

Progress Report 12

Stop TB Partnership
Global Drug Facility

1 January 2008 – 31 December 2008



Stop TB Partnership Secretariat
Geneva, Switzerland

Global Drug Facility Annual Report 2008

A word from the GDF Chief of Operations

1.0 Summary

2.0 Strategic Developments

- Business Trends
- Donor Investments

3.0 First Line Anti-Tuberculosis Medicines

- Grants of Adult and Paediatric anti-TB Medicines
- Procurement Data for First Line anti-TB medicines
- Adult Grant and Direct Procurement Services
- Childhood Tuberculosis and Paediatric Grant Services
- Diagnostics

4.0 Second Line Drugs

- Grants of MDR-TB Medicines
- Direct Procurement of MDR-TB Medicines
- Drug Management Sub-Committee

5.0 Technical Support for Drug Management

- Country Missions

6.0 GDF Operations

- Key Developments
- Business Advisory Committee

7.0 Challenges for 2009

Annex I: GDF Performance, Process and Impact indicators

Annex II: Statement of Income and Expenditure

Contact person for report queries: Raegan Boler, GDF Business Services Officer (bolerr@who.int)

A WORD FROM THE CHIEF OF OPERATIONS

In 2008 the GDF continued to make significant progress in increasing access to quality and affordable TB treatment and diagnosis. In this calendar year alone, GDF supplied 2.75 million treatments bringing the total number of treatments provided since GDF's inception in 2001 to nearly 14 million.



Highlights this year for GDF are manifold but of particular note were:

Securing funds from UNITAID for innovative, new initiatives such as the Strategic Rotating Stockpile for second-line medicines to treat MDR-TB (US\$ 11.5M) and the Strategic Revolving Fund (US\$ ~20M) to provide urgent bridge financing to eligible countries requiring second-line medicines prior to receiving normative funds from external sources. GDF also significantly increased the number of basic diagnostics supplied to countries and, together with the Global Laboratory Initiative and Foundation for Innovative New diagnostics, concluded an Agreement with UNITAID to supply new, rapid diagnostics for MDR-TB from 2009 - 2011.

The Direct Procurement Service continued to grow, assisting, among others, numerous Global Fund Principal Recipients. With financial support principally from USAID and CIDA, the GDF Grant Service enabled dozens of countries without support from other sources to receive emergency or regular supplies of quality assured, affordable first-line TB medicines and thereby avoid treatment interruptions. Additionally, GDF furthered its efforts to strengthen drug management capacity through technical support missions to countries and training activities at regional and country level.

On the operations front, GDF was able to recruit crucial additional staff positions including a Business Services Officer and Quality Systems Manager, both of whom are dedicated to ensuring that GDF's business management processes and tools are client oriented, optimize efficiency and achieve continuous improvement.

Although the above achievements are noteworthy the challenges remain formidable: there are still too few sources of quality assured MDR-TB medicines; forecasting of treatment demand at the global and country levels, while improving, is still sub-optimal; GDF remains understaffed; and funding for GDF operations and technical support activities is becoming strained as donors increasingly earmark funding for commodities.

In 2009, GDF will continue to work in close collaboration with the Green Light Committee, ramp up collaboration with the Global Laboratory Initiative and TB TEAM, further strengthen procurement and market interventions with the Global Fund and UNITAID, and partner with other key players under the Stop TB Partnership umbrella to ensure that high quality care with effective TB medicines and diagnostics is available to as many countries as possible.

I would like to express my sincere gratitude to my team whose hard work, industry and dedication give the GDF secretariat its solid foundation. On behalf of the GDF I would also like to thank all those partners who have enabled so many patients worldwide to be treated this year. We look forward to continuing to work together to overcome the challenges and seize the opportunities that lie ahead.

A handwritten signature in black ink, appearing to read 'R. Matiru'.

Robert Matiru
Chief of Operations, GDF

1.0 SUMMARY OF SERVICE DELIVERY IN 2008

This report covers the activities of the Global Drug Facility (GDF) from 1 January to 31 December 2008, which are summarized below. Further details are given in sections 1-7 (and annexes I and II).

Grants of free anti-TB medicines

In 2008 GDF continued to provide grants for free adult, first-line anti-TB medicines. Using monies from UNITAID, GDF also continued to provide grants of paediatric medicines as well as transitional grants of adult first-line medicines to countries facing temporary shortfalls.

During 2008 forty-seven (47) applications were reviewed by the TRC or through delegated reviews of which thirty-seven (37) were approved for GDF grants of anti-TB medicines and two (2) were direct procurement requests. These grants represent treatments for 899,633 patients being treated under DOTS programs worldwide at an estimated total cost of US\$ 25,097,247.

In 2008, one hundred and ten (110) grant orders were placed for first-line adult and paediatric anti-TB medicines. These orders had a total value of approximately US\$ 38 million. Furthermore, one hundred and thirty-three (133) orders were delivered to countries in need, with a total value of US\$ 35.3 million. GDF delivered 1,993,938 patient treatments to fifty-four (54) grant recipients.

In 2008, thirty-five (35) orders were placed for paediatric medicines through GDF's grant service. These orders, for thirty-two (32) countries, had a total value of US\$ 482,554. GDF delivered sixty-four (64) orders to forty-four (44) grant recipients. These orders, with a cumulative value of US\$ 1,087,575 allowed for the provision of 163,804 curative and 91,786 preventative treatments for children with TB.

Through the UNITAID MDR-TB Scale-up Project, twelve (12) of the seventeen (17) approved countries placed twenty-nine (29) orders in 2008. These orders had a total product value of US\$ 3,032,994¹. GDF delivered twenty-seven (27) second line medicine grant orders to 12 recipient countries. These orders had a total product value of US\$ 2,115,238 and comprised treatments for approximately 1,598 patients.

Direct Procurement (DP) of anti-TB medicines

In 2008, fifty-nine (59) first-line DP orders were placed by forty-two (42) countries with a value of US\$ 12,842,847. Of these fifty-nine (59) orders, twenty-one (21) orders were placed using Global Fund monies. The total product value of orders placed using Global Fund monies was US\$ 8,180,376. Other countries used a variety of complementary sources of funds including WHO, UNDP, CERF² Emergency Funding and government funds from national budget lines.

From 1 January 2008 - 31 December 2008, GDF delivered 65 first-line DP orders to 43 countries. These orders represented 763,145 patient treatments (a 73.1% increase

¹ The difference between the values in this section and the values reported in the UNITAID 2008 annual report are the result of further analysis of GDF's data identifying orders not previously attributed to the UNITAID project and order KGZ/GR/08/449 being reported as delivered in 2008 when delivery actually occurred in 2009.

² Central Emergency Response Fund

over the 440,752 patient treatments ordered through the DP service in 2007) and had a total product value of US\$ 18,207,966.

2008 also saw the growth of GDF's MDR-TB medicine DP service with the delivery of 68 orders to 30 recipient countries approved by the Green Light Committee with a total product value of US\$ 9,959,424 (see Table 8 below for more details). Additionally, GDF saw 69 orders placed for second-line medicines by 32 countries for a cumulative total of US\$ 15,441,769. This shows a 58% growth in orders placed for second-line anti-TB medicines over 2007 (US\$ 9,750,306).

In 2007, GDF began providing diagnostic equipment through its DP service to assist country programs with the detection of TB. 2008 saw a marked increase in the total number of units ordered. In 2008, nine (9) countries placed orders for diagnostic equipment, totaling a value of US\$ 559,089.

GDF technical support for drug management

During this reporting period GDF performed 76 missions to 63 different countries in all six WHO Regions. Of these, five (5) were pre-delivery country visits, forty-one (41) were grant monitoring missions, twenty-two (22) were DP technical support missions and eight (8) were technical assistance missions.

In 2008, GDF also organized, assisted with or participated in many support interventions for programs accessing second-line anti-TB medicines through the GLC Initiative.

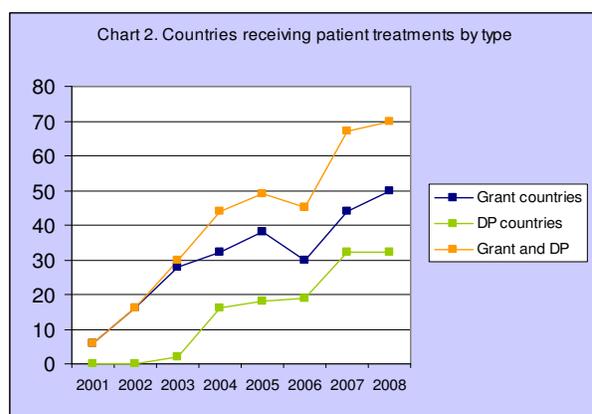
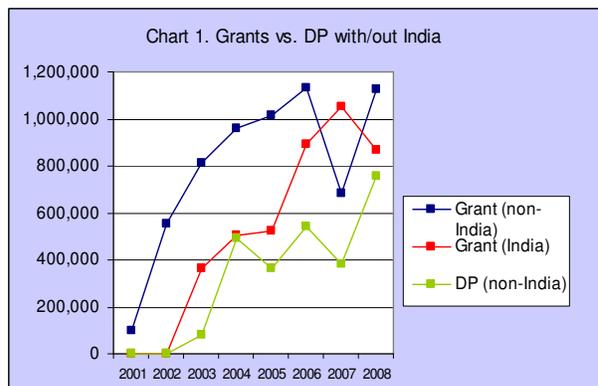


Photo: Vaneet Bhatia

2.0 STRATEGIC DEVELOPMENTS

Business Trends

- GDF saw an increase in the number of patient treatments delivered under its grant services in 2008 (1.99 million patient treatments) compared to 2007 (1.73 million patient treatments). This increase in patient treatments provided through grants can be attributed to large orders made by: Kenya, Myanmar, Nigeria and Pakistan compared to their orders made in 2007.
- The number of patients treated through the direct procurement (DP) service in 2008 was 763,145, a 73.1% increase over the 440,752 patient treatments ordered through the DP service in 2007. This increase is due, in part, to large DP orders being placed by: Bangladesh, Indonesia, Pakistan and the Philippines.
- The number of countries receiving grant orders increased slightly (from 44 to 50) with the number of countries receiving direct procurement orders increasing from 32 to 43.



