i>Second term applications</i>											
Togo	21264	1138	2276	40968	20484	967	21.2	27	18	8	30
<i>Monitoring countries</i>											
Bangladesh	319252	55700	111400	2005200	1002600	47345	21.2	28	17	0	46
Bosnia-Herzegovina	2055	2725	5450	98100	49050	2316	21.2	9	25	0	45

⁵² The table provides information on countries and NGOs approved for support during this report period (July 1 2005 - Dec 31 2005).

⁵³ WHO TB Estimates 2004 from WHO REPORT 2006.

⁵⁴ Figures are taken from the country grant agreement letter and from the application form. The figures correspond to the number of patients provided with GDF drugs.

⁵⁵ Figure is taken from the country grant agreement letter and corresponds to the number of patients supplied with GDF drugs multiplied by two for those countries receiving buffer stock.

⁵⁶ Cost of drugs, insurance, and freight. No figure includes cost of batch testing and pre-shipment inspection. For the figures an average value of 18 has been used to reflect the average cost to treat a patient, a figure derived from averaging the total grant value for those countries for which a regular grant order has been placed.

⁵⁷ 85% of total patients to be treated with GDF drugs (not including buffer). The figure is derived from the estimated cure rate of 85 % - the official global target for TB control.

⁵⁸ Cost per estimated patient cured, excluding buffer.

⁵⁹ Time taken from receipt of application in the Secretariat to when it was reviewed by the Technical Review Committee.

⁶⁰ Time taken from review by Technical Review Committee to approval by the Stop TB Co-ordinating Board.

⁶¹ Time taken from approval by the Stop TB Coordinating Board to grant agreement being sent.

⁶² Time taken from grant agreement being sent to order placed by GDF secretariat.

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A	B	C	D	E	F	G	H	I	J	K	L
Country	Estimated TB cases ⁵³	Total patients to be treated with GDF drugs (not including buffer) ⁵⁴	Total patients to be treated with GDF drugs (including buffer) ⁵⁵	Estimated Total Value of grant including buffer (D*18) ⁵⁶	Estimated value of grant not including buffer (C*18)	Estimated TB Cases to Cure (C*0.85) ⁵⁷	Cost per additional cure in US dollars (F/G) ⁵⁸	Indicator 1 APPLY TO REVIEW in days ⁵⁹	Indicator 2 REVIEW TO APPROVAL in days ⁶⁰	Indicator 3 APPROVAL TO GRANT in days ⁶¹	Indicator 4 GRANT TO ORDER in days ⁶²
Burkina Faso	24540	1635	3270	58860	29430	1389	21.2	14	0	5	64
Cape Verde	851	310	620	11160	5580	263	21.2	31	18	8	36
Chad	26371	6500	6500	117000	117000	5525	21.2	21	26	2	67
Eritrea	11482	4220	8440	151920	75960	3587	21.2	23	11	0	63
Gambia	3448	1963	3926	70668	35334	1668	21.2	19	NA	NA	40
Guinea	22062	5700	11400	205200	102600	4845	21.2	15	NA	NA	27
Haiti	25707	16320	32640	587520	293760	13872	21.2	15	20	12	23
India (Orissa State)	1848867	52651	96352	1734336	947718	44753	21.2	15	NA	NA	-6
Maldives	157	165	330	5940	2970	140	21.2	NA	NA	9	NA
Mali	36914	5900	11800	212400	106200	5015	21.2	11	24	0	29
Mozambique	89384	37817	75634	1361412	680706	32144	21.2	18	6	0	41
Niger	21250	8165	16330	293940	146970	6940	21.2	10	98	0	30
Philippines	239459	10000	20000	360000	180000	8500	21.2	52	27	166	NA
Rwanda	32949	12846	25692	462456	231228	10919	21.2	2	20	NA	NA
Syrian Arab Republic	7577	500	1000	18000	9000	425	21.2	10	49	-8	15
Uganda	111716	59180	118360	2130480	1065240	50303	21.2	29	54	-1	-27

Table 4 - Details of GDF Country Support for grant countries: Cumulative (up to December 2005) - Supply statistics and supply indicators in GDF supported countries to date (countries are in alphabetical order and year refers to year of grant)

Country	Date Applied / monitoring report received in GDF Secretariat	Date Independent Review completed	Date Grant Agreement signed ⁶³	Date purchase order placed ⁶⁴	Date drugs arrived in country	Indicator 1 APPLY to GRANT in days ⁶⁵	Indicator 2 GRANT to ORDER in day ⁶⁶	Indicator 3 ORDER TO ARRIVAL in days ⁶⁷
Afghanistan (E)	9 March 05	31 Mar 05	13 April 05	26 April 05	6 Oct 05	35	13	163
Algeria (1 st year)	9 Aug 03	17 Sep 03	NA	NA	NA	NA	NA	NA
Angola (E)	8 Jul 02	24 Jul 02	6-Nov-02	05-Dec-02	07-May-03	121	29	153
Angola (1 st year)	29 Aug 03	8 April 04	11 May 04	27 May 04	13-Nov-04	256	16	170
Angola (2 nd year)	6 June 05	27 Jun 05	11 Jul 05	18 Aug 05	NA	35	38	NA
Armenia (E)	14 Mar 02	23 Apr 02	1-Jul-02	30-Sep-02	11-Jan-03	109	91	103
Azerbaijan (1 st year)	24 Aug 02	1 Nov 02	18-Dec-02	22-Jan-03	16-Jun-03	116	35	145
Azerbaijan (2 nd year)	04 April 04	8 April 04	10 May 04	24-May 04	19-Sep-04	36	14	118
Bangladesh (1 st year)	11 Mar 02	23 Apr 02	10-Jul-02	08-Aug-02	20-Feb-03	121	29	196
Bangladesh (2 nd year)	05 Nov 03	10 Mar 04	15 Mar 04	17 Jun 04	20-Dec-04	131	94	186
Bangladesh (3 rd year)	30 Sept 05	28 Oct 05	26 Dec 05	30 Dec 05	NA	87	4	NA
Benin (1 st year)	26 Sep 02	13 Mar 03	9 Oct 03	07 Nov 03	12 Mar 04	378	29	126
Benin (2 nd year)	8 March 05	31 Mar 05	22 Apr 05	9 May 05	NA	55	7	NA
Bosnia and Herzegovina (1 st year)	7 Aug 02	13 Mar 03	12-May-03	17-Jun-03	30 Oct 03	254	36	135
Bosnia and Herzegovina (2nd year)	2 June 04	21 July 04	16 August 04	28-Sep-04	21-Jan-05	74	42	115
Bosnia and Herzegovina (3 rd year)	11 Oct 05	20 Oct 05	15 Dec 05	29 Dec 05	NA	65	14	NA
Burkina Faso (1st year)	31 Jul 03	5 Aug 04	19 August 04	17-Sep-04	19 Feb 05	385	29	155
Burkina Faso (2 nd year)	25 Jul 05	08 Aug 05	22 Aug 05	18 Oct 05	NA	28	57	NA

⁶³ For dates before 01/07/2005 the date will represent the "Date Grant Agreement Sent." This indicator was changed to "Date Grant Agreement Signed" as it accurately indicates the date the grant was formalized.

⁶⁴ Grant Agreements typically translate into split purchase orders. Factors in this process include specific country needs, in-country drug storage capacity and procurement contingencies. This table is recording the date of the purchase order that corresponds to the bulk of the total order as per the signed Grant Agreement

⁶⁵ Time taken from receipt of new application or monitoring report in the Secretariat to grant agreement being sent/signed (see footnote 23).

