

Progress Report 13

Stop TB Partnership
Global Drug Facility

1 January 2009 – 31 December 2009



Over 16.5 million patient treatments delivered since 2001

Stop TB Partnership Secretariat
Geneva, Switzerland

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Global Drug Facility Annual Report 2009

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A WORD FROM THE MANAGER

Greetings from the Global Drug Facility!

The year was quite busy as usual and we are proud to say that in 2009 GDF delivered over 2.4 million patient treatments, with approximately 16.5 million patient treatments delivered world-wide since 2001.

GDF continues to provide free grants to countries but an increasing number of countries are paying for their own medicines as they secure funding from national resources, the Global Fund, DFID, World Bank or other partners.

Second Line Medicine (SLM) orders to treat multidrug resistant TB (MDR-TB) increased 27% (by value) this year compared to 2008. Starting in 2010 increases are expected to be even more dramatic related to both the Expand-TB project which is providing laboratory strengthening to 27 countries to improve the diagnosis of MDR-TB and the coordinated efforts of WHO/partners in the scale up of MDR TB treatments worldwide. Of the estimated 450,000 cases of MDR-TB untreated today, 60,000 more patients will be diagnosed and potentially treated in 2010-2011 through the GLC mechanism. GDF's role in the scale up is being guided by a task force set up by WHO and MDR-TB partners in early 2010.

GDF has spent considerable time this year continuing to support prequalification of suppliers for both First Line Medicines (FLM) and Second Line Medicines. This has resulted in at least 3 approved suppliers for each FLM and 2 suppliers for many of the SLM. GDF has been procuring FLM for approximately 25 grantees of the Global Fund and plans to continue its collaboration as more and more countries win grants. In addition, GDF began harmonization of its quality assurance (QA) policy with that of the Global Fund in 2009, which should be in place by end of 2010. Harmonization will result in less confusion for principal recipients and NTPs as they procure anti-TB medicines.

No business goes without its challenges and GDF was tested extensively in 2009 by needing to cover gaps in NTPs access to drugs when funding from their donors was delayed. To cope with the problem, GDF expanded use of its rotating stockpile of TB medicines, the issuance of emergency one year grants and communicated regularly with Global Fund portfolio managers to help expedite release of funds to countries. Building on the 2009 activities, GDF will implement the strategic revolving fund and select a new procurement agent allowing even quicker responses to NTP needs during 2010.

Let me take this opportunity to thank our many donors who have made possible the provision of TB medicines and the funding of staff to carry out the important services of GDF during 2009. Unquestionably, both dedicated donors and staff are responsible for GDF's successes so far.

On a personal note it has been my pleasure to serve as interim operations manager for part of 2009 since Robert Matiru, long time chief operating officer of GDF was assigned by the Director General to work on the WHO efforts on procurement and delivery of H1N1 vaccines to eligible countries worldwide.

Looking forward to working with you again in 2010.

Warm regards,

A handwritten signature in black ink that reads "Thomas Moore". The signature is written in a cursive style with a large, stylized 'T' and 'M'.

Thomas Moore

1.0 2009 EXECUTIVE SUMMARY

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.

This report covers the activities of the Global Drug Facility (GDF) from 1 January to 31 December 2009, which are summarized below. Further details are given in sections 1-7 and annexes I - IV.

Donor Support

- In 2009, GDF received approximately US\$ 105.85 million from donors, including gifts in kind of free medicines to countries as well as support for staff to assist with GDF operations and partner participation in country missions and workshops.

First Line anti-TB Medicines

- In 2009 GDF delivered 2,454,274 first line patient treatments. 1,586,426 patient treatments were delivered through GDF's grant service. 867,848 patient treatments were delivered through GDF's direct procurement service
- During 2009 sixty-two (62) applications were reviewed by the Technical Review Committee or through ad hoc or delegated reviews of which fifty-eight (58) were approved for grants and four (4) for direct procurement. These represent 404,957 grant patient treatments and 376,899 direct procurement patient treatments under DOTS programmes worldwide at an estimated total cost of US\$ 24.8 million.
- Eighteen (18) countries placed orders through GDF's first line adult grant service. Fifty-two (52) countries placed orders through GDF's first line adult direct procurement service. Forty-two (42) countries ordered paediatric medicines through GDF's grant service. Fifteen (15) countries placed direct procurement orders for diagnostic equipment.