Donor Investments

GDF's mandate is to contribute to the realization of the TB-related Millennium Development Goals and to the eventual elimination of TB through the provision of timely, quality assured and affordable anti-TB medicines and related supplies. In order to be successful in this mission, GDF relies strongly on the generosity of its donors. Monies from donors are used to provide grants of first line anti-TB medicines to eligible countries that do not have sufficient funds for this purpose. Also, minimal funds are used for GDF operational costs while still ensuring that GDF has the adequate resources to effectively and efficiently perform its services.

In 2008, GDF received approximately US\$ 63.7 million from donors, including donations in kind, which includes the secondment of staff to assist with GDF operations.

Table 1: Contributions received for GDF 2001 - 2008									
(including in-kind contribution US\$' 000)									
	2001	2002	2003	2004	2005	2006	2007	2008	Total
CIDA	9,944	3,723	8,530	11,347	20,643	22,862	7,139	9,202	93,390
Netherlands	4,041	1,959	2,587	194			750		9,531
USAID	1,250	2,000	3,000	3,000	4,700	5,000	5,250	14,879	39,079
UK (DFID)			595						595
Norway			748	810	743	899	991	788	4,979
World Bank		250	250						500
Open Society Institute			250						250
Harvard University Medical School (in kind)			130						130
Japan (for Cambodia)			46						46
Research Institute of Tuberculosis, Japan (in-kind)		21							21
Procter & Gamble			25						25
Partners in Health									0
Management Sciences for Health (in Kind)		137		188	188	125	0	495	826
Novartis Foundation for Sustainable Development (in kind) ³					2,605	3,226	2,340	1,033	9,204
DFID (India program)						11,962	13,601	14,330	39,893
UNITAID							31,436	22,832	54,268
Gate's Foundation								113	
Medecins sans Frontieres (in kind)								114	
Total	15,235	8,091	16,349	15,539	28,879	44,074	61,507	63,786	252,737

In 2008:

- GDF continued to receive ongoing support from its long time donors for the provision of quality anti-TB medicines to countries in need, as well as for operational costs.
- The Canadian International Development Agency (CIDA), a GDF partner since 2001, contributed approximately US\$ 9.2 million for first-line anti-TB medicine grants and related costs.
- The United States Agency for International Development (USAID), also a GDF partner since its inception in 2001, contributed approximately US\$ 14.9 million to assist GDF to meet its first-line anti-TB medicines grant service mandate.
- The Government of Norway gave US\$ 788,000, continuing their annual contributions beginning in 2001.
- Novartis Foundation for Sustainable Development's support to GDF was approximately US\$ 1 million.

³ Anti-TB medicines

- Department for International Development (DFID) funds continued to be used to provide quality first-line anti-TB treatments in India, the country with the highest burden of TB.
- Management Sciences for Health (MSH) continued to assist GDF with their in-kind donation of staff time and expertise, supporting GDF with several key projects in 2008, including the development of a drug database to monitor the quality assurance of medicines provided by GDF.
- During 2008 UNITAID increased their commitment from US\$ 5,665,000 to US\$ 11,603,952 for GDF to procure and supply quality-assured paediatric medicines from 2007 - 2011. In the first year of project implementation, operations have been focused on rapid scale-up of supply through aggregated demand and pooled procurement as a means of expanding access and positively impacting the limited market for paediatric TB medicines.
- An addendum to the original MDR TB Scale up Project funded by UNITAID was approved in July 2008, raising the budget ceiling from US\$ 20,820,000 to US\$ 37,662,000 thereby enabling an increase to the total number of patients receiving treatments from 4,716 to of 5,756 MDR-TB patients through the Project.
- In November 2008, GDF and UNITAID signed an Agreement for the MDR-TB Acceleration of Access Initiative: 2008 - 2011. This Agreement will allow for the establishment of Strategic Rotating Stockpile (SRS) i.e. an increase of the current Stockpile from 800 patient treatments worth of second-line drugs to 5800. The SRS is expected to become fully operational in Q2 2009.
- The Gates foundation supported GDF through a donation of US\$ 113,000.
- Mediciens sans Frontieres provided GDF with support in kind equaling US\$ 114,000.

3.0 FIRST LINE ANTI-TUBERCULOSIS MEDICINES

In 2008, GDF continued to provide quality support to countries in need of anti-TB medicines that were unable, through government or alternate funding, to secure the finances needed. GDF continued to provide grants of free adult anti-TB medicines to countries worldwide that were assessed by the GDF Technical Review Committee (TRC) and approved by the Stop TB Partnership Coordinating Board. Additionally, with the support of UNITAID, GDF continued to provide high quality paediatric anti-TB medicines as well as transitional grants to countries facing temporary first-line anti-TB medicine shortfalls.

Grant and DP requests for Adult and Paediatric anti-TB Medicines evaluated through the Technical Review Committee (TRC)

Two (2) rounds of the TRC were held in 2008, three (3) countries were reviewed through ad hoc TRC reviews and five (5) countries were reviewed through delegated reviews.⁴

⁴ Delegated technical reviews: Approvals made based on a monitoring mission report combined with an assessment by an external desk auditor do not need to go to the TRC for review.

Review of Programme Applications

During 2008 forty-seven (47) applications were reviewed by the TRC or through delegated reviews of which thirty-seven (37) were approved for GDF grants of anti-TB medicines and two (2) were direct procurement requests. These grants represent treatments for 899,633 patients being treated under DOTS programs worldwide at an estimated total cost of US\$ 25,097,247.

Of the forty-seven (47) applications reviewed by the TRC, twenty-two (22) were new applications and five (5) were emergency requests. This raises the cumulative number of new applications reviewed by the GDF TRC to two hundred and thirteen (213) since 2001, with one hundred and seventy (170) being approved for a GDF grant.

Summary of Adult Grants Approved

In 2008, twenty-six (26) grant and DP applications for Adult anti-TB medicines plus one (1) application for diagnostics were reviewed by the TRC or through delegated technical reviews. Of these, 23 applications were approved.

Applications received contained:

- 5 applications for new 1st term grants
- 4 applications for Emergency Adult grants
- 10 applications for Adult Monitoring grants⁵
- 4 applications for Adult 2nd term grants
- 2 applications for Direct Procurement
- 1 application for a 7th year grant (exception)

Three (3) 1st term grant applications were approved, however one (1) grant approval was conditional (Ethiopia) pending further information or action from the country. Emergency grants for Guinea Bissau, Liberia, Nepal, and Timor Leste were all approved. Nine (9) of the adult monitoring grant requests were approved as were the four (4) applications for Adult 2nd term grants, however, the approval for Tanzania was conditional pending further information from the country. Gabon was approved for its Direct Procurement request; however the drug request was conditional. A 7th year grant was exceptionally granted to the Democratic People's Republic of Korea.

In total, in 2008, grants were approved for 876,028 patients with an estimated cost of US\$ 24,306,597.

⁵ Monitoring Grant = approval for 2nd or 3rd year grant of a previously approved 3 year grant cycle.