⁶⁶ Time taken from grant agreement being sent to grantee to Purchase Order being placed by the Procurement Agent UNDP/IAPSO.

⁶⁷ Time taken from Purchase Order being placed by Procurement Agent, to TB drugs arriving in the country.

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Country	Date Applied / monitoring report received in GDF Secretariat	Date Independent Review completed	Date Grant Agreement signed ⁶³	Date purchase order placed ⁶⁴	Date drugs arrived in country	Indicator 1 APPLY to GRANT in days ⁶⁵	Indicator 2 GRANT to ORDER in day ⁶⁶	Indicator 3 ORDER TO ARRIVAL in days ⁶⁷
Burundi (1 st year)	8 Jul 02	24 Jul 02	20-Dec-02	22-Jan-03	11-Jun-03	165	33	140
Burundi (2 nd year)	26 March 04	8 April 04	7 May 04	28 May 04	22-Sep-04	42	21	117
Burundi (3 rd year)	1 April 05	15 Apr 05	12 May 05	16 May 05	6 Dec 05	41	4	204
Cameroon (E)	26 Sep 02	1 Nov 02	4 Jul 03	7-Aug-03	10 Oct 03	281	34	64
Cameroon (1 st year)	8 Jul 05	18 Aug 05	27 Sept 05	19 Oct 05	NA	81	22	NA
Cape Verde (1 st year)	30 March 04	8 April 04	4 August 04	5 Oct 04	16-Dec-04	127	62	72
Cape Verde (2 nd year)	18 Jul 05	18 Aug 05	3 Oct 05	19 Oct 05	NA	77	16	NA
CAR (E)	3 Apr 02	23 Apr 02	10-Jul-02	16-Jul-02	31-Dec-02	98	6	168
CAR (E-1 st half)	19 Feb 03	8 April 04	14 April 04	03 May 04	21 June 04	420	19	49
CAR (E-2 nd half)	19 Jan 05	11 Feb 05	24 Feb 05	02 Mar 05	5 April 05	36	6	34
Congo (E)	14 Mar 01	25 Jul 01	30 Aug 01	11 Sep 01	14 Jan 02	169	12	125
Chad (E)	28 Jul 05	18 Aug 05	1 Nov 05	NA	NA	96	NA	NA
Congo (1 st year)	16 Apr 02	23 Apr 02	30-Aug-02	23-Oct-02	20-Jan-03	136	54	89
Congo (2 nd year)	5 Dec 03	8 April 04	11 May 04	14 Jun 04	27 Oct 04	158	34	135
Congo (3 rd year)	16 May 05	4 Jun 05	19 Jul 05	15 Aug 05	NA	63	27	NA
Côte d'Ivoire (E)	8 Jul 02	24 Jul 02	6-Mar-03	26-Mar-03	30-Jun-03	241	20	96
Côte d'Ivoire (E)	22 Jan 03	13 Mar 03	16 Jun 03	03-Jul-03	09 Nov 03	145	17	129
DPR Korea (1 st year)	13 Jul 01	25 Jul 01	12 Oct 01	26 Oct 01	15 Nov 01	91	14	20
DPR Korea (2 nd year)	8 Sep 02	1 Nov 02	14-Jan-03	05-Mar-03	03 Jul 03	128	50	120
DPR Korea (3 rd year)	01 March 04	8 April 04	10 May 04	26 May 04	08-Jul-04	70	16	43
DRP Korea (2 nd term, 1 st year)	15 Dec 05	NA	NA	NA	NA	NA	NA	NA
DR Congo (1 st year)	06 June 01	25 Jul 01	27 Nov 01	06 Dec 01	18 May 02	174	9	163
DR Congo (2 nd year)	10 Jan 03	13 Mar 03	13 Jun 03	24 Jun 03	9 Sep 03	154	11	77
DR Congo (3 rd year)	3 June 04	5 Aug 04	30 August 04	15 Oct 04	7 April 2005	88	46	172
DR Congo (2 nd term, 1 year)	25 Mar 05	15 Apr 05	22 June 05	28 June 05	NA	89	6	NA
Djibouti (1 st year)	27 Mar 01	25 Jul 01	6 Dec 01	17 Jan 02	25 Apr 02	254	42	98
Djibouti (2 nd year)	10 Jan 03	13 Mar 03	13 Jun 03	7 Jul 03	24 Aug 03	154	24	48

Stop TB Partnership's *Global Drug Facility (GDF)*

Country	Date Applied / monitoring report received in GDF Secretariat	Date Independent Review completed	Date Grant Agreement signed ⁶³	Date purchase order placed ⁶⁴	Date drugs arrived in country	Indicator 1 APPLY to GRANT in days ⁶⁵	Indicator 2 GRANT to ORDER in day ⁶⁶	Indicator 3 ORDER TO ARRIVAL in days ⁶⁷
Djibouti (3 rd year)	3 Feb 04	17 Mar 04	31 Mar 04	15 Apr 04	12 Sep 04	57	15	150
East Timor (1 st year)	1 Jul 04	18 Nov 04	14 Jan 05	17 Jan 05	22 May 05	197	3	125
Egypt (1 st year)	3 Mar 03	13 Mar 03	9 Oct 03	20 Nov 03	4 Mar 04	220	42	105
Egypt (2 nd year)	24 May 05	14 Jun 05	4 July 05	9 Aug 05	NA	41	36	NA
Eritrea (1 st year)	13 Mar 02	13 Mar 03	7 Nov 03	4 Feb 04	28 June 04	604	89	145
Eritrea (2 nd year)	18 Nov 04	30 Nov 04	14 Jan 05	24 Jan 05	7 June 05	57	10	134
Eritrea (3 rd year)	19 Oct 05	11 Nov 05	8 Dec 05	29 Dec 05	NA	50	21	NA
Equatorial Guinea (1 st year)	12 Aug 03	18 Sep 03	9 Dec 03	23 Dec 03	5 Mar 04	119	14	73
Equatorial Guinea (2 nd year)	21 Nov 04	25 Nov 04	17 Dec 04	22 Dec 05	19 Apr 05	26	11	118
Gambia (1 st year)	4 Mar 02	23 Apr 02	25-Nov-02	05-Dec-02	15-May-03	266	10	161
Gambia (2 nd year)	15 March 04	8 April 04	11 May 04	06 Jul 04	24 Dec 04	57	56	171
Gambia (3 rd year)	7 Aug 05	26 Aug 05	5 Sept 05	12 Oct 05	NA	29	37	NA
Guinea (1 st year)	20 April 04	25 Nov 04	22 Dec 04	24 Jan 05	7 June 05	246	33	134
Guinea (2 nd year)	4 Dec 05	19 Dec 05	30 Dec 05	NA	NA	26	NA	NA
Haiti (1 st year)	3 Jul 02	24 Jul 02	24-Jan-03	28-Jan-03	25-Jun-03	205	4	148
Haiti (2 nd year)	17 June 04	11 July 04	28 July 04	10 Aug 04	3 Mar 05	41	13	205
Haiti (3 rd year)	3 Aug 05	18 Aug 05	22 Sep 05	12 Oct 05	NA	40	20	NA
India (1 st year)	13 Jul 01	25 Jul 01	27-Sep-02	28 Nov 02	15-Jun-03	441	62	199
India (2 nd year)	1 Nov 03	12 Nov 03	13 Jan 04	30 Jan 04	02 Apr 04	73	17	63
India (3 rd year)	NA	26 Sep 04	29 Sep 04	11 Oct 04	21 Apr 05	NA	12	192
Indonesia (1 st year)	18 Apr 02	23 Apr 02	8-Nov-02	18-Nov-02	28-May-03	204	10	191
Indonesia (2 nd year)	18 June 04	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Iraq (E)	22 May 05	3 June 05	23 June	29 June 05	8 Dec 05	32	6	162
Kenya (1 st year)	19 Feb 01	14 Mar 01	29 Jun 01	10 Aug 01	20 Feb 02	130	42	194
Kenya (2 nd year)	24 Sep 02	1 Nov 02	18-Dec-02	12-Feb-03	13-Jun-03	85	56	121
Kenya (3 rd year)	6 Feb 04	8 April 04	31 March 04	15 April 04	13 Sep 04	54	15	151