Second Line anti-TB Medicines

- In 2009, twelve (12) countries placed orders through GDF's second line grant procurement service.
- GDF continued to see a steady increase in the volumes of second line anti-TB medicines procured through its direct procurement service. In 2009, 38 countries purchased anti-TB second line medicines through direct procurement, an increase of 33 countries when compared to 2008. The value of medicines procured also increased from US\$ 17,562,399 in 2008 to US \$22,349,833 in 2009.

Key Partnerships in 2009

- In addition to their existing support of projects in first and second line medicines as well as paediatrics, in 2009, UNITAID approved and provided funding for a project to accelerate access to diagnostics for patients at risk of multidrug-resistant tuberculosis in 27 countries. The EXPAND-TB (Expanding Access to New Diagnostics for TB) Project is collaboration between the World Health Organization (WHO), the Global Laboratory Initiative (GLI), the Foundation for Innovative New Diagnostics (FIND), and the Stop TB Partnership's Global Drug Facility (GDF).
- 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 2009 being no exception.
- Reflecting GDF's continued commitment in providing technical assistance to countries, collaboration increased in 2009 when GDF's Capacity Building Officer joined the TBTEAM (Stop TB Partnership's TB Technical Assistance Mechanism housed in WHO's Stop TB Department) to assist with increasing coordination between GDF and other partners providing technical assistance to countries. In 2009, GDF performed eighty-eight (88) missions to sixty-four (64) different countries in all six WHO Regions



Challenges and Opportunities for 2010

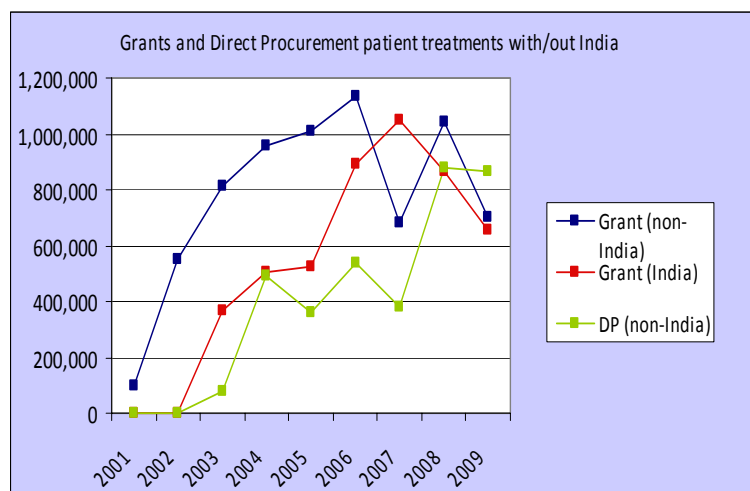
- **STRATEGIC PLAN 2011-2015:** In Q2 2010 the Boston Consulting Group will be conducting a consultancy considering GDF achievements in the past 9 years and the changing TB landscape. The consultancy will review and analyse future strategic directions for GDF and make recommendations to ensure that GDF continues to play an essential role in continuing to provide value added quality service to countries in need.
- **MDR-TB SCALE UP:** In anticipation of a significant increase in countries procuring SLD, GDF is ramping up its engagement with 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 future introduction of new paediatric formulations following the new WHO recommendations for TB treatment in children, GDF will continue to closely interact with country programmes and suppliers to ensure that adequate drugs are provided during the transition phase.
- **FORECASTING:** GDF will continue building on improvements to existing forecasting mechanisms needed to allow for greater manufacturer engagement.
- **GLOBAL FUND COLLABORATION:** Ensuring effective implementation of the renewed Stop TB Partnership-Global Fund Memorandum of Understanding: key outcomes would be complete alignment of GDF and Global Fund Quality Assurance policies as well as a 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 (related to MDR-TB).
- **DIRECT PROCUREMENT:** As the volume of direct procurement service increases development of a sustainable financing model may be essential; enhanced marketing and branding is required to demonstrate the comparative advantages and value added by GDF.

2.0 STRATEGIC DEVELOPMENTS

Business Trends

- In 2009 GDF delivered 2,454,274 first line patient treatments¹.
- 1,586,426 patient treatments were delivered through GDF's first-line grant service. This decrease of 29.03% in patient treatments provided between 2008 (1,908,689) highlights the increase in TB drug financing, especially from the Global Fund.
- 867,848 patient treatments were delivered through GDF's first-line direct procurement service. This number is consistent with 2008 (878,569).
- 28 countries received shipments of first line medicines through GDF's first line grant service and 52 countries through GDF's direct procurement service countries.