Table 2: Adult TRC Grant Applications

Country Reviewed	Applied for	TRC Recommendation/ Coordinating Board Approval	Patients Approved	Income Level Classification	Total Cost
Liberia	Adult Emergency	Approved	5060	LIC	230,000
Iraq	Adult - New	Approved	10,500	LMIC	432,000
Sierra Leone	Adult - Monitoring	Approved	9800	LIC	386,260
Zambia	Adult-Monitoring	Approved	45,000	LIC	1,436,000
Burkina Faso	Adult 2 nd Term Grant	Approved	3052	LIC	85,343
Guinea	Adult 2 nd Term Grant	Approved	4761	LIC	47,006
Nigeria	Adult 2 nd Term Grant	Approved	127,500	LIC	6,500,000
Tanzania	Adult 2 nd Term Grant	Yellow Light/Conditional	65,000	LIC	620,000
Gabon	DP	Approved/Conditional	40,000	UMIC	109,399
Gabon (lab kits)	DP	Approved		UMIC	8,930
Swaziland	Adult - New	Under Consideration		LMIC	
Zimbabwe	Adult - New	Approved	54,000	LIC	2,022,676
Kiribati	Adult - New	Under Consideration		LMIC	
Ethiopia	Adult - New	Conditional	184,482	LIC	3,500,000
Democratic Republic of Timor-Leste	Adult Emergency	Approved	2743	LMIC	140,260
Guinea-Bissau	Adult Emergency	Approved	2400	LIC	158,966
Nepal	Adult Emergency	Approved	35,000	LIC	639,766
Burundi	Adult Monitoring	Approved	9109	LIC	276,122
Malawi	Adult Monitoring	Approved	24,500	LIC	657,373
Congo Brazzaville	Adult Monitoring	Not Approved		LIC	
Nigeria	Adult Monitoring	Approved	100,038	LIC	1,750,000
Democratic People's Republic of Korea	Adult 7 th year Exception	Approved	88,630	LIC	3,000,000
Ukraine	Adult - Monitoring	Approved	20,083	LMIC	1,296,000
Laos	Adult - Monitoring	Approved	5635	LIC	121,092
Djibouti	Adult - Monitoring	Approved	4218	LMIC	96,863
Cote D'Ivoire	Adult - Monitoring	Approved	34,517	LIC	792,541
		Total Number	876,028		24,306,597

Summary of Paediatric Grants Approved

In 2008, twenty-two (22) applications were reviewed for paediatric grants by the TRC or through delegated reviews. Of these, fourteen (14) were approved.

Applications received contained:

- 16 applications for new Paediatric Grants

- 6 applications for Monitoring Grants

Nine (9) of the requests for new Paediatric Grants were approved, however four (4) of these approvals were conditional (Mongolia, Mozambique, Senegal, and Tanzania). Of the six (6) Monitoring Grants, five (5) were approved, with two (2) of the approvals being conditional (Burundi and Egypt).

Overall in 2008, grants were approved for 23,605 paediatric patients totaling US\$ 790,650.

Table 3: Paediatric TRC Grant Applications

Country Reviewed	Applied for	TRC Recommendation/ Coordinating Board Approval	Patients Approved	Income Level Classification	Total Cost
Burkina Faso	Paediatrics - New	Approved	175	LIC	10,446
Georgia	Paediatrics - New	Approved	414	LMIC	9,400
Mozambique	Paediatrics - New	Yellow Light/Conditional	3410	LIC	126,000
Senegal	Paediatrics - New	Approved/Conditional	750	LIC	25,715
United Republic of Tanzania	Paediatrics - New	Yellow Light/Conditional	1300	LIC	41,500
Togo	Paediatrics - New	Under Consideration		LIC	
Uganda	Paediatrics - New	Not approved		LIC	
Guinea	Paediatric Monitoring	Approved	344	LIC	48,421
Zambia	Paediatric Monitoring	Under Consideration		LIC	
Mongolia	Paediatrics - New	Yellow Light/Cautious	286	LMIC	9,170
Thailand	Paediatrics - New	Approved	4600	LMIC	207,755
Liberia	Paediatrics - New	Not Approved		LIC	
Swaziland	Paediatrics - New	Under Consideration		LMIC	
Nigeria	Paediatrics - New	Approved	5911	LIC	222,516
Togo	Paediatrics - New	Under Consideration		LIC	
Papua New Guinea	Paediatrics - New	Approved	2400	LIC	27,700
Zimbabwe	Paediatrics - New	Not Approved		LIC	
Kiribati	Paediatrics - New	Under Consideration		LMIC	
Burundi	Paediatrics Monitoring	Conditional	455	LIC	3,664
Egypt	Paediatrics Monitoring	Conditional	569	LMIC	23,900
Cambodia	Paediatric - Monitoring	Approved	2871	LIC	30,808
Benin	Paediatric - Monitoring	Approved	120	LIC	3,655
		Total Number	23,605		\$790,650

Procurement Data for First Line anti-TB medicines



Photo: Ron Wehrens, Phasuma

Tuberculosis in Adults

With an estimated 13.7 million prevalent cases of TB in 2007⁶, GDF's mandate to provide quality medicines to countries in need is more important than ever. Continuing its core service since 2001, GDF continued, in 2008, to provide adult anti-TB medicines via both its grant and direct procurement services.

Adult Grants

In 2008, one hundred and ten (110) grant orders were placed for first-line adult and paediatric anti-TB medicines. These orders had a total value of approximately US\$ 38 million. Furthermore, one hundred and thirty-three (133) orders were delivered to countries in need, with a total value of US\$ 35.3 million. GDF delivered 1,993,938 patient treatments to 54 grant recipients (see Table 4).

Table 4: Deliveries of anti-TB medicines to GDF Grant Recipients in 2008⁷

Country	Grant Type	Patient Treatments
Afghanistan	Adult 1 st Line	29,738
Burundi	UNITAID Paediatric	687
Benin	UNITAID Paediatric	115
Bangladesh	UNITAID Paediatric	16,800
Bosnia and Herzegovina	UNITAID 1 st Line	3,727
Cote d'Ivoire	UNITAID 1 st Line	34,517
Cameroon	UNITAID Paediatric	1,380
Congo	UNITAID Paediatric	398
Congo	Adult 1 st Line	12,210
Cape Verde	UNITAID Paediatric	48
Cape Verde	Adult 1 st Line	363
Cape Verde	UNITAID Paediatric	0
Djibouti	UNITAID 1 st Line	4,218
Egypt	UNITAID Paediatric	168
Egypt	UNITAID Paediatric	0
Eritrea	UNITAID Paediatric	408

⁶ Global Tuberculosis Control 2009, Epidemiology, Strategy, Financing, World Health Organization

⁷ UNITAID 1st Line = paid for using UNITAID monies, Adult 1st Line = paid for using funds from a non-UNITAID source, UNITAID Paediatric = paid for using UNITAID monies, India Adult and Paediatric= paid for using DFID funds.

Eritrea	UNITAID Paediatric	0
Georgia	UNITAID Paediatric	418
Guinea	UNITAID Paediatric	1,196
Guinea	UNITAID 1 st Line	9,427
Gambia	UNITAID Paediatric	180
Guinea-Bissau	UNITAID Paediatric	255
Guinea-Bissau	Adult 1 st Line	5,093
Haiti	UNITAID 1 st Line	22,294
India	India - Adult	790,600
India	India - Paediatric	74,700
Iraq	Adult 1 st Line	15,724
Jordan	UNITAID Paediatric	156
Kazakhstan	UNITAID Paediatric	5,647
Kenya	UNITAID 1 st Line	128,508
Kyrgyzstan	UNITAID Paediatric	1,440
Kyrgyzstan	Adult 1 st Line	4,543
Cambodia	UNITAID Paediatric	2,871
Lao People's Democratic Republic	Adult 1 st Line	5,635
Lebanon	UNITAID Paediatric	36
Liberia	Adult 1 st Line	8,682
Sri Lanka	Adult 1 st Line	12,854
Sri Lanka	UNITAID Paediatric	434
Lesotho	UNITAID Paediatric	1,121
Lesotho	Adult 1 st Line	20,685
Morocco	UNITAID Paediatric	2,948
Madagascar	UNITAID Paediatric	2,297
Madagascar	UNITAID 1 st Line	33,968
The Former Yugoslav Republic of Macedonia	UNITAID Paediatric	86
Mali	UNITAID Paediatric	312
Myanmar	UNITAID Paediatric	29,218
Myanmar	Adult 1 st Line	100,552
Mozambique	Adult 1 st Line	23,439
Mauritania	UNITAID Paediatric	158
Malawi	UNITAID Paediatric	5,280
Niger	UNITAID Paediatric	1,200
Nigeria	Adult 1 st Line	155,614
Nepal	Adult 1 st Line	24,871
Pakistan	Adult 1 st Line	138,006
Democratic People's Republic of Korea	Adult 1 st Line	85,577
Democratic People's Republic of Korea	UNITAID Paediatric	3,564
Sudan	UNITAID Paediatric	624
Sierra Leone	UNITAID Paediatric	1,494
Sierra Leone	Adult 1 st Line	17,821
Somalia	UNITAID Paediatric	1,591
Turkmenistan	UNITAID Paediatric	214
Turkmenistan	Adult 1 st Line	7,373
Democratic Republic of Timor-Leste	Adult 1 st Line	2,061
United Republic of Tanzania	Adult 1 st Line	43,998
Yemen	UNITAID Paediatric	360
Zambia	UNITAID Paediatric	6,000
Zambia	Adult 1 st Line	88,036
Total Countries: 50⁸	Total Patient Treatments:	1,993,938

Since beginning its grant program in 2001, GDF has delivered approximately 10,584,660 patient treatments through its grant services.

⁸ Table does not include: Indonesia, Rwanda, Tajikistan and Uganda - these countries received deliveries, however all patient treatments were reported in 2007.

Adult Direct Procurement

In 2008, fifty-nine (59) DP orders were placed by forty-two (42) countries with a value of US\$12,842,847. Of these fifty-nine (59) orders, twenty-one (21) orders were placed using Global Fund monies. The total product value of orders placed using Global Fund monies was US\$ 8,180,376. Other countries used a variety of other sources of funds including WHO, UNDP, CERF⁹ Emergency Funding and government funds from national budget lines.