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Country	Date Applied / monitoring report received in GDF Secretariat	Date Independent Review completed	Date Grant Agreement signed ⁶³	Date purchase order placed ⁶⁴	Date drugs arrived in country	Indicator 1 APPLY to GRANT in days ⁶⁵	Indicator 2 GRANT to ORDER in day ⁶⁶	Indicator 3 ORDER TO ARRIVAL in days ⁶⁷
Kenya (2 nd term, 1 st year)	20 June 05	22 June 05	7 July 05	9 July 05	NA	37	2	NA
Kosovo (1 st year)	16 Oct 02	1 Nov 02	26-Mar-03	8-Apr-03	24 Jul 03	161	13	107
Kosovo (2 nd year)	16 Feb 04	8 April 04	10 May 04	27 May 04	17 Sep 04	84	17	113
Kosovo (3 rd year)	21 Apr 05	28 Apr 05	18 May 05	20 May 05	9 Nov 05	27	2	173
Lao DPR (1 st year)	10 Mar 05	14 Apr 05	21 Dec 05 ⁶⁸	NA	NA	286	NA	NA
Liberia (1 st year)	25 Jan 01	25 Jul 01	6-Dec-01	12-Feb-02	3-Oct-02	315	68	233
Liberia (2 nd year)	8 Jan 04	8 April 04	6 May 04	16 Jun 04	3 Nov 04	119	41	140
Macedonia (1 st year)	27 Feb 03	18 Sep 03	6 Nov 03	28 Nov 03	5 Apr 04	252	22	129
Macedonia (2 nd year)	1 Oct 04	22 Nov 04	8 Dec 04	1 Feb 05	14 June 05	68	49	133
Madagascar (1 st year)	27 Feb 03	18 Sep 03	6 Nov 03	27 Nov 03	5 Jul 04	252	21	221
Mali (E)	19 Sep 02	13 Mar 03	13 Jun 03	03 Jul 03	17 Nov 03	267	20	137
Mali (1 st year)	18 Aug 04	25 Nov 04	4 Mar 05	10 Mar 05	19 Jul 05	198	6	131
Mali (2 nd year)	4 Dec 05	15 Dec 05	NA	NA	NA	NA	NA	NA
Maldives (1 st year)	26 Sept 03	8 April 04	4 Aug 04	23 Oct 04	28 Feb 05	313	80	105
Maldives (2 nd year)	8 Nov 05	NA ⁶⁹	22 Dec 05	NA	NA	44	NA	NA
Mauritania (1 st year)	15 Apr 02	23 Apr 02	19-Aug-02	23-Oct-02	1-Feb-03	126	65	101
Mauritania (2 nd year)	6 Feb 04	8 April 04	13 May 04	24 Jun 04	5 Nov 04	97	42	134
Mauritania (3 rd year)	8 May 05	20 May 05	25 May 05	1 Jun 05	7 Nov 05	17	7	159
Moldova (1 st year)	27 Feb 01	14 Mar 01	27 Jun 01	30 Jul 01	15 Oct 01	120	33	77
Moldova (2 nd year)	28 Aug 02	24 July 02	24 Oct 02	21 Nov 02	19 May 03	57	28	179
Moldova (3 rd year)	16 Feb 04	8 April 04	10 May 04	27 May 04	24 Sep 04	84	17	120
Mozambique (1 st year)	6 Nov 03	8 April 04	28 May 04	16 Jun 04	13 Feb 05	204	19	242
Mozambique (2 nd year)	8 Aug 05	26 Aug 05	6 Sept 05	13 Oct 05	NA	29	37	NA
Myanmar (1 st year)	26 Feb 01	14 Mar 01	28 Jun 01	10 Aug 01	24 Mar 02	122	43	226
Myanmar (2 nd year)	8 Sep 02	1 Nov 02	14 May 03	30 May 03	7 Sep 03	248	16	100

⁶⁸ The timeline for the drug order has been discussed and agreed with the Lao TB Programme.

⁶⁹ Independent review not deemed necessary

Stop TB Partnership's *Global Drug Facility (GDF)*

Country	Date Applied / monitoring report received in GDF Secretariat	Date Independent Review completed	Date Grant Agreement signed ⁶³	Date purchase order placed ⁶⁴	Date drugs arrived in country	Indicator 1 APPLY to GRANT in days ⁶⁵	Indicator 2 GRANT to ORDER in day ⁶⁶	Indicator 3 ORDER TO ARRIVAL in days ⁶⁷
Myanmar (3 year)	25 May 04	21 June 04	25 June 04	4 Jul 04	16 Jan 05	31	9	196
Myanmar 2 nd term, 1 year	13 Jan 05	16 Apr 05	7 Sep 05	NA ⁷⁰	NA	237	NA	NA
Niger (1st year)	11 Jul 03	8 April 04	13 May 04	9 Jun 04	8 Nov 04	307	27	152
Niger (2nd year)	1 Aug 05	11 Aug 05	9 Nov 05	16 Dec 05	NA	100	37	NA
Nigeria (1 st year)	28 May 01	25 Jul 01	23-Nov-01	22-Dec-01	22-Oct-02	179	29	304
Nigeria (2 nd year)	3 May 03	18 Sep 03	7 Nov 03	3 Dec 03	10 Jun 04	188	26	190
Nigeria (3 year)	18 Feb 05	16 Apr 05	21 Apr 05	29 Apr 05	3 Nov 05	62	8	188
Orissa State - India (1 st year)	7 Mar 02	23 Apr 02	12-Aug-02	28 Nov 02	7 June 03	158	108	221
Orissa State - India (2 nd year)	2 Aug 04	13 Sep 04	27 Sep 04	2 Nov 04	29 Jan 05	56	36	88
Orissa State - India (3 rd year)	29 Sep 05	14 Oct 05	14 Dec 05	NA	NA	76	NA	NA
Pakistan (1 st year)	12 Jul 01	25 Jul 01	15-Nov-01	31-Jan-02	23-Dec-02	126	77	326
Pakistan (2 nd year)	7 March 04	30 Jun 04	7 Jul 04	2 Aug 04	20 Apr 05	122	26	261
Pakistan (E)	4 Nov 05	11 Nov 05	22 Nov 05	24 Nov 05	NA	18	2	NA
Philippines (E)	22 Jul 02	24 Jul 02	29-Nov-02	22-Jan-03	3 Aug 03	130	54	193
Philippines PPP (1 st year)	22 Jul 02	24 Jul 02	25-Nov-02	22-Jan-03	22-Jun-03	126	58	151
Philippines PPP (2 nd year)	27 June 05	18 Aug 05	NA	NA	NA	NA	NA	NA
Rwanda (1 st year)	21 Oct 02	1 Nov 02	17-Dec-02	11 Apr 03	17 Oct 03	57	115	189
Rwanda (2 nd year)	16 Aug 05	18 Aug 05	8 Sep 05	18 Oct 05	NA	24	40	NA
Sierra Leone (1 st year)	16 Jul 01	25 Jul 01	16-Dec-02	6-Feb-03	4 Sep 03	518	52	210
Sierra Leone (2 nd year)	22 June 04	21 July 04	16 Aug 04	29 Sep 04	21 Feb 05	55	44	145

⁷⁰ The timeline for the drug order has been discussed and agreed with the Myanmar TB Programme.