Table 1: Grants and Direct Procurement patient treatments



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 our mission, GDF relies strongly on the generosity of its donors. Monies from donors are used to provide grants of first and second line anti-TB medicines as well as diagnostics to eligible countries that do not have sufficient funds for this purpose. Nominal funds are used for GDF operational costs to ensure that GDF has adequate resources to effectively and efficiently perform its services.

In 2009, GDF received approximately US\$ 105.85 million from donors, including donations in kind through the provision of donations of free medicines to countries as well as staff to assist with GDF operations and partner participation in country missions and workshops.

¹ Total number of patient treatments for all shipments on an order included in calendar year of first shipment.

Table 2: Donor Contributions received 2001 - 2009

Contributions received for GDF 2001 - 2009

(including in-kind contribution US\$'000)

	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total
Cash contributions										
CIDA	9,944	3,723	8,530	11,347	20,643	22,862	7,139	9,202	6,288	99,678
Netherlands	4,041	1,959	2,587	194			750		200	9,731
USAID	1,250	2,000	3,000	3,000	4,700	5,000	5,250	14,879	15,000	54,079
USAID / OGAC									350	350
UK (DFID)			595							595
DFID (India program)						11,962	13,601	14,330	10,676	50,569
UNITAID							31,436	22,832	23,088	77,356
Norway			748	810	743	899	991	788	69	5,048
World Bank		250	250						86	586
Open Society Institute			250							250
Japan (for Cambodia)			46							46
Procter & Gamble			25							25
Gate's Foundation								113		113
Zambia									233	233
Kuwait									160	160
Others				64						64
Total Cash contribution	15,235	7,933	16,031	15,415	26,086	40,723	59,167	62,144	56,150	298,882
In kind contribution										
Harvard University Medical School (in kind)			130							130
Research Institute of Tuberculosis, Japan (in-kind)		21								21
Management Science for Health (in Kind)**		137	188	188	188	125	0	495	30	1,351
Novartis					2,605	3,226	2,340	1,033	1,690	10,894
Medicine sans Frontier								114		114
Total in kind	0	158	318	188	2,793	3,351	2,340	1,642	1,720	12,510
Total cash & in kind contributions	15,235	8,091	16,349	15,603	28,879	44,074	61,507	63,786	57,870	311,392
Contributions for Direct Procurements			5,786	6,613	13,433	6,165	12,500	15,463	47,979	107,939
Total income	15,235	8,091	22,135	22,216	42,312	50,239	74,007	79,249	105,849	419,331

** Management Science for Health In-kind contribution for 2008, US\$ 495,000, was realised after 2008 report was published and therefore was not reported in 2008.

In 2009:

GDF continued to receive support from its long term donors for the provision of quality anti-TB medicines to countries in need, as well as for operational costs.

- In 2009 UNITAID continued its collaboration with GDF on multiple projects including first line, second line and paediatric medicines as well as diagnostics.

- The United States Agency for International Development (USAID), also a GDF partner since its inception in 2001, contributed approximately US\$ 15 million to assist GDF in meeting its first line anti-TB medicines grant service mandate.
- Department for International Development (DFID) funds continued to provide quality first line anti-TB treatments in India, the country with the highest burden of TB.
- The Canadian International Development Agency (CIDA), a GDF partner since 2001, contributed approximately US\$ 6.3 million for first line anti-TB medicine grants and related costs.
- Novartis Foundation for Sustainable Development provided in-kind support to GDF of approximately US\$ 1.7 million.
- USAID/PEPFAR contributed US\$ 350,000 to support countries in implementing Global Fund grant projects through technical assistance missions and capacity building workshops.
- Management Sciences for Health (MSH) continued to assist GDF with in-kind donations of staff time and expertise, supporting GDF with several key projects in 2009.
- The Kuwait Patient Helping Fund (KPHF) has partnered with GDF to provide quality first line medicine and technical support for drug management to selected countries.
- The Government of Zambia cost shared with GDF on the purchase of adult first line anti-tuberculosis medicines.



3.0 FIRST LINE ANTI-TUBERCULOSIS MEDICINES

In 2009, through its grant service, 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. Grants were provided 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.