From January 1, 2008 - December 31, 2008 GDF delivered sixty-five (65) DP orders to forty (43) countries. These orders represented 763,145 patient treatments and had a total product value of US\$ 18,207,966.

Table 5: Direct Procurement orders delivered in 2008

Country	Patient Treatments	Type	All Products
Angola	23,939	Direct Procurement	513,413.49
Armenia	2,560	Direct Procurement	58,997.37
Azerbaijan	762	Direct Procurement	242,748.22
Bangladesh	163,163	Direct Procurement	3,247,097.42
Belarus	762	Direct Procurement	221,376.32
Democratic Republic of the Congo	72,849	Direct Procurement	1,876,164.06
Djibouti	Diagnostics	Direct Procurement	22,500.00
Ghana	18,031	Direct Procurement	394,405.26
Gambia	1,648	Direct Procurement	23,589.15
Indonesia	123,258	Direct Procurement	3,551,060.80
India		WHO Direct Procurement	513,820.62
Iraq	8,398	Direct Procurement	246,712.84
Israel	Pyrazinamide	WHO Direct Procurement	157.76
Cambodia	Diagnostics	WHO Direct Procurement	16,900.00
Lebanon	2,157	Direct Procurement	38,221.95
Republic of Moldova	5,902	Direct Procurement	158,142.85
The Former Yugoslav Rep of Macedonia	1,005	Direct Procurement	12,661.47
Mali	RHE, E, Syringes	Direct Procurement	8,226.73
Myanmar	9,382	Direct Procurement	507,085.58
Mongolia	5,904	Direct Procurement	112,654.41
Mauritania	357	Direct Procurement	8,089.71
Malawi	Diagnostics	WHO Direct Procurement	21,510.00
Niger	Diagnostics	Direct Procurement	63,215.48
Niger	3,014	Direct Procurement	60,278.00
Nigeria	Diagnostics	WHO Direct Procurement	237,104.00
Nepal	30,369	Direct Procurement	599,924.13
Oman	300	Direct Procurement	6,219.00
Pakistan	71,224	Direct Procurement	1,350,857.13
Philippines	123,740	Direct Procurement	2,007,598.62
Philippines		WHO Direct Procurement	304,998.93
Papua New Guinea	Diagnostics	Direct Procurement	29,844.00
Papua New Guinea	9,285	Direct Procurement	228,997.65
Democratic People's Republic of Korea	Diagnostics	WHO Direct Procurement/Diagnostics	29,744.00
Sudan	Diagnostics	Direct Procurement	46,380.00
Sudan	27,300	Direct Procurement	300,699.34
Sudan		WHO Direct Procurement	23,091.97
Solomon Islands	840	Direct Procurement	15,615.00
Somalia	15,686	Direct Procurement	306,950.39
Republic of Serbia	1,760	Direct Procurement	48,492.45
Swaziland	10,471	Direct Procurement	260,533.64
Syrian Arab Republic	3,180	Direct Procurement	71,564.40
Chad	3,696	Direct Procurement	22,810.76
Togo	2,651	Direct Procurement	47,363.60
Turkmenistan		WHO Direct Procurement	3,124.00
Democratic Republic of Timor-Leste	Diagnostics	WHO Direct Procurement	6,230.00
Uzbekistan	10,671	Direct Procurement	292,154.88
Samoa	106	WHO Direct Procurement	2,619.12
Zimbabwe	Diagnostics	Direct Procurement	46,020.00
Total Countries: 43	754,370		\$18,207,966.50

Since its inception in 2001, GDF has delivered approximately 3,325,978 patient treatments to countries in need through its DP service.

⁹ Central Emergency Response Fund

Paediatric Grants

Currently Paediatric medicines are only available via GDF's Grant service; however, in 2009 GDF will explore the possibility of providing these medicines for eligible countries through the DP service as well.

GDF's partnership with UNITAID has been instrumental in increasing the profile of combating TB in children and has directly contributed to more countries seeking to purchase quality anti-TB medicines in paediatric formulations.

UNITAID's commitment of US\$ 11,603,952 to GDF to procure and supply quality-assured paediatric drugs from 2007 - 2011 has enabled GDF to provide grants to countries in need for over 300,000 paediatric treatments. In January 2009, GDF and UNITAID finalized a Memorandum of Understanding within which UNITAID enlarged its support for paediatric medicines by increasing its contribution by US\$ 5,623,409 allowing for provision of an additional 150,000 patient treatments.

In 2008, thirty-five (35) orders were placed for paediatric medicines through GDF's grant service. These orders, for thirty-two (32) countries, had a total value of US\$ 482,554. GDF delivered 64 orders to 44 grant recipients. These orders, with a cumulative value of US\$ 1,087,575 allowed for the provision of 163,804 curative and 91,786 preventative treatments for children with tuberculosis.

Since the launch of the UNITAID Paediatric TB Project in January 2007, fifty-five (55) countries, in Africa, Central, South and South-East Asia and in the Middle-East and the Caucasus, have been approved for and/or are receiving Grants of quality-assured paediatric-formulated drugs for the curative and preventive TB treatment of more than 300,000 children.

New dosages anticipated: GDF was involved in the July 2008 meeting of the *Childhood TB subgroup* of the Stop TB Partnership's *DOTS Expansion Working Group*. The meeting reviewed the evidence supporting current formulation and dosage guidelines for paediatric TB drugs and resulted in recommendations of new dosages¹⁰. These recommendations are in the process of endorsement by WHO and are expected to be published sometime in mid-2009. This will dramatically impact the strategy for supplying paediatric medicines in recipient programmes adhering to WHO's new recommendations. GDF has undertaken preparatory steps to face this upcoming challenge/opportunity in close collaboration with WHO's relevant actors in the Stop TB Department and the WHO Prequalification Programme.

Diagnostics

In 2007, GDF began providing diagnostic equipment through its DP service to assist country programs with the detection of TB. 2008 saw a marked increase in the total number of units ordered. In 2008, nine (9) countries placed orders for diagnostic equipment, totaling a value of US\$ 559,089. Further growth in this area is anticipated in 2009, with the signing of a collaborative agreement between GDF, the Global Laboratory Initiative (GLI), UNITAID and the Foundation of Innovative New Diagnostics (FIND). The overarching objective of the "Expand-TB Project" is to

¹⁰ http://www.who.int/selection_medicines/committees/subcommittee/2/TB.pdf

provide quality diagnostic equipment to selected countries to increase the speed and accuracy with which MDR-TB is detected. GDF, as the procurement partner for this project, will therefore see further increases in number of order requests for diagnostic equipment.

Table 6: Diagnostic product orders through GDF

	2008	2007		Cumulative
Number of Countries that placed Diagnostic orders	9	8		
Consumables Kits	1786	1130	units	2916
Microscope kits*	131	94	units	225
Sputum Containers	1755	945	units	2700
Equipment Starter Kits	450	73	units	523
Total Value:	\$559,089	\$361,117		\$920,206
* Includes Microscope kits without microscope (1 order)				

4.0 SECOND LINE ANTI-TUBERCULOSIS MEDICINES

The collaboration between the Green Light Committee (GLC) and GDF for the provision of quality second-line medicines to eligible countries began in late 2006. Since its inception, this partnership has seen much growth and development with 2008 being no exception.

In September 2008, GDF launched a global invitation to manufacturers to submit Expressions of Interest (EOI) to supply second-line anti-TB medicines through GDF. The list of eligible products included: Amikacin, Amoxicillin + Clavunavic acid, Capreomycin, Clofazamine, Cycloserine, Ethionamide, Kanamycin, Levofloxacin, Linezolid, Moxifloxacin, Ofloxacin, Prothionamide, PAS Acid, PAS Sodium, Terizidone and Thioacetazone.

In total 53 dossiers were received and will be evaluated in Q1 2009 for acceptability by a GDF-appointed Technical Evaluation Committee (TEC) comprising a pharmacist from GDF and key Stop TB Partners in collaboration with experts from WHO PQ. Those product dossiers that are deemed complete by the TEC and in full compliance with the Quality Assurance standards of the EOI will be automatically eligible for submission into GDF/IDA's Tender (scheduled for end Q2 2009).

In addition to the above, four (4) dossiers for second-line anti-TB medicines were submitted and accepted for evaluation by the WHO Prequalification Programme. Drugs covered by the dossiers include: Capreomycin, Cycloserine, Levofloxacin and Prothionamide. GDF will continue to monitor these submissions to determine the final approval outcome.

Grants

Through the UNITAID MDR-TB Scale-up Project, twelve (12) of the seventeen (17) approved countries placed twenty-nine (29) orders in 2008. These orders had a total product value US\$ 3,032,994¹¹.

¹¹ The difference between the values in this section and the values reported in the UNITAID 2008 annual report are the result of further analysis of GDF's data identifying orders not previously attributed to the UNITAID project and order KGZ/GR/08/449 being reported as delivered in 2008 when delivery actually occurred in 2009.

In 2008 GDF delivered twenty-seven (27) second line medicine grant orders to 12 recipient countries. These orders had a total product value of US\$ 2,115,238 and comprised treatments for approximately 1,598 patients.