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Country	Date Applied / monitoring report received in GDF Secretariat	Date Independent Review completed	Date Grant Agreement signed ⁶³	Date purchase order placed ⁶⁴	Date drugs arrived in country	Indicator 1 APPLY to GRANT in days ⁶⁵	Indicator 2 GRANT to ORDER in day ⁶⁶	Indicator 3 ORDER TO ARRIVAL in days ⁶⁷
Sierra Leone (E)	14 July 05	NA ⁷¹	9 Aug 05	16 Aug 05	18 Sep 05	26	7	33
Sierra Leone (3 rd year)	14 Sep 05	27 Sep 05	6 Oct 05	1 Nov 05	NA	22	26	NA
Somalia (1 st year)	28 Feb 01	14 Mar 01	28 Jun 01	08 Aug 01	09 Jun 02	120	41	305
Somalia (2 nd year)	6 Jan 03	13 Mar 03	6 Nov 03	10 Dec 03	10 Mar 04	304	34	92
Somalia (3 rd year)	4 Jan 05	17 Jan 05	21 Jan 05	4 Feb 05	31 Aug 05	17	14	208
Sri Lanka (E)	30 June 04	5 Aug 04	29 Nov 04	16 Dec 04	2 Jan 05	152	17	17
Sri Lanka (1 st year)	27 May 05	18 Aug 05	12 Dec 05	22 Dec 05	NA	199	10	NA
Sudan (1 st year)	16 Jul 01	25 Jul 01	12 Nov 01	10 Dec 01	2 May 02	119	28	143
Sudan (2 nd year)	31 Jan 03	17 Sep 03	13 Nov 03	18 Feb 04	22 Aug 04	286	97	186
Sudan (3 rd year)	7 Feb 05	15 Apr 05	2 Jun 05	9 Jun 05	NA	115	7	NA
Syrian Arab Republic (1 st year)	20 Aug 03	17 Sep 03	30 Mar 04	17 Jun 04	21 Nov 04	223	79	157
Syrian Arab Republic (2 nd year)	20 Sep 05	30 Sep 05	12 Nov 05	5 Dec 05	NA	53	23	NA
Tajikistan (1 st year)	26 Feb 01	14 Mar 01	28 Jun 01	24 Aug 01	23 Feb 02	122	57	183
Tajikistan (2 nd year)	10 Jan 03	13 Mar 03	13 Jun 03	7 Jul 03	7 Sep 03	154	100	62
Tajikistan (3 rd year)	12 July 04	5 Aug 04	30 Aug 04	8 Dec 04	8 Jul 05	49	98	212
Tanzania (1 st year)	18 Nov 04	25 Nov 04	25 Feb 05	23 Mar 05	NA	99	26	NA
Togo (1 st year)	25 Jan 01	25 Jul 01	14-Nov-01	22-Dec-01	3-Sep-02	293	38	255
Togo (2 nd year)	4 Aug 03	18 Sep 03	7 Nov 03	10 Dec 03	23 Jan 04	95	33	44
Togo (3 rd year)	20 July 04	5 Aug 04	30 Aug 04	20 Sep 04	1 Mar 05	41	21	162
Togo (2 nd term, 1 st year)	22 Jul 05	18 Aug 05	16 Sept 05	18 Oct 05	NA	56	32	NA
Turkmenistan (E)	15 Aug 03	8 April 04	7 May 04	24 May 04	15 Sep 04	266	17	115
Turkmenistan (1 st year)	12 Apr 05	15 Apr 05	12 May 05	23 May 05	27 Oct 05	30	11	157

⁷¹ Independent review not deemed necessary for this Emergency supply of syringes

Stop TB Partnership's *Global Drug Facility (GDF)*

Country	Date Applied / monitoring report received in GDF Secretariat	Date Independent Review completed	Date Grant Agreement signed ⁶³	Date purchase order placed ⁶⁴	Date drugs arrived in country	Indicator 1 APPLY to GRANT in days ⁶⁵	Indicator 2 GRANT to ORDER in day ⁶⁶	Indicator 3 ORDER TO ARRIVAL in days ⁶⁷
Uganda (1 st year)	18 May 01	25 Jul 01	14-Nov-01	22-Dec-01	8-Dec-02	180	38	351
Uganda (2 nd year)	13 Oct 03	15 Feb 04	1 March 04	27 April 04	3 Oct 05	140	57	524
Uganda (3 rd year)	20 Sep 05	19 Oct 05	23 Nov 05	28 Nov 05	NA	64	5	NA
Ukraine (1 st year)	27 July 05	18 Aug 05	NA	NA	NA	NA	NA	NA
Uzbekistan (1 st year)	5 Apr 02	23 Apr 02	11-Dec-02	3 Jun-03	21 Aug 03	250	174	140
Uzbekistan (2 nd year)	30 July 04	5 Aug 04	29 Sep 04	20 Oct 04	17 June 05	61	21	239
Yemen (E)	13 Jul 01	25 Jul 01	11 Sep 01	18 Oct 01	09 Mar 02	60	37	142
Yemen (1 st year)	10 Feb 03	13 Mar 03	9 Oct 03	10 Dec 03	29 Mar 04	241	62	110
Yemen (2 nd year)	16 Dec 04	24 Dec 04	5 Jan 05	26 Jan 04	24 June 05	20	21	149
Zambia (E)	15 Apr 02	23 Apr 02	12-Jul-02	16-Jul-02	30-Dec-02	88	4	167
Zambia (1 st year)	1 Aug 03	18 Sep 03	9 Jan 04	30 Jan 04	2 Jul 04	161	21	154
Zambia (2 nd year)	21 Dec 04	9 Jan 05	21 Jan 05	10 Feb 05	24 Aug 05	31	20	195

NA = Information not available;

OTP = Order to be placed next period following receipt of grant agreement letter from country;

E = Emergency (one-off grant) (X year) refers to year of grant;

UC = "Under Consideration"

Table 5a - Key Indicators for GDF Monitoring Countries during the reporting period 1 January - 30 June 2005 (data taken from the GDF monitoring checklist reports or GDF desk audit reports)

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
Bangladesh	92 ^{lxxii}	100	Partially	Yes	403,034 ^{lxxiii}	4,662,828	There are weak commodity management systems and lack of a plan to strengthen both drug and laboratory supply systems. Human resources in drug management are insufficient. Managerial and technical shortfalls at central level, including weak management systems to support the NTP. No evidence that drugs diverted from NTP. Strong messages disseminated about provision of free drugs throughout the country. NTP follows WHO treatment recommendations, except for category III where 3 FDCs were still being used. MoH took control of import duties and reported to carry out quality control (QC) on drugs. No registration is required for drugs in country. There was no stock out within the last 12 months. Storage inadequate at central level but plans to rebuild warehouse.	Approved with "Green Light" for 3 rd year of 1 term grant
Bosnia-Herzegovina	100	100	Partially	Yes	2,041,386 ^{lxxiv}	2,165,000 ^{lxxv}	Evidence drugs used only for TB patients and free of charge. Port clearance in theory simple, but there was a 1 month delay last year. GDF Drugs meet registration requirements. The MOH has no QC mechanism in place for TB drugs. No drugs out of stock, but it appears that buffers stocks will expire by next year. Distribution system needs strengthening.	Approved with "Green Light" for 3 rd year of 1 term grant
Burkina Faso	100 ^{lxxvi}	100	Fully	Yes	108,000	144,000	No separate budget line for the procurement of TB drugs. Currently no national guide exists for the management of drugs. Evidence that drugs only available to TB patients and free of charge. Drugs cleared from port in 9 days. They are registered and the MoH conducts QC on drugs in country. No stock-outs recorded. Improvements have been made, but still remain for stock management at central stores- procedures and manual have not been finalized.	Approved with "Green Light" for 2 nd year of 1 term grant