GDF saw growth in its direct procurement service for adult anti-TB medicines and opened its paediatric medicines service for direct procurement (DP) by interested countries.

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

Two (2) plenary rounds of the TRC were held in Geneva in 2009. Additionally two (2) countries were reviewed through ad hoc TRC reviews, and twenty-five (25) countries through delegated reviews.²

Review of Programme Applications

During 2009 sixty-two (62) applications were reviewed by the TRC or through ad hoc or delegated reviews of which fifty-eight (58) were approved for grants and four (4) for direct procurement. These represent 404,957 grant patient treatments and 376,899 direct procurement patient treatments under DOTS programmes worldwide at an estimated total cost of US\$ 24.8 million.

Of the sixty-two (62) applications reviewed by the TRC or through delegated reviews, seven (7) were new applications. This raises the cumulative number of new applications reviewed by the GDF TRC to two hundred and twenty-four (224) since 2001.

Summary of Adult Grants Approved

In 2009, twenty (20) applications for Adult anti-TB medicines were approved by the TRC or through ad hoc or delegated technical reviews.

Applications received contained:

- One (1) new application for first term adult anti-TB medicines grant
- Two (2) applications for an exceptional 7th year of grant funding
- Eleven (11) adult monitoring applications for continued grant cycle funding
- One (1) emergency funding request
- One (1) new application for second term adult anti-TB medicines grant
- Four (4) reviews of direct procurement applications

In total, in 2009, adult grants were approved for 283,871 patients with an estimated cost of US\$ 12,571,554, direct procurement applications were approved for 376,899 patients with an estimated cost of US\$8,995,078.

Summary of Paediatric Grants Approved

In 2009, all forty-two (42) applications received were approved for paediatric grants by the TRC or through ad-hoc or delegated reviews.

² 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.

Applications received contained:

- Five (5) new applications for grant funding for paediatric medicines
- Thirty-seven (37) paediatric monitoring applications for continued grant-cycle funding

Overall in 2009, grants were approved for 121,086 paediatric patients totaling US\$ 3,315,152.

Table 3: Summary of 20th meeting of the Technical Review Committee

Country Reviewed	Applied for	TRC Recommendation/CB Approval	Patients Approved	Total Estimated Cost
TOGO	New Paed Grant	Approved	100	\$6,937
Kiribati	New Paed Grant	Approved	105	\$4,196
Swaziland	New Paed Grant	Approved	849	\$11,006
Sudan north	New Paed Grant	Approved	2,903	\$120,362
Philippines	New Paed Grant	Approved	9,260	\$263,433
Kiribati	New Adult Grant	Approved	247	\$19,339
Myanmar	Adult 7th Year	Approved	53,522	\$1,600,506
DPRKorea	Adult 7th Year	Approved	47,368	\$1,197,522
Iraq	Adult Monitoring	Cautionary approval	9,500	\$239,932
Sierra Leone	Adult Monitoring	Approved	9,800	\$269,743
Bangladesh	Adult Monitoring	Approved	43,251	\$1,247,367
Lesotho	Adult Monitoring	Cautionary approval	13,506	\$586,191
Cape Verde	Adult Monitoring	Approved	340	\$13,918
Afghanistan	Adult Monitoring	Approved	9,821	\$174,654
Mali	Paediatric Monitoring	Cautionary approval	195	\$2,638
Afghanistan	Paediatric Monitoring	Conditional approval	5,251	\$369,789
Iraq	Paediatric Monitoring	Cautionary approval	1,030	\$57,930
Sierra Leone	Paediatric Monitoring	Approved	1,600	\$9,922
Bangladesh	Paediatric Monitoring	Approved	4,248	\$69,305
Myanmar	Paediatric Monitoring	Approved	29,261	\$612,449
Nepal	Paediatric Monitoring	Approved	1,672	\$40,613
Nepal	Direct Procurement	Approved	22,548	\$612,449
Total:			266,377	\$7,530,200