Table 7: UNITAID MDR-TB Orders delivered 2008

Country	Patient Treatments	All Products
Azerbaijan	120	172,659.05
Azerbaijan		73,776.77
Azerbaijan		225,238.85
Cambodia	40	32,687.64
Cambodia		35,447.04
Democratic Republic of the Congo	275	254,891.56
Democratic Republic of Timor-Leste	8	19,860.30
Dominican Republic	201	98,535.88
Dominican Republic		48,011.28
Guinea	16	4,620.33
Guinea		322.40
Haiti	24	31,625.40
Haiti		33,903.87
Kyrgyzstan	160	164,700.78
Kyrgyzstan		2,547.70
Lesotho	100	155,497.38
Lesotho		10,911.20
Lesotho		324.57
Lesotho		6,971.80
Nepal	450	29,394.90
Nepal		38,588.54
Nepal		68,465.86
Republic of Moldova	150	139,787.35
Republic of Moldova		202,947.82
Uzbekistan	54	145,236.96
Uzbekistan		105,145.20
Uzbekistan		13,137.83
Total:	1,598	\$2,115,238.26

As the need for quality Second Line anti-TB medicines increases, GDF and its grant financing partner in this arena, UNITAID, are striving to meet this demand. In 2008 UNITAID demonstrated its commitment to the fight against MDR-TB by increasing its contribution to the MDR-TB Scale-up Project by an additional US \$16,840,000 (from US\$ 20,820,000 to US\$ 37,662,000) allowing for a revised total of 5,756 MDR-TB patients (previously 4,716 patients) to benefit from the treatments provided through the Project.

Direct Procurement

2008 also saw the growth of GDF's second-line MDR-TB medicine DP service with the delivery of 68 orders to 30 recipient countries with a total product value of US\$ 9,959,424 (see Table 8 below for more details). Additionally, GDF saw 69 orders placed for second-line medicines by 32 countries for a cumulative total of US\$ 15,441,769. This shows a 58% growth in orders placed for second-line anti-TB medicines over 2007 (US\$ 9,750,306).

Table 8: Value of Second Line Direct Procurement orders delivered in 2008

Country	All Products		
Armenia	\$3,306.30	Mongolia	\$298.68
Armenia	\$29,089.02	Mongolia	\$22,141.91
Armenia	\$58,204.98	Mongolia	\$23,980.92
Bangladesh	\$98,465.18	Mongolia	\$41,130.52
Burkina Faso	\$26,779.14	Mongolia	\$13,357.13
China	\$194,598.40	Mongolia	\$14,067.01
Costa Rica	\$3,517.59	Nepal	\$12,671.89
Democratic Republic of the Congo	\$256,642.27	Nicaragua	\$1,725.15
Egypt	\$74,751.40	Paraguay	\$7,238.24
Egypt	\$92,790.64	Peru	\$406,962.80
Egypt	\$202,490.37	Peru	\$74,280.00
Egypt	\$4,645.55	Peru	\$1,726,249.52
El Salvador	\$4,012.64	Philippines	\$15,460.70
Estonia	\$138,760.26	Philippines	\$654,308.20
Estonia	\$74,339.14	Philippines	\$587,762.72
Georgia	\$57,485.47	Philippines	\$117,654.48
Georgia	\$45,956.96	Philippines	\$237,181.93
Georgia	\$27,595.03	Republic of Moldova	304,748.40
Georgia	\$24,423.52	Republic of Moldova	\$76,554.65
Georgia	\$22,227.85	Russian Federation	\$166,685.86
Georgia	\$261,235.41	Russian Federation	\$173,954.02
Georgia	\$571,646.43	Russian Federation	\$1,159,224.99
Guatemala	\$88,553.14	Rwanda	\$94,854.12
Honduras	\$49,339.13	Samoa	\$1,458.73
India	\$64,754.72	Syrian Arab Republic	\$16,572.86
India	5324.72	Tunisia	\$26,510.00
India	32542.22	Tunisia	\$3,981.60
Jordan	\$3,751.00	Tunisia	\$10,146.50
Jordan	\$19,178.20	Uzbekistan	\$20,515.68
Kazakhstan	\$34,668.00	Uzbekistan	\$7,010.85
Kazakhstan	\$121,841.66	Uzbekistan	\$304,969.10
Kenya	\$43,241.28	Uzbekistan	\$149,963.26
Kenya	\$43,241.28	Uzbekistan	\$250,931.56
Kyrgyzstan	\$452,455.16	Uzbekistan	\$3,016.00
		Total	\$9,959,424.04

Of the overall total orders placed for second-line anti-TB medicines through the GDF DP service, forty-seven (47) were placed using monies from the Global Fund. These orders had a total product value of US\$14,246,566.

Due to the wide variety of treatment regimens used in countries and the long duration of the treatment cycle (18 - 24 months) determining the exact number of patient treatments provided to recipients is difficult. However, GDF estimates having provided between 9,000 and 11,000 patient treatments¹² to new and continuation phase patients enrolled in GLC approved programs. For more specific information on Second-Line patient treatments, please consult the GLC Annual Report: 2008 on the GLC website at: <http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/index.html>

¹² From Verification of Patient Enrolment vs. drug delivered of Forecast for 2009_STM.doc

Expert Committee to assist with issues related to Second Line anti-TB medicines Management

Drug Management Sub-Committee (DMSC)

Since its inception in September 2007 the DMSC of the Stop TB Partnership's MDR-TB Working Group, convened and hosted by GDF, has been instrumental in assisting GDF in addressing the growing needs relating to MDR-TB drug management. The DMSC meets, via teleconference, once a month to assist GDF in addressing key issues relating to the procurement of quality anti-MDR-TB medicines. The DMSC has assisted GDF in securing interim suppliers to avoid stock out situations, performing market research and in identifying potential new sources of second-line anti-TB drugs. Below are a few key areas where the DMSC has aided GDF during this reporting period:

- Identifying producers for Levofloxacin, Moxifloxacin and Kanamycin
- Supported GDF in negotiations with Eli Lilly re: Capreomycin quota
- Requested access to particular drugs from suppliers at concessional prices
- Advised GDF on the content of the Strategic Rotating Stockpile, which drugs and percentage of drugs within the drug categories e.g. fluoroquinolones and injectables.
- Endorsed provisional approval of some drugs to meet specific country demand due to shortages of supply from the approved source (i.e.: Capreomycin from Macleods for Russian GLC approved projects)
- Participation of the Chair at key meetings convened by GDF to address second-line drug procurement issues

5.0 Technical Assistance through GDF Missions

TB Control

As part of its efforts to increase countries' capacity GDF provides technical support to National TB Programmes (NTPs), primarily via in-country missions. These missions monitor various aspects required to ensure successful implementation of NTPs according to the Stop TB Strategy and allow GDF to identify any existing bottlenecks within the supply chain that could affect the programme's level of care and the effectiveness of program implementation. These missions are provided to countries using GDF's grant or direct procurement services, or to provide information and assistance to countries considering using GDF's services. Four types of missions are conducted:

- Pre-delivery country visits for countries that are approved or placed "under consideration" for GDF support
- Grant Monitoring missions which are annual visits conducted to all grant supported countries
- Direct Procurement technical support missions for countries using the GDF Direct Procurement Services

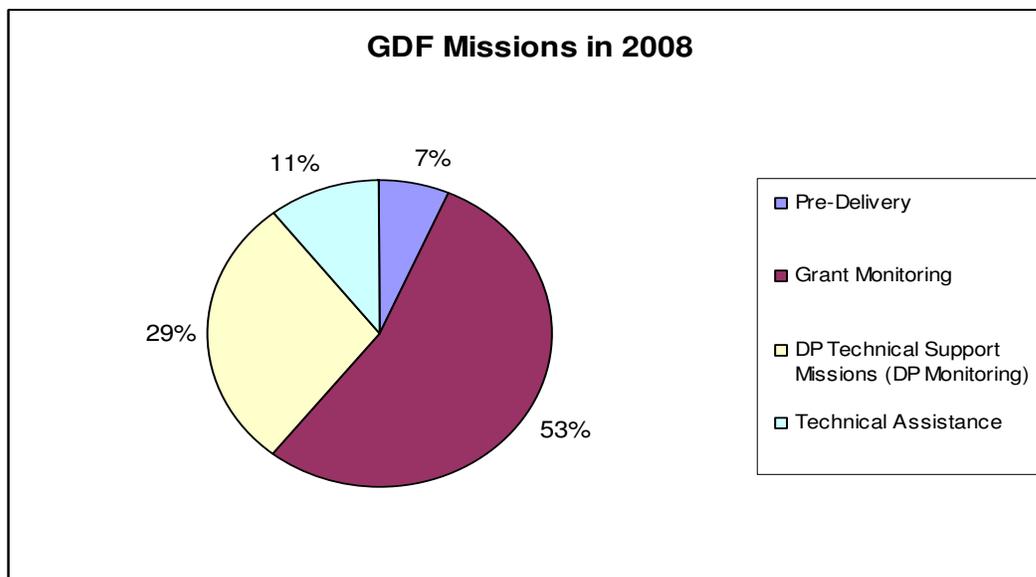
- Technical Assistance missions covering areas that fall outside of the regular scope of a monitoring mission including: training, information regarding services e.t.c (Added in 2008 as GDF has increased its commitment to providing support for technical assistance to countries)

Summary of GDF Missions for January 1 - December 31, 2008

During this reporting period GDF performed seventy-six (76) missions to sixty-three (63) different countries in all six WHO Regions (See Table 10 for more information). Of these, five (5) were pre-delivery country visits, forty-one (41) were grant monitoring missions, twenty-two (22) were DP technical support missions and eight (8) were technical assistance missions.