^{lxxii} Source: Progress Report 5: July to December 2003

^{lxxiii} Source: Progress Report 5: July to December 2003

^{lxxiv} Source: Progress Report 6: January to June 2004

^{lxxv} Source : MM report July 2005

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
Chad	25 ^{lxxvii}	NA	NA	NA	36,500 ^{lxxviii}	NA	The NTP distributes drugs twice a year to the regional stores and then from there quarterly to the districts. The conditions of the warehouses were acceptable. Drugs are offered free to TB patients. GDF drugs are exempted from importation fees. Drugs meet registration requirements. Customs clearance is quick - 3 days. No quality control exists in country, but labs in Niger and France are used when necessary (note, not clear from report if GDF drugs are controlled).	3 year grant not approved at TRC12 - but given 1 year Emergency Grant
Democratic People's Republic of Korea (North Korea)	33	100	Partially ^{lxxix}	Yes	571,009	3,792,857	Reporting system is excellent. However, the grant from GDF not been able to avoid stock-outs. Between October 2004 and May 2005, there was a central stock-out of streptomycin. The central TB store has adequate conditions. However, FEFO not practiced. Stock cards not accurate. Distribution from central to peripheral level is apparently good: all treatment centres visited had sufficient amounts of drugs. Storage conditions were excellent in all centres visited.	Apply to TRC 13 for a 2 nd term 3 year grant. ^{lxxx}
Equatorial Guinea	98	100	No	No ^{lxxxi}	4,000	NA ^{lxxxii}	Condition in regional drug stores in Malabo improved. Staff of TB services trained in 4 FDC. There are practically no funds to run the program. Reporting and recording not efficient. Central stocks out did occur: Pyrazinamide lacking in May and June 2005. "Drug distribution is still improvised at the central level. Due to a lack of communication, the GDF drugs were delivered to the capital Malabo and got lost during two months until they reappeared. 80% of the drugs are needed on the continent so that the drugs should be shipped from Malabo to Bata, but this has not been possible so far as there is no budget. 5ml syringes are lacking on the continent while there is a 40 year supply in Malabo.	Not approved for 3 rd year of support.

^{lxxvi} Source: Global TB Control WHO Report 2005 for 2003

^{lxxvii} Source: Global TB Control WHO Report 2005 for 2003

^{lxxviii} Source: Pre delivery Report July 2005 for 2004

^{lxxix} Most terms and conditions were met except for certain financial matters. From report "The NTP budget was not available in written form nor is it well known by the NTP management. There is no specific budget line for drugs as there are no specific budget lines at all".

^{lxxx} DPR Korea approved at TRC 13 for a 2nd term grant.

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
							<i>Supply of drugs to peripheral facilities takes place monthly in theory. In reality, it happens when there is some transport, and during supervisory visits.</i> ^{lxxxiii} Drugs provided to patients at no cost. NTP not following WHO recommended dosage.	
Eritrea	55	100	Partially ^{lxxxiv}	Yes	46,000 ^{lxxxv}	825,800 ^{lxxxvi}	NTP not trained in drug management. Drugs used for TB patients only and free of charge. Most health facilities providing DOTS, if a patient is identified outside one of these facilities then drugs are sent to that facility to treat patient. NTP follows WHO recommended regimens. NTP took responsibility for port clearance. Drugs are registered and QC is conducted. No stock outs occurred in last 12 months.	Approved with "Green Light" for 3 rd year of 1 term grant
Gambia	87 ^{lxxxvii}	100	Yes	Partially	19,100 ^{lxxxviii}	75,158	Four focal TB persons for the 6 divisions doing the drug ordering. Monitoring team found mislabelling of some drugs; the consignment of drugs was quarantined until the clarifications were obtained. Evidence that the drugs are used only for TB patients free of cost. Quick clearance of drugs from port (3 days). GDF drugs meet national registration requirements. Quality control is not carried out on the drugs. No stock outs reported in the last 12 months. No expired drugs were found however "it was noted that the consignment of RH (150/75) was expiring in December 2005. The NTLP said they would only require 12,288 units out of the available 84,672 units in stock.... The balance ...would be used at the hospital for daily treatment of adults and children."	Approved with "Green Light" for 3 rd year of 1 term grant

^{lxxxi} From the mission report November 2005: "The government has not adhered to any of the recommendations. The Spanish advisers, on the other hand, have adhered to the majority of the recommendations made specifically to them"

^{lxxxii} During mission the team was not able to obtain any financial data. Due to this and others concerns GDF support to the country was withdrawn.

^{lxxxiii} Extracted from mission report.

^{lxxxiv} Most terms and conditions were met except for certain financial matters.

^{lxxxv} Figure taken from Progress Report 7. Amount represents government expenditure on anti-TB drugs.

^{lxxxvi} Total budget is US \$878 800. \$53,000 for anti-TB drugs and \$825 800 for other NTP activities.

^{lxxxvii} Source: Progress Report 5 - 1 July to 31 December 2003

^{lxxxviii} Ibid

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
Guinea	100 ^{lxxxix}	100	Yes	Yes	NA	91,000	Central warehouse refurbished. Creation of budget line for anti-TB drugs. System for buffer stock all regions established. Improvements to management of drugs at national level. Logistical challenges at peripheral level. Difficulties with port clearance and transport to central stores. Lack of drug management tools and training of staff. There were no stock-outs recorded. Drugs appear to only be used for TB patients and free of charge.	Approved with "Green Light" for 2 nd year of 1 term grant
India (Orissa state)	46 ^{xc}	100	Yes	yes	22,800 ^{xcj}	NA ^{xcii}	No reported stock out in last 12 months. Need for more storage space at the state level. FEFO not strictly enforced. Suboptimal drug and logistics management by STC. Evidence that drugs only used for TB patients and at no charge. GDF drugs are registered. The GoI and GoO conducts random quality assurance checks on drugs.	Approved with "Green Light" for 3 rd year of 1 term grant
Maldives	100 ^{xciii}	100	Yes	Yes	55,888	73,655	Anti-TB drugs available through gov't system, not available at private pharmacies. DM is "reasonably good". All regions report stock levels on monthly basis, using standardized forms. Evidence that all drugs are only used for TB patients and free of charge. Quick clearance of drugs from port (2 days). Drugs meet registration requirements and government carries out QC. No drugs were out of stock or expired at time of mission.	Approved with "Green Light" for 2 nd year of 1 term grant
Mali	68 ^{xciv}	100	Yes	Yes	NA	400,000	Expansion of drug storage facilities available to NTP realized with addition of 1 additional store. NTP drug management personnel require further training. Warehouses need refurbishment (particularly to protect against fires). Technical guide not finalized. Evidence that drugs only used for TB patients and free of charge. Drugs were available in all the health centres visited. Quick clearance from port (4 days for first delivery and 3 days for second delivery). GDF drugs meet national drug regulations. GDF drugs	Approved with "Green Light" for 2 nd year of 1 term grant

^{lxxxix} Source: Global TB Control WHO Report 2005 for 2003

^{xc} 14 districts out of 30 (number of population not mentioned): GDF 1st year monitoring checklist report.