Table 4: Summary of 21st meeting of the Technical Review Committee

Country Reviewed	Applied for	TRC Recommendation/CB Approval	Patients Approved	Total Estimated Cost
Turkmenistan	New Adult 2nd Term Grant	Cautionary Approval	5102	\$230,511
Guinea-Bissau	Emergency Grant	Cautionary Approval	2232	\$73,948
Guinea	Adult Monitoring	Approved	5997	\$539,829
Tanzania	Adult Monitoring	Approved	51711	\$5,283,432
Turkmenistan	Paediatric Monitoring	Approved	150	\$11,136
Guinea-Bissau	Paediatric Monitoring	Approved	100	\$1,363
Cameroon	Paediatric Monitoring	Conditional Approval	476	\$57,441
Guinea	Paediatric Monitoring	Approved	1,247	\$39,548
Morocco	Paediatric Monitoring	Cautionary Approval	2,189	\$65,233
Pakistan	Paediatric Monitoring	Cautionary Approval	20,000	\$553,683
Indonesia	Direct Procurement	Conditional Approval	340367	\$7,746,932
Chad	Direct Procurement	Cautionary Approval	5484	\$193,423
Total			435,055	\$14,796,480

Table 5: Summary of Ad hoc reviews by Technical Review Committee 2009

Country Reviewed	Applied for	TRC Recommendation	Patients Approved	Total Estimated Cost
Tajikistan	Direct Procurement	Cautionary Approval	8500	\$442,274
Tajikistan	Paediatric Monitoring	Cautionary Approval	700	\$57,976
Haiti	Adult Monitoring	Approved	13774	\$451,342
Total:			22,974	\$951,591

Table 6: Summary of Delegated Technical Reviews 2009

Country Reviewed	Applied for	Recommendation	Patients Approved	Total Estimated Cost
Kyrgyzstan	Adult Monitoring	Green Light	7,200	\$263,574
Benin	Paediatric Monitoring	Green light	131	\$10,040
Burkina Faso	Paediatric Monitoring	Green Light	252	\$7,806
Cambodia	Paediatric Monitoring	Green Light	506	\$96,518
Cape Verde	Paediatric Monitoring	Green Light	40	\$1,010
Djibouti	Paediatric Monitoring	Green Light	557	\$11,272
DPRK	Paediatric Monitoring	Green Light	5,000	\$104,828
Gambia	Paediatric Monitoring	Green Light	121	\$2,065
Georgia	Paediatric Monitoring	Green Light	320	\$12,691
Guinea Bissau	Paediatric Monitoring	Green Light	190	\$5,265
Jordan	Paediatric Monitoring	Green Light	130	\$3,311
Kenya	Paediatric Monitoring	Green Light	12,804	\$159,007
Kyrgyzstan	Paediatric Monitoring	Green Light	720	\$11,059
Lebanon	Paediatric Monitoring	Green light	40	\$106
Lesotho	Paediatric Monitoring	Green Light	1,351	\$54,201
Madagascar	Paediatric Monitoring	Green Light	1,939	\$51,571
Malawi	Paediatric Monitoring	Green Light	3,541	\$50,312
Mauritania	Paediatric Monitoring	Green Light	150	NA
Nepal	Paediatric Monitoring	Green Light	2,544	\$70,604
Sierra Leone	Paediatric Monitoring	Yellow Light	2,000	\$53,074
Somalia	Paediatric Monitoring	Green Light	1,573	\$56,469
Sierra Leone	Adult Monitoring	Yellow Light	10,500	\$379,746
TFYR Macedonia	Paediatric Monitoring	Green Light	41	\$2,435
Yemen	Paediatric Monitoring	Green Light	300	\$14,636
Zambia	Paediatric Monitoring	Green Light	5,500	\$181,913
Total:			57,450	1,603,512

Procurement of First Line anti-TB medicines

Tuberculosis in Adults

With 9.4 million new cases of TB reported in 2008³, GDF continues to provide a valuable service procuring quality medicines and providing technical assistance to countries. GDF continued, in 2009, to provide adult anti-TB medicines via both its grant and direct procurement (DP) services.

Adult Grants

In 2009, fifty-nine (59) orders were placed by 18 countries. These orders had a total value of approximately US\$ 18.2 million. Furthermore, shipments valuing an estimated US \$ 30 million were delivered to 28 countries⁴. In 2009, 1,212,466 patient treatments were delivered through GDF's adult grant service.⁵

Since beginning its grant program in 2001, GDF has delivered approximately 11,495,737 adult patient treatments through its grant services.

Adult Direct Procurement

In 2009, eighty-seven (87) direct procurement orders were placed by fifty-two (52) countries with an approximate value of US\$ 25.6 million. Countries used a variety of

³ Global Tuberculosis Control 2009

⁴ Includes countries that placed orders in 2008

⁵ Total Patient treatments are included in the year that first shipment is received

sources of funds including among others: The Global Fund, WHO, UNDP, KfW, PEPFAR, CERF⁶ Emergency Funding and government funds from national budget lines.