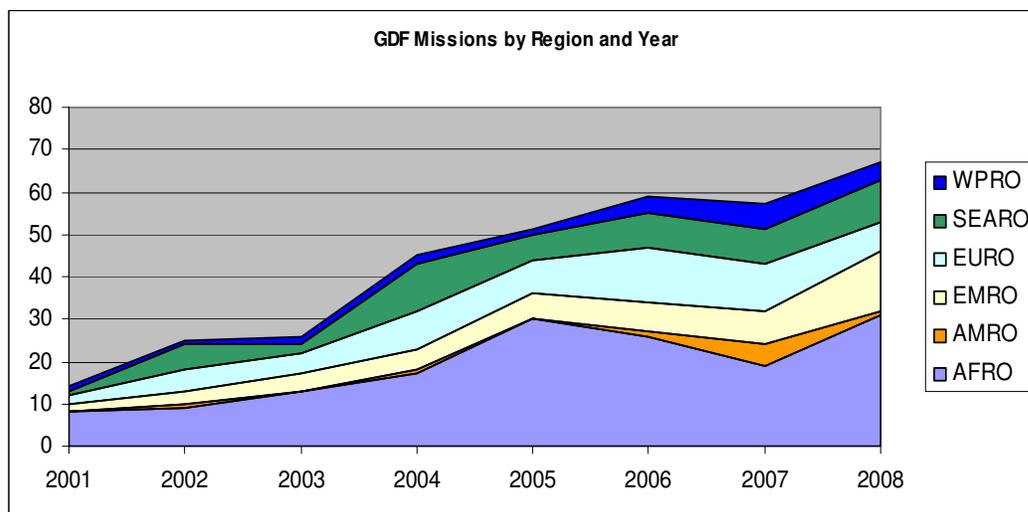
The increase in missions in 2008 (76) as compared to 2007 (57) illustrates GDF's growing commitment to increasing awareness at the country level of the importance of technical assistance and effective drug management. However, in order for this message to be effectively implemented financing needs to be made available to countries for technical assistance and drug management. As such, GDF will liaise in 2009 with key donors to determine whether funding can be secured for projects focused on supporting technical assistance and drug management initiatives in country. GDF will continue to increase its support to countries, through missions, trainings and other support for technical assistance and drug management improvements. (Subject to a concomitant increase in donors funds for this purpose).

Table 9: GDF Missions for 1 January - 31 December, 2008



Since 2001, GDF has sent a total of three hundred and forty-four (344) teams of TB and Drug Management experts into GDF supported countries. The graph below shows the breakdown of missions per WHO region since the inception of GDF in 2001.

Table 10: Breakdown of GDF Missions by Region and Year: 2001 - 2008



Technical Assistance through GDF Regional Support Officers

Since 2006, GDF has placed Regional Support Officers (RSOs) in WHO regions: Eastern Mediterranean and South-East Asia enhancing GDF's ability to provide and/or broker timely and relevant technical assistance and support. RSOs conduct annual missions and identify needed TA in the area of drug management to strengthen procurement and supply system in GDF supported countries. They also hold regional and national level drug management workshops for National TB Programmes and Central Medical Store staff in collaboration with Stop TB Partnership partners. Further, GDF's RSOs are instrumental in identifying resources at the regional level to support TA requests. This year GDF recruited a RSO for the African region who joined the GDF team in September 2008.

GDF Drug Management Technical Support for MDR-TB Programs

In 2008, GDF organized, assisted with or participated in many support interventions for programs accessing second-line anti-TB medicines through the GLC Initiative including:

- Presenting on the MDR-TB Procurement Process of the GLC mechanism in the Workshop on MDR-TB Control Management in the CIS setting, organized by Partners in Health and held in Istanbul from the 15 to 18th April 2008
- Presenting the GDF process for the Quality Assurance of TB Medicines at a workshop on "Streamlining TB case, medicine and commodity management information: strengthening health systems response" organized by Management Sciences for Health (MSH) in Paris, France.
- Presenting on Drug Management of Second Line anti-TB medicines at a "Post-graduate course clinical and programmatic management of MDR-TB and XDR-TB" organized by the IUATLD in Paris, France.

- Presenting an overview of the technical assistance available for drug management in GLC Programs at "The Green Light Committee (GLC) consultants workshop" organized by the GLC in Paris, France.
- Presenting on Quality Assurance of drug resistant anti-TB medicines and the Drug Management of Second-Line Drugs cycle at the 3rd DR-TB consultants course organized by GLC in Lima, Peru.
- Participated, with GLC, in providing the drug management component to Monitoring and Evaluation missions of GLC Programs in 2008 including: Burkina Faso, Democratic Republic of Congo, Haiti, Mongolia, Nepal, Peru and the Philippines.

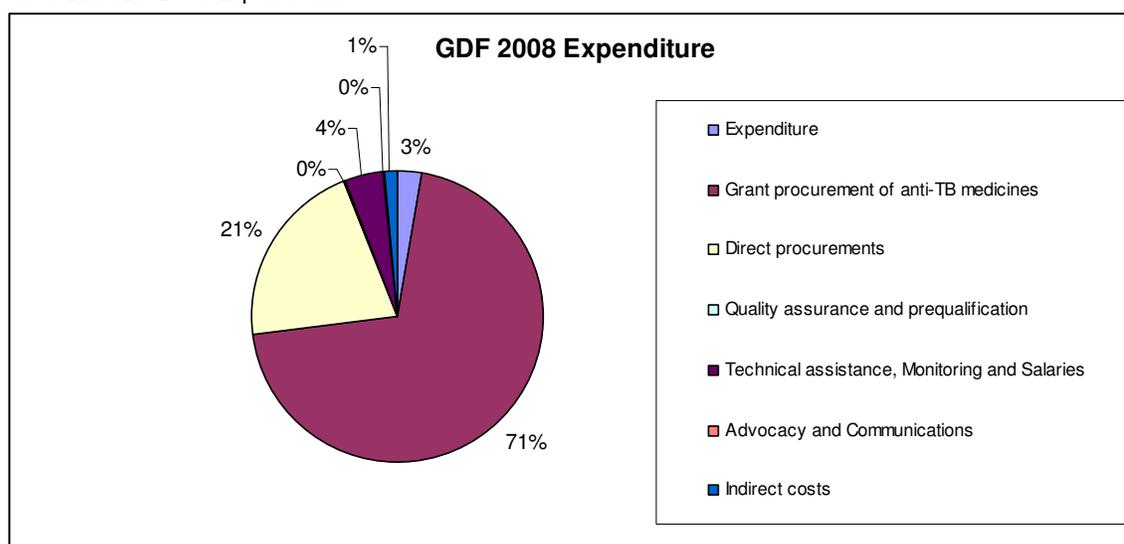
6.0 GDF OPERATIONS

In 2008, the following key developments characterized GDF's functions at the management and operational levels:

- A new Order tracking/management system became operational in Q2 2008, incorporating all areas of the GDF Portfolio: first-line, second-line and diagnostics.
- A systematic customer feedback survey was implemented that identifies an overall customer (country TB programme) satisfaction ratio of 79 %.
- Key new staff positions were filled in 2008 including: a Procurement Officer, India (stationed in Delhi), a Procurement Officer for Diagnostics, UNITAID Paediatrics and MDR-TB projects, a Quality Systems Manager, a Business Services Officer, a Regional Support Team Leader/Capacity Building Officer and a Regional Support Officer for the Africa region. Moreover, a Stop TB partner secondment position (first MSH then MSF) was converted into a permanent Technical Officer position within GDF to advise on Quality Assurance of all TB medicines supplied by GDF.
- Collaboration with the GLC improved and increased.
- GDF was recertified as  ISO 9001:2000 compliant in December by an independent Swiss audit agency, validating that GDF's business management processes and tools are being implemented in a manner that optimizes efficiency and promotes continual improvement pursuant to core objectives e.g.: systematic corrective action/preventive action, systematic customer feedback, systematic quarterly reporting on key performance indicators, real time order lead time monitoring e.t.c.
- Significant funding was secured by GDF from UNITAID to support GLC approved programmes through the establishment in 2009 of a Strategic Revolving Fund for facilitating second-line anti-TB medicines financing.

- As part of its continued attempt to provide suppliers with incentives and support when submitting dossiers to the WHO Prequalification Programme for approval, GDF entered into a partnership with the United States Pharmacopeia Drug Quality and Information (USP DQI) Programme to facilitate the pre-qualification of second-line anti-TB medicines. The main function of USP DQI will be to prepare companies to submit into the WHO Prequalification process (both in terms of GMP site and product dossier preparation) and to provide follow-up technical assistance to ensure a successful prequalification audit.
- GDF's Procurement team held a key stakeholder meeting in Mumbai, in May 2008 that addressed key bottleneck issues with service providers and manufacturers.
- With the implementation of the Strategic Rotating Stockpile for first and second-line drugs GDF has seen decreasing drug delivery lead times.