^{xcj} Information for the financial year 2003/2004. The government bears the cost of manpower and infrastructure in addition to funds for TB drugs.

^{xcii} The only information available is that for the financial year 2005/2006 the government bears the cost of manpower and infrastructure.

^{xciii} Source: Global TB Control WHO Report 2005 for 2003

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
							quality is not controlled, but anti-TB drugs purchased prior to GDF were tested. No stock outs were found No expired drugs were found.	
Mozambique	100 ^{xcv}	50	Yes	Yes	821,610	821,610	Quality control lab lacks some of the necessary equipment (High Pressure Liquid Chromatography). Evidence that drugs are used only for TB patients and free of charge. 14 days were needed to clear drugs from port. GDF drugs meet registration requirement and the government carried out QC on anti-TB drugs. No drugs were found to be out of stock nor expired during visit.	Approved with "Green Light" for 2 nd year of 1 term grant
Niger	50 ^{xcvi}	90	Partially ^{xcvii}	Partially	0	30,000	Evidence anti-TB drugs used only for TB patients and free of charge. Delay in the clearance of drugs from port - 70 days, although, the government waives fees. GDF drugs meet regulatory standards and there is QC. No evidence of stock outs or expired drugs.	Approved with "Green Light" for 2 nd year of 1 term grant
Pakistan	12	100	Yes	Yes	7,231,000	12,756,327	In order to review and improve the drug management situation a 'National Workshop on Drug Management for Tuberculosis' was held in September 2005 (hosted by JICA and GLRA). NTP is planning to develop Drug Management Module and training for trainers will be held in all the provinces. In spite of these activities and improvements drug management remains a weak component of the National and Provincial TB Control. Currently there is lack of national policy on drug management. Procurement of anti TB drugs is still based on cost of medicines without specific considerations of quality, safety and efficacy. There is also lack of drug management expertise at all levels. Both first and second line TB drugs are available and utilized in the private sector without control. There is not enough space available at the Federal and most of the Provincial levels for storage of anti TB drugs. Drug management information system is rudimentary and not functioning at its	Approved with "Green Light" for 3 rd year of 1 term grant

^{xciv} Source: Global TB Control WHO Report 2004 for 2002

^{xcv} Source: Global TB Control WHO Report 2005 for 2003

^{xcvi} Source: Global TB Control WHO Report 2005 for 2003

^{xcvii} Most of the conditions have been met except for those made to the administration of the NTP, which were partially met.

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
							optimal level. No evidence that drugs are being used for other diseases nor that patients were being charged for these drugs. Quick drug clearance from port - less than week. Drugs meet national registration requirements and the Government does <i>not</i> carry-out QC. No evidence of stock-out in the past 12 months and no expired drugs were found.	
Rwanda	100	100	Yes	Yes	201,900	470,745	Evidence that the drugs are only used for TB patients and free of charge. Delay on the clearance of drugs of 60 days. There are no processes for registration of drugs and there is no quality control of drugs. There were no stock-outs, nor expired drugs recorded in the last 12 months.	Approved with "Green Light" for 3 rd year of 1 term grant
Sierra Leone	50	100	Partially ^{xcviii}	Yes	33,269	344,733	Central medical stores lack the human and material capacity to effectively manage. Evidence drugs only used for TB patients and free of charge. Drugs provided free of charge, however, registration of 3 US\$ fee are levied, but when a patients is truly unable to pay it is reported that treatment will not be refused. Delays in clearing drugs from port - 39 days and there was a shortage of boxes in the shipment (Police are investigating). Drugs meet registration requirements and QC is carried out on all drugs. There was a stock out of needles and syringes for 3 months.	Approved with "Green Light" for 3 rd year of 1 term grant
Somalia	73 ^{xcix}	100, 51, 21 ^c	Partially ^{ci}	Yes	0	0	Evidence that drugs used only for TB patients and free of charge. Clearance of drugs from port quick - 1 day. GDF drugs exempt from import duties and taxes. Drugs are not registered because there is no regulatory authority and no QC carried out on drugs. Stocks outs were reported in last 12 months and no expired drugs found.	

^{xcviii} Most terms and conditions were met except "port clearance" which was partially met.

^{xcix} Source: Global TB Control WHO Report 2002 for 2000.

^c DOTS coverage has been divided by administrative levels. 100% at regional level, 51% at district, 21% at health facility.

^{ci} Partial adherence for financial management and port clearance. Full adherence for NTP management, drug registration and stock management.

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
Sri Lanka	97	-	NA ^{cii}	NA ^{ciii}	? ^{civ}	NA ^{cv}	Drugs registered- but FDCs were not registered but "no objection" for use was given by relevant authority. Import duties were waived for GDF drugs. Drug distribution has been centralized. Storage space at the central drug store is not adequate. All drug stores visited were either air-conditioned or had good ventilation systems in place. Drugs were stored on shelves. First Expire First Out (FEFO) and First In First Out (FIFO) rules are observed. In none of the health facility drug stores visited were bin cards being used. All stores have updated stock information recorded in registers. There is no standard mechanism for monitoring drug flow within the programme. The NPTCCD does not follow international policy of keeping 100% buffer stock in the country. Although all sites visited reported no drug stock outs in the previous year but there have been reports of stock outs in the past particularly during 2003.	Approved for 1st year of 1st term at TRC 12
Syrian Arab Republic	100 ^{cvi}	100	Partially ^{cvi}	Yes	NA	2,536,444	Extreme delay in drugs in port - 6 months. Inventory control needs improvement in central warehouse - there were no doors, lack of ventilation, no shelves or cupboards in some rooms, temperature and humidity readings not recorded. Evidence that GDF drugs only used for TB patients and free of charge. GDF drugs meet registration requirements, but GDF drugs were not registered as MoH policy permits exemption to drugs that are provided as a part of grant. QC is carried out on drugs. There was no record of batches from GDF that failed inspection. No instances of stock outs in the last 12 months and no expired drugs were found.	Approved for 2 nd year of 1st term at TRC 12

^{cii} Pre-delivery Mission - no assessment of adherence to Terms and Conditions as this occurs at the beginning of grant, before any GDF drugs have arrived in country.

^{ciii} Pre-delivery Mission - no assessment of the follow-up on recommendations as this occurs at the beginning of grant, before any GDF drugs have arrived in country or any recommendations have been made.

^{civ} Sri Lanka has no specific budget line for TB drugs at Central level. GFATM grant (6.16 million US\$) since 2003 - no monies from this for procurement of anti-TB drugs. NTP received funds from WHO (33,500 US\$) and from FIDELIS (242,754 US\$).

^{cv} Sri Lanka was just approved for a grant during this period; therefore the data is not yet available for the budget line "after GDF support."

^{cvi} Source: Global TB Control WHO Report 2005 for 2003

^{cvii} Terms and condition fully met for NTP management and drug registration, partially met for stock and financial management and not met for port clearance.