In 2009 GDF delivered shipments of adult first line medicines to fifty-seven (57) countries⁷ with an all inclusive value of over US\$ 26.5 million. 867,848 patient treatments were delivered through the direct procurement service in 2009.

Since its inception in 2001, GDF has delivered approximately 4,309,250 patient treatments to countries in need through its DP service.

Paediatric Grants

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.

Since the launch of the UNITAID paediatric tuberculosis (TB) Project in January 2007, implemented by the Stop TB Partnership's Global Drug Facility (GDF) as part of its mandate to enable access to TB treatment and diagnosis worldwide, 58 countries, in Africa, Central, South and South-East Asia and in the Middle-East and the Caucasus, have received quality-assured paediatric medicines.

This achievement has been made possible thanks to UNITAID's commitment of US\$ 11,603,952 to GDF to procure and supply quality-assured paediatric drugs from 2007 to 2011. Since 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 drugs. GDF became a unique source for the provision of quality-assured paediatric products in line with both WHO's childhood TB treatment recommendations for formulations, dosages and presentations of these drugs, and WHO's quality assurance requirements. In the second year of project operations, joint UNITAID/GDF visibility for this important role has developed significantly, with an increasing number of countries benefiting from paediatric grant access.

In 2009, fifty-three (53) orders were placed for paediatric medicines through GDF's grant service. These orders, for forty-two (42) countries, had a total value of more than US\$ 2.8 million. GDF delivered paediatric medicines to forty-five (45), an all inclusive value of US\$3.1 million. 145,691 curative and 228,269 prophylaxis treatments were delivered through the project in 2009.



⁶ Central Emergency Response Fund

⁷ Includes orders that were placed in 2008

New dosages anticipated: The initiative for better medicines for children has led to the examination by WHO of appropriate dose recommendations for anti TB medicines, specific to the needs of children.

A systematic review of evidence for appropriate doses of first line medicines for TB has been completed. Based on this review and consultations^{8 9}, the WHO recommendations for these medicines have been revised according to weight. Subsequent to the approval of the WHO Expert Committee on selection and use of essential medicines' recommendations in May 2009, the Childhood TB guidelines are in the process of revision according to WHO policy and processes.

During this reporting period to ensure continuity of treatment in GDF supported countries, GDF has worked with WHO and the Essential Medicines Program (EMP) on guidance for countries on how to use current paediatric formulations to comply with new recommended doses, pending the availability of appropriately formulated drugs. Dosing charts were reviewed by a panel of experts in the area of TB, both pharmacologists and clinicians and have been endorsed by WHO.

Service development: Prior to 2009 paediatric medicines were only available via GDF's grant service; however, in 2009 GDF began to offer paediatric medicines through its direct procurement service for eligible countries.

First Line Diagnostics

In 2007, GDF began providing diagnostic kits through its DP service to assist country programmes with the detection of TB. Since the initiation of this product line GDF has seen steady growth in this area. In 2009, fifteen (15) countries placed orders for diagnostic kits, with a total value of US\$ 1,291,809.

Table 7: Diagnostic Orders Placed 2008 and 2009

Year of Order placement	Product	Number of Units	Product Costs	All Inclusive Costs
2008	Consumables kit	1,610	305,165	489,149
	Equipment starter kit	450	57,930	97,457
	Microscope kit	47	55,930	87,204
	Microscope Kit without Microscop	84	15,550	20,391
	Sputum container	1,755	94,770	164,922
2008 Total		3,946	529,345	859,123
2009	Consumables kit	1,676	341,204	557,878
	Equipment starter kit	260	34,580	56,827
	Microscope kit	339	403,410	598,344
	Sputum container	799	43,146	78,759
2009 Total		3,074	822,340	1,291,809

⁸ http://www.who.int/selection_medicines/committees/expert/17/application/TB/en/index.html