Table 11: GDF 2008 Expenditure



External Committee focused on GDF Operational and Strategic Issues

Business Advisory Committee

As GDF has taken on further challenges, with the supply of diagnostic kits, paediatric formulations, second line anti-TB medicines and increased involvement in country capacity building, technical assistance and drug management, unique strategic and operational issues can arise.

To execute such broad ranging operations, the GDF is required to have significant expertise and develop relationships in the fields of raw material manufacturing, pharmacy, product formulation for drugs and diagnostics, quality assurance, regulatory law, contract law, business development, competitive procurement processes, pricing and distribution, strategic planning, technical assistance and capacity building.

In order to ensure this required expertise, the Business Advisory Committee was established by the Stop TB Partnership Coordinating Board in 2006 to assist GDF in identifying and resolving any potential difficulties and opportunities in the areas of procurement operations, strategy implementation, quality systems and resource management, drug management, technical assistance and capacity building, risk management.

The Committee is composed of approximately 10 members with a strong background in pharmaceutical and diagnostic business operations. Due consideration is given to appropriate Geographic representation and expertise.

In 2008 the BAC held its 3rd and 4th meetings which saw the establishment of three separate subgroups to focus on: 1) Business Operations, 2) Marketing and Procurement and 3) Country Support. Each subgroup works to address specific issues raised in its particular area.

In 2008 some of the key areas identified and recommendations made for were:

- The benefits of aligning the GDF Quality Policy with the Global Fund's Quality Policy to ensure a more streamlined approach to medicines procurement.
- Identification of additional sources of funding to pursue for technical assistance.
- Recommendations on how GDF can better support country financial sustainability.
- Assistance with identified bottlenecks in the Drug Supply Chain, including freight complications, prequalification of anti-TB medicines.
- A potential compensation system for suppliers holding buffer stocks for GDF.

7.0 CHALLENGES FOR 2009

- **MDR-TB SCALE UP:** In anticipation of a significant increase in countries procuring second line anti-TB medicines, GDF will need to ramp up its engagement of the market to ensure adequate numbers of suppliers of quality MDR-TB medicines and address key bottlenecks in the drug supply chain.
- **PAEDIATRICS:** With the introduction of the new Paediatric formulations following new recommendations due in May 2009, GDF will need to enter into close communication with country programs and suppliers to ensure that adequate drugs are provided during the transition to the new formulations.
- **HUMAN RESOURCES:** An anticipated hiring freeze/staffing restrictions at WHO in 2009, especially at a time when scale-up is being planned and momentum is there (e.g. for MDR-TB) will be particularly challenging. It may require GDF to seek alternative hosting arrangements for new staff.
- **FORECASTING:** Introduction of more effective forecasting tools and methodologies at the global and country levels. This will be a particularly complex exercise for MDR-TB.
- **GLOBAL FUND COLLABORATION:** Ensuring effective implementation of the renewed Stop TB Partnership-Global Fund MoU: from GDF's perspective, key outcomes here would be formal association with the new Global Fund Voluntary

Pooled Procurement Service (where first-line drugs are concerned) and increasing the effectiveness of collaboration with the Global Fund in joint areas of partnership with UNITAID (mostly MDR-TB). Lastly, the Stop TB Partnership and Global Fund will need to ensure, as per the spirit of the MoU, that no duplication of initiatives on TB medicines procurement and technical support for TB drug management occurs.

- FINANCING: Ensuring sufficient and sustainable financing for operations (technical assistance, staffing and capacity building) when many donors are earmarking the majority of their funds for commodities.
- DIRECT PROCUREMENT: Scaling up and making the GDF DP service more sustainable - enhanced marketing and branding is required to demonstrate value-added and GDF comparative advantages.
- Harmonization of procurement policies at the global level.

As the global awareness of TB and MDR-TB grows, GDF will endeavour to form new partnerships, streamline its services and even expand into new areas e.g. new diagnostics and TB-HIV prophylaxis support, in order to ensure that it continues to provide the most cost effective and efficient services possible and in doing so contribute significantly to the reduction of the burden of TB worldwide.

Annex I. GDF performance, process and impact indicators

GDF core functions	Activity	Results		
		Current reporting period (2008)	Previous year (2007)	Cumulative (2001-2008)
Funding	Funds raised for GDF operations, in US\$ '000 (includes contributions "in kind") ¹³	79,249 ¹⁴	74,007	268,200
Patient Treatment Grant and DP	No. of patient treatments supplied via GDF Grants and the Direct Procurement Service	2,757,083	2,176,700	13,910,758
Countries receiving deliveries	No. of countries that received first-line drug deliveries	69	67	88
	No. of countries that received second-line deliveries	37	34	42
	No. of High Burden Countries that received drugs through a Grant or Direct Procurement Service	17	n/a	17
GDF core functions	Activity	Current reporting period (2008)	Previous year (2007)	Cumulative (2007 -
First-line Grants approved by the TRC	Value of GDF grants approved, in US\$ '000			
	Adult	24,306	26,252 ¹⁵	50,558
	Paediatric	790	1,449	2,239
	Total	25,097	27,701	52,798
	Number of grants approved			
	Adult	23	28	51
	Paediatric	14	33	47
	Total	37	61	98
	Number of patient treatments approved via grants ¹⁶			
	Adult	876,028	920,983	1,797,011
Paediatric	23,605	92,805	116,410	
Total	899,633	1,013,788	1,913,421	
First-line monitoring and evaluation	No. of rounds of grant application and review	2	3	19
	Number of Countries approved for a grant	31	44	n/a
	No. of pre-delivery country visits to GDF countries	5	5	10
	No. of monitoring missions to GDF Grant countries	41	35	76
	No. of DP technical support missions to countries using the Direct Procurement Service	22	17	39
	No of Technical Assistance missions	8	n/a	8
	Total No. of missions to GDF Grant Countries	76	57	133
Second-line Grants approved	Value of GDF second-line grants approved, in US\$ '000	12,875 ¹⁷	14,265	27,140
	No. of patient treatments approved for grants	1,040	4,716	5,756

¹³ Include non-monetary contributions i.e. secondments, experts etc.

¹⁴ This figure includes funds received for direct procurement orders

¹⁵ This data was not recorded last year, this figure is an approximation based on Progress Report 11

¹⁶ The number of patient treatments delivered to grant recipients during the reporting period (table 2.7).

¹⁷ Includes the increase in estimated cost for the UNITAID MDR Scale Up project and the additional 1040 patient treatments

Anti-TB Drug Prequalification & GMP Compliance ¹⁸	No. of first-line manufacturers that are WHO GMP ¹⁹ compliant (out of 8 manufacturers used by GDF in 2007)	6	6	6
	No. of first-line prequalified products from those listed in the GDF catalogue (out of 31 products in the GDF catalogue)	12	10	12
	No. of first-line prequalified products from those listed in the GDF catalogue (out of 31) that have 2 of more suppliers	9	5	9
	No. of second-line manufacturers that are WHO GMP ²⁰ compliant (out of 8 manufacturers used by GDF)	8	8	8
	No. of second-line prequalified products from those listed in the GDF catalogue (out of 14)	2 of 14	2 of 10	2
	No. of second-line prequalified products from those listed in the GDF catalogue (out of 14) that have 2 of more suppliers	1	0	1
Area	Indicator	GDF price per tablet/vial	Lowest Other Price per tablet/vial	
Direct Procurement (Affordability)	GDF drug price (US\$) compared to the lowest price offered by a competitive selection of international suppliers ²¹			
	Capreomycin	3.2100	13.70	
	Cycloserine	.5102	.6900	
	Kanamycin (powder)	.5805	.5300	
	Ofloxacin	.0360	n/a	
	RHZE 150/75/400/275	.0502	.0620	
	EH 400/150	.0250	.0346	
	RH 150/75	.0216	.0243	
Cure Rates/Treatment Costs	Estimated number of TB patients that will be cured with drugs supplied via GDF Grants ²²	1,766,000	1,458,479	
	Estimated number of TB patients that will be cured with drugs supplied via GDF Direct Procurement ²³	641,214	357,870	
	Total estimated number of TB patients that will be cured (Grants and Direct Procurement)	2,334,015	1,816,349	
	Average cost per treatment in US dollars (including product costs, insurance and delivery fees)			
	Adult First Line	18.65 ²⁴ 34.95 ²⁵	19.20 35.98	
	Paediatric	8.22 ²⁶ 16.80 ²⁷	10.63 ²⁸	
	Adult Second Line	1,584.47 ²⁹ 4,920.84 ³⁰	n/a	

¹⁸ 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.

¹⁹ Or carry an equivalent compliancy, such as through a recognized stringent regulatory authority.

²⁰ Or carry an equivalent compliancy, such as through a recognized stringent regulatory authority.

²¹ Source: International Drug Price Indicator Guide 2007, <http://erc.msh.org/>.