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
Togo	100	100	NA	Yes	174,976	150,000	Strengthen team with the appointment of accountant and public health technician but still needs additional human resources. Evidence that drugs are only used for TB patients and that they are free of charge. Acceptable clearance of drugs from port - 10 days for first delivery and 3 days for second delivery. Currently the MoH does not have drug registration regulations - drugs that meet WHO criteria are automatically approved. There is also no QC carried out on drugs. A stock-out was recorded for streptomycin for 40 days from 29 October 2004 to 8 December 2004. No expired drugs were documented.	Approved for a 2 nd term grant of 3 years.
Uganda	100	100	Partially	Partially	430,783	1,692,112	The NTLF, with the technical assistance of DELIVER/JSI (and financial support of DELIVER and AIM) has introduced a new TB drug management system nation wide. Over 1,300 supervisors and health workers were trained on the system. Significant stock-out of many drugs (RH 150, RH 60, Pyrazinamide, RH 150 blisters, E 400, Isoniazid, Pyridoxine, RH+Z) were recorded.	Approved with "yellow light" for 3 rd year of 1 st term grant.
Ukraine	15	NA	^{cviii}	^{cix}	^{cx}	NA ^{cx}	Suppliers deliver drugs to state-owned UkrVaccine warehouse, which then distributes the yearly allocation of drugs to the regions. In 2005 there was a misallocation of drugs, which led to the redistribution of stocks between oblasts. Appears that there is a tendency to over-prescribe. Key concerns: unfamiliarity with FDC's, quantification requirements, possible delays in customs clearance and registration. Drug management training is scheduled for 2006 at regional level. No stock-outs have been reported for the last year. Medical stores are required to keep stock level records.	Approved for 1st year of 1st term at TRC 12

^{cviii} Pre-delivery Mission - no assessment of adherence to Terms and Conditions as this occurs at the beginning of grant, before any GDF drugs have arrived in country.

^{cix} Pre-delivery Mission - no assessment of the follow-up on recommendations as this occurs at the beginning of grant, before any GDF drugs have arrived in country or any recommendations have been made.

^{cx} From Pre-delivery mission: "State financing for TB control activities comes from national and local budgets and in a World Bank loan (\$29.7 million of a \$60 million project is allocated for TB. With an additional amount for TB from within the Penitentiary system component). Since 1999, TB drugs have been centrally financed and procured, with expenditures in 2004, 2005 and budget for 2006 - 2004= 6,415,094, 2005 - 6,332,797 and 2006 - 6,900,000."

^{cx} Ukraine was just approved for a grant during this period; therefore the data is not yet available for the budget line "after GDF support."

Country	Case management		Adherence to all GDF terms + Conditions of support	Evidence of Follow up from recommendation of Previous Visit + Technical Review Committee	Financial Management All figures in US\$		Drug Management (Note: Where weaknesses/shortcomings have been identified, clear recommendations have been made by monitoring consultants and the GDF Technical Review Committee, to the relevant entity. Progress made towards addressing these recommendations is monitored by GDF).	Year for which grant approved
	% DOTS coverage before GDF	% DOTS coverage with GDF			Govt. TB expenditure prior to GDF support	Govt. TB expenditure after GDF support		
Zambia	0	100	Partially ^{cxii}	Yes	NA ^{cxiii}	^{cxiv}	Drug management suffered - due in part to the death of the NTP manager. Expansion of FDCs to more provinces was postponed. GDF drugs arrived in two consignments. The first severely damaged by water (monsoons in Bombay). The second arrived safely. DM in central and provincial drug stores improved considerably. Evidence that drugs only for TB patients and free of charge. Quick clearance from port - less than a week. GDF drugs not registered because as GDF suppliers still have not submitted application for registration. Quality control is conducted by Medical Stores Limited through Pharco- a local pharmaceutical company. First GDF consignment was rejected because of severe water damage. Second delivery passed QC tests. No stock-outs recorded.	Approved with "Green Light" for 3 rd year of 1 term grant

^{cxii} Zambia NTP fully met the terms and conditions for NTP programme management, drug registration and stock management and partially met terms and conditions for financial management and port clearance.

^{cxiii} As taken from Progress Report 7 - July to December 2004.

^{cxiv} Zambia does not have a specific TB budget line.

**Table 5b - Key Indicators for GDF Monitoring Countries
(Data on additionality of TB Drug budget line)**

Country	Source of TB Drugs Funding (US\$) ^{cxv}	Year before GDF Grant	During GDF Grant Year 1	During GDF Grant Year 2	During GDF Grant Year 3
Bangladesh	Government funding	403,034	3,778,571	4,662,828	
	Donor funding	443,776	9,450,835	9,478,788	
	GDF funding	-	779,148	207,480	
Bosnia-Herzegovina	Government funding	2,041,386 ^{cxvi}	2,100,000	2,140,000	
	Donor funding	0 ^{cxvii}	25,000	25,000	
	GDF funding	-	93,876	40,000	
Burkina Faso	Government funding	108,000	144,000		
	Donor funding	503,546	NA		
	GDF funding	-	60,000		
Chad	Government funding	36,500 ^{cxviii}			
	Donor funding	15,000			
	GDF funding	-			
Democratic People's Republic of Korea (North Korea)	Government funding	450,000 ^{cxix}	181,550 ^{cxx}	181,550 ^{cxxi}	3,792,857
	Donor funding	NA	NA	291,481 ^{cxvii}	407,164 ^{cxviii}
	GDF funding	-	437,659	620,000	430,000
Equatorial Guinea	Government funding	4,000	NA	NA	
	Donor funding	NA	125 000	NA	
	GDF funding	-	15,519	2,300	
Eritrea	Government funding	46,000	0 ^{cxvii}	75 158	
	Donor funding	NA	175 933	174 025	
	GDF funding	-	98,369 ^{cxv}	75,039	11,903

^{cxv} GDF funding data taken directly from GDF Grant Agreements for respective years.

^{cxvi} Source: 1st year mission report June 2004

^{cxvii} Ibid

^{cxviii} Source: Pre delivery Report July 2005 for 2004

^{cxix} The regular expenditure for effective implementation for DPR Korea NTP in 2000/2001. *From Progress Report 5.*

^{cxx} Source. Monitoring Mission 2003

^{cxv} Source. Monitoring Mission 2003

^{cxvii} Principle Donor for DPR Korea: CIDA

^{cxviii} Ibid

^{cxvii} The country has allocated the same amount of funds (US \$28 500 used for TB drugs in the previous year for other activities of the programme. The total TB budget has increased from US \$44 500 in the year before GDF grant to US \$47 166 during the first year of the GDF grant. A total budget of 657 274 is planned for 2005 under the TB action plan. GDF provides 100% of anti TB drugs needed.

^{cxv} Source 1st year grant agreement.

Country	Source of TB Drugs Funding (US\$) ^{cxxv}	Year before GDF Grant	During GDF Grant Year 1	During GDF Grant Year 2	During GDF Grant Year 3
Gambia	Government funding	NA	71,579	75,158	
	Donor funding	cxxvi	175,933 ^{cxxvii}	174,025 ^{cxxviii}	
	GDF funding	-	27,300	17,500	62,816
Guinea	Government funding	91,000	91,000		
	Donor funding	411,035	354,026		
	GDF funding	-	35,000		
India (Orissa state)	Government funding	28,000	cxxix	cxxx	
	Donor funding	cxxxi	cxxxii	684,932	
	GDF funding	-	551,379	523,385.4	695,682.86
Maldives	Government funding	NA	55,888		
	Donor funding	NA	0 ^{cxxxiii}		
	GDF funding	-	5,200	10,514 ^{cxxxiv}	
Mali	Government funding	NA	400,000	400,000	
	Donor funding	NA	241,026	1,504,860	
	GDF funding	-	75,334	187,677	
Mozambique	Government funding	821,610	821,610		
	Donor funding	NA ^{cxxxv}	4,378,690 ^{cxxxvi}		
	GDF funding	-	670,000	1,285,778 ^{cxxxvii}	

^{cxxvi} KNCV in 2002 for the NTP was 86 156 Euros.