⁹ http://www.who.int/selection_medicines/committees/subcommittee/2/TB.pdf

4.0 SECOND LINE ANTI-TUBERCULOSIS MEDICINES

In April 2009, the Government of the People's Republic of China and the World Health Organization (WHO) hosted Ministers of Health from the 27 high multidrug-resistant tuberculosis (MDR-TB) burden countries (plus six additional countries) at a meeting in Beijing. The participating nations unanimously endorsed a declaration calling for rapid scale-up of high-quality MDR-TB treatment globally, and pledged to move their own countries towards universal access. This meeting was followed in May 2009 by a WHO World Health Assembly resolution calling for universal access to diagnosis and treatment of MDR-TB and extensively drug-resistant tuberculosis (XDR-TB). The resolution called on WHO "to provide support to Member States in developing and implementing strategies to engage all relevant public, voluntary, corporate and private healthcare providers in the training for and scaling up of prevention and control of tuberculosis including MDR-TB and XDR-TB and all aspects of tuberculosis-HIV co-infection."¹⁰

Key Partner - The Green Light Committee (GLC)

Component two of the Stop TB Strategy calls for the control and prevention of multidrug-resistant tuberculosis (MDR-TB) through: (i) increased access to quality-assured second line anti-TB drugs; and (ii) prevention of development of resistance to anti-TB drugs.

The Green Light Committee (GLC) Initiative, together with the Working Group on MDR-TB, promotes implementation of this strategy in accordance with the Global Plan to Stop TB (2006–2015) and the Global MDR/XDR-TB Response plan (2007–2008).

Established in 2000, the GLC Initiative is the mechanism that enables access to affordable, high-quality, second line anti-TB medicines for the treatment of MDR-TB. Its objectives are:

- ensuring effective treatment of patients with MDR-TB in accordance with guidelines published by the World Health Organization (WHO) on the programmatic management of MDR-TB;
- increasing access to technical assistance to facilitate rapid scale-up of MDR-TB management;
- increasing access to high-quality, low-cost, second line anti-TB medicines for the treatment of MDR-TB among well-performing programmes; preventing the development of resistance to second line anti-TB drugs by ensuring rational drug use;
- Advising WHO on policy-related matters to effectively prevent and control MDR-TB based on the best available scientific evidence.

¹⁰ Quoted from Message from the Chair, GLC 2008 Annual Report

The GLC Initiative therefore contributes to reducing transmission of TB, preventing further drug resistance and ultimately reducing the global burden of TB. The Initiative is coordinated by the GLC Secretariat, which is hosted and administered by WHO.¹¹

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 2009 being no exception.

- In 2009, the GLC reviewed fifty-three (53) applications and approved 13,389 patients for enrolment in treatment.
- At the end of 2009, a total of seventy-two (72) countries had received GLC approval and fifty-two (52) had started implementation.
- In October 2009, the First Green Light Committee Forum was held in Geneva providing the opportunity to one hundred and sixty-eight (168) participants including representatives from thirty-four (34) countries to share knowledge and promote best practices.
- Recognizing the need for universal access to DR TB management the GLC is gradually moving towards the support of nationwide implementation plans.
- In total, the Green Light Committee has reviewed one hundred and eighty-four (184) applications and approved 64,447 patients in one hundred and fifteen (115) projects and seventy-two (72) countries

For more information regarding MDR patient treatments provided and enrollment kindly see the GLC annual report to be located at:

<http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/index.html>

Increases to Second line medicine availability through GDF

Expression of Interest for Manufacturers of Second line anti-TB medicines (EOI)

As reported in the 2008 annual report, GDF issued an Invitation for submission of Expressions of Interest (EOI) to manufacturers of second line anti-TB drugs in September 2008. This process was completed in Q3 2009. The EOI outcome is encouraging and a milestone was reached for increased availability/production capacity for quality-assured MDR-TB medicines. Since the goal of up to three (3) approved suppliers for each MDR-TB product was however not reached, product qualification will continue apace with other potential suppliers in 2010.

As a continuation of the EOI, GDF entered into price negotiations with suppliers of GDF approved products and established a Task Force on Price Negotiation which comprised of representatives from Donors, the Green Light Committee and GDF to facilitate this work.

The first price negotiation meetings took place during Q4 2009.

¹¹ http://www.who.int/tb/challenges/mdr/greenlightcommittee/faq1_initiative/en/index.html

WHO Prequalification Programme (PQP) of Anti-TB medicines

The WHO Prequalification Programme launched the 8th and 9th Invitations to manufacturers of anti-tuberculosis medicines to submit an Expression of Interest (EOI) for product evaluation (March and August 2009 respectively). Both EOI lists included