²² 85% of patient treatments delivered via GDF grants during this reporting period. Patients may be treated outside of reporting period. Does not account for product expiry, damage or loss. Does not include second-line treatments.

²³ 85% of patient treatments delivered via the Direct Procurement Service during this reporting period

²⁴ Regimen: Cat. I & III - 2(RHZE)/4(RH) = 2 months Rifampicin+Isoniazid+Pyrazinamide+Ethambutol + 4 months Rifampicin+Isoniazid

²⁵ Regimen: Cat. II - 2S(RHZE)/1(RHZE)/5(RHE) = 2 months - Streptomycin, Rifampicin+Isoniazid+Pyrazinamide+Ethambutol, 1 month - Rifampicin+Isoniazid+Pyrazinamide+Ethambutol, 5 months - Rifampicin+Isoniazid+Ethambutol

²⁶ Curative and preventive, inclusive of drug related costs: freight, QC, insurance and agent fee.

²⁷ Curative only, inclusive of drug related costs: freight, QC, insurance and agent fee.

²⁸ This price reported in 2007 was advised *not to be regarded "as definitive as it is only based on complete grant deliveries for 10 countries. Once more data is available GDF will be able to provide a more accurate estimate."*

²⁹ Example of low end-of-range cost calculation for one country

³⁰ Example of high end-of-range cost calculation for one country (includes Capreomycin)

Service Indicators: Direct Procurement

Service	Indicator	Results		
		Current reporting period (2008)	Previous year (2007)	Cumulative (2007-onwards)
First-line Direct Procurement (includes First-line, Paediatrics and Diagnostics)	Number of orders placed	59	49	108
	Value of Orders placed (product costs only, US\$) ³¹	\$12,842,847	\$10,805,650	\$23,648,497
	Number of orders delivered	65	40	105
	Value of Orders delivered (product costs only, US\$)	\$18,207,966	\$7,065,807	\$25,273,773
	Number of patient treatments delivered	763,145	424,473	1,187,618 (3,325,978 since 2001)
	No. of countries that received drug deliveries	43	32	n/a
	Number of requests delivered (Global Fund Orders)	24	16	40
	Total Value of orders delivered (Global Fund Orders)	\$11,116,131	\$4,714,319	\$15,830,450
	Average lead time for order delivered ³²	107	118	
	% of requests dispatched from manufacturers on schedule ³³	65.86 ³⁴	74.29	
	% of requests arriving in countries on schedule	63.07 ³⁵	55.56	
Average number of days from order finalization to first delivery (all orders)	107	84		
Second-line Direct Procurement	Number of orders placed	69	62	131
	Number of Countries placing orders	32	30	n/a
	Total value of orders placed (product costs only, US\$)	\$15,441,769	\$9,750,306	\$25,192,075
	Number of requests delivered	68	54	122
	<i>Number of requests delivered (Global Fund orders)</i>	<i>44</i>	<i>30</i>	<i>74</i>
	Countries receiving deliveries (all orders)	30	30	
	Average number of days from order finalization to first delivery (all orders) ³⁶	109	107	
	Total value of requests delivered (product costs only, US\$)	\$9,959,424	\$4,283,525	\$14,242,949
	<i>Total value of requests delivered (Global Fund orders, US\$)</i>	<i>\$8,517,012</i>	<i>\$2,716,693</i>	<i>\$11,233,705</i>
First Line Diagnostics	Number of Countries who placed Diagnostic orders	9	8	n/a
	Consumables Kits	1786	1130	2916
	Microscope kits*	131	94	225
	Sputum Containers	1755	945	2700
	Equipment Starter Kits	450	73	523
	Total		\$559,089	\$361,117

³¹ Costs do not include Freight, PSI, QA, Buffer or Agent Fees

³² Calculates time from order placed with procurement agent to first drug delivered in country

³³ A Direct Procurement order is considered "on schedule" if date of arrival is equal to or less than estimated date of arrival specified on pro-forma invoice.

³⁴ Calculated using only non-migrated orders (migrated orders = orders that were placed prior to the implementation of GDF's order management system)

³⁵ Order considered on time if it arrives in country within 120 days of order placed with suppliers (OMS)

³⁶ It is important to note that for second line orders, projects will often place their orders in advance for delivery at a specified later date, therefore standard lead time calculations (i.e. order placed with supplier to first drug delivery) do not give an accurate representation of order production and delivery time. Information comparing actual delivery date with requested delivery date is available upon request to GDF.

Service Indicators: Grants

Service	Indicator	Results		
		Current reporting period (2008)	Previous year (2007)	Cumulative (2007-onwards)
First-line: All grants	Number of Orders Placed	110	109	219
	Value of Orders Placed (product costs only, US\$)	\$38,049,672	\$25,739,631	\$63,789,303
	Number of requests delivered	133	82	215
	Value of Orders Delivered (product costs only, US\$)	\$35,332,787	\$27,517,508	\$62,850,295
	No. of grant recipients that received drug deliveries	54	45	99
	Number of patient treatments delivered	1,993,938	1,759,031 ³⁷	3,752,969 (10,584,660 since 2001)
	% of requests dispatched from manufacturers on schedule ³⁸	76% ³⁹	98%	
	% of requests arriving in countries on schedule	60.90%	59.8%	
	Average number of days from order finalization to arrival in country (all orders)	113	107	
Average total cost of a delivered request (all orders, US\$)	\$705,515	\$335,579		
First-line: Transitional grants	Number of purchase requests made	14	26	39
	Value of Orders Placed (product costs only, US\$)	\$7,258,791	\$8,085,689	\$15,344,480
	Number of requests delivered	17	20	36
	Value of Orders Delivered (product costs only, US\$)	\$10,404,304	\$3,211,801	\$13,616,105
	Number of patient treatments delivered	415,712	332,314	748,026
	% of requests dispatched from manufacturers on schedule	88	95	
	% of requests arriving in countries on schedule	76	70	
	Average number of days from order finalization to arrival in country (all orders)	96	95	
	Average total cost of a delivered request (all orders, US\$)	715,316	196,999	
UNITAID: Paediatric grants	Number of orders placed	35	47	82
	Number of countries (Orders Placed)	32	35	
	Number of requests delivered (incls Orders placed in 2007 but were delivered in 2008)	64	12	76
	Number of Countries who received deliveries (incls Orders placed in 2007 but were delivered in 2008)	44	12	56
	Number of curative treatments delivered	89,104	52,217	141,321
	Number of preventative treatments delivered	91,786	80,988 ⁴⁰	175,049
	Average lead time (Orders placed in 2008)	103	111	n/a
	Total Value of Orders (Placed in 2008)	\$672,067	\$1,507,771	\$2,179,838
	Total Value of all Orders Delivered	\$1,516,100	\$326,691	\$1,842,791
	Average total cost of a delivered request (all orders, US\$) (incls Orders placed in 2007 but were delivered in 2008)	\$26,116	\$27,224	

³⁷ Includes treatments delivered in 2007 not reported on GDF Progress Report 11

³⁸ A Grant order is considered "on schedule" if the manufacturer takes less than 120 days from when receiving an order to the order's satisfactory inspection for shipment (PSI).

³⁹ Calculated using only non-migrated orders (migrated orders = orders that were placed prior to the implementation of GDF's order management system)

⁴⁰ This sum is an approximation as this data has not previously been measured. Calculated using overview sheet for Year 1 and 2 (total treatments supplied - treatment delivered in 2008 and curative treatments delivered in 2007)

Second Line All Grants	Number of orders placed	29	6	38
	Number of requests delivered	27	9	27
	Number of Countries placing orders	12	n/a	13
	Number of Countries receiving Deliveries	12	n/a	12
	% of requests arriving in countries on schedule	74.07%	n/a	
	Average lead time	113	n/a	
	Total Cost of all orders placed (2008)	\$3,032,994 ⁴¹	\$1,706,718	\$1,706,718
	Total Value of all orders delivered (2008)	\$2,115,238	n/a	\$2,115,238
	Average total cost of a delivered request (all orders, US\$)	\$78,342	n/a	

⁴¹ Difference between this amount and amount reported on UNITAID annual report is due to several orders being identified as UNITAID orders that had been previously incorrectly identified

Annex II: Statement of Income and Expenditure

Stop TB Partnership Global TB Drug Facility Financial Management Report Statement of Income and Expenditure including Direct Procurement for the year ending 31 December 2008 (All figures are in US\$'000)		
	2007	2008
Income		
Governments and their Agencies - specified	59,167	62,032
In-kind contribution for anti-TB medicines from Novartis	2,340	1,033
Contributions for direct procurement	12,500	15,463
Other income (Bill & Melinda Gate's Foundation: US\$ 113 and MSF: US\$ 114)	0	227
Total Income	<u>74,007</u>	<u>78,755</u>
Expenditure		
Grant procurement of anti-TB medicines	36,847	52,098
Direct procurements	12,500	15,463
Quality assurance and prequalification	106	140
Technical assistance, Monitoring and Salaries	2,384	3,068
Advocacy and Communications	182	231
Indirect costs	893	982
Total Expenditure	<u>52,912</u>	<u>71,982</u>
Surplus of Income over Expenditure	21,095	6,773