^{cxxvii} Donors include: KNCV(\$14,838), CIDA (\$117,050), and WHO (\$44,500)

^{cxxviii} Donors include: KNCV(\$23,525), CIDA (\$106,000), and WHO (\$44,500)

^{cxxix} GDF provided 100% of the state's need. According to the 1st year monitoring mission, in the previous year Government funding covered 1.4% of the states budget for TB drugs. GDF has not displaced resources that would otherwise have been available from the government or other donors- on the contrary, GDF filled the identified gap.

^{cxxx} The only information available is that for the financial year 2005/2006 the government bears the cost of manpower and infrastructure.

^{cxxxi} DANIDA provided US\$ 1 060 000. Budget breakdown not available to report TB drugs fund.

^{cxxxii} DANIDA provided US\$ 1 280 000. Budget breakdown not available to report TB drugs fund

^{cxxxiii} However, WHO supports the NTP: 2004-2005 biennium = \$34,000US

^{cxxxiv} The delivery of these drugs may be postponed until the following year as existing drugs stocks maybe be sufficient to meet this years drug needs.

^{cxxxv} No data available for Donor funds, however, there was 360,831 US\$ from GFATM.

^{cxxxvi} In addition to these Donor funds there is 1,600,000 US\$ from GFATM

^{cxxxvii} Advanced information - data for government and donor funding not available until 2nd year monitoring mission takes place.

Country	Source of TB Drugs Funding (US\$) ^{cxv}	Year before GDF Grant	During GDF Grant Year 1	During GDF Grant Year 2	During GDF Grant Year 3
Niger	Government funding	0	30,000		
	Donor funding	15,000 ^{cxviii}	15,000 ^{cxvix}		
	GDF funding	-	170,000 ^{cxl}	163,024	
Pakistan	Government funding	7,231,000	4,088,133	12,756,327	
	Donor funding	2,168,900 ^{cxli}	See footnote ^{cxlii}	3,759,199 ^{cxliii}	
	GDF funding	-	1,926,000	650,000 ^{cxliv}	
Rwanda	Government funding	201,900	102,400	470,745	
	Donor funding	NA	994,466	4,240,282	
	GDF funding	-	140,860	213,344	
Sierra Leone	Government funding	33,269	NA	344,733	
	Donor funding	NA	1,975,841	1,887,722	1,962,014 ^{cxlv}
	GDF funding	-	116,166	160,000	306,995
Somalia	Government funding	0	0	0	0
	Donor funding	NA	NA	214,000 ^{cxlvi}	214,586 ^{cxlvii}
	GDF funding	-	69,370	30,830	300,000
Sri Lanka	Government funding	^{cxlviii}			
	Donor funding	6,436,254 ^{cxlix}			
	GDF funding	-	32,896 ^{cl}		
Syrian Arab Republic	Government funding	NA	2,536,444		
	Donor funding	31,000 ^{cli}	7,000 ^{clii}		
	GDF funding	-	3,900	14,944	

^{cxviii} Funding source: WHO

^{cxvix} Ibid

^{cxl} Niger received two emergency grants prior to the first year of support which started in 07/05/2004. 1st emergency grant on 01/07/02 for 60,986 US\$ and second emergency on 15/12/03 for 18,000 US\$.

^{cxli} Figures multi-year grants which cover a period of 2003-2005.

^{cxlii} Figure not specific for one year period. It is represented in the figure 2,168,900 which covers a period from 2003 - 2005.

^{cxliii} Figures for year 2005-2006

^{cxliv} As a result of the Earthquake in 2005 an emergency grant was granted in November 2005 for a value of \$88,194.

^{cxlv} Committed figures: Donors include: GFATM, World Bank, GLRA.

^{cxlvi} Donor : WHO

^{cxlvii} Donor : WHO

^{cxlviii} See "donor funding". No specific government expenditure information was available.

^{cxlix} Donors include: 6.16 million US\$ from GFATM received in 2003 as a multi year grant, 33,500 US\$ from WHO, and 242,754 US\$ from FIDELIS.

^{cl} In addition Sri Lanka also received an emergency grant in August 2004 for a value of 145,000 US\$.

^{cli} Source: Country Visit Report March 2004.

^{clii} Ibid

Country	Source of TB Drugs Funding (US\$) ^{cxv}	Year before GDF Grant	During GDF Grant Year 1	During GDF Grant Year 2	During GDF Grant Year 3
Togo	Government funding	cliii	cliv	120,000	150,000
	Donor funding	clv	clvi	1,077,309 ^{clvii}	951,073 ^{clviii}
	GDF funding	-	34,200	24,932	50,000 ^{clix}
Uganda	Government funding	430,783	2,492,112	1,692,112	
	Donor funding	NA	3,272,742	3,581,356	
	GDF funding	-	520,000	90,000	1,980,678
Ukraine	Government funding ^{clx}	6,332,797			
	Donor funding ^{clxi}	NA			
	GDF funding	-	1,087,767 ^{clxii}		
Zambia	Government funding ^{clxiii}	NA ^{clxiv}	NA	NA	
	Donor funding	NA	5,650,000 ^{clxv}	3,960,000 ^{clxvi}	
	GDF funding	-	643,000 ^{clxvii}	490,000	

cliii Breakdown of the TB programme budget not available. A total budget of 174,976 US\$ was reported for the programme.

cliv GDF provided 100% of country's drug need; however, the total programme budget remained as previous year 174,976 US\$.

clv No budget breakdown, but GLRA and WHO provided 183,000 US\$ and 22,000 respectively for the TB programme (Source: first year monitoring mission report.)

clvi GDF 1st year monitoring mission report (June 2003) GLRA: 183,000 US\$ and WHO: 22,000 US\$.

clvii Donors include: DAHW, WHO, GFATM.

clviii Ibid

clix Togo has been approved for a 2nd term - 3 year grant. The 1st year of the 2nd term grant has a value of 40,968 US\$. It was approved in September 2005.

clx From Pre-delivery mission: "State financing for TB control activities comes from national and local budgets and in a World Bank loan (\$29.7 million of a \$60 million project is allocated for TB. With an additional amount for TB from within the Penitentiary system component). Since 1999, TB drugs have been centrally financed and procured, with expenditures in 2004, 2005 and budget for 2006 - 2004= 6,415,094, 2005 - 6,332,797 and 2006 - 6,900,000."

clxi See footnote above for "Government Funding"

clxii The final grant agreement currently being processed. This number represents a close estimation on the value in US\$ of the first year drug order.

clxiii Zambia does not have a separate budget line for TB.

clxiv Quote from the GDF Country Visit dated Nov/Dec 2003 " GDF has not displaced resources that would otherwise have been available from the government or other donors. No evidence to this effect has been found. The GDF emergency supply has supported to maintain drug availability in the country in a time that commitments by other donors could not be made. In the meantime JICA has committed itself to a smaller project providing only a "one-year" anti-TB drug supply to three provinces. The JICA drug order is expected to arrive in Zambia in June 2004 and will therefore reduce the original planned first year order through GDF".

clxv Donors include: CIDA, GFATM, CDC, and WHO. Additionally, JICA provided donation in-kind: one year supply of single drugs and laboratory supplies.

clxvi Donors include: CIDA, GFATM, CDC, and WHO. Additionally, JICA provided donation in-kind: one year of laboratory supplies.

clxvii Prior to receiving a 3 year grant Zambia received a 1 year emergency grant in 2002. This emergency grant had a value of 492,429 US\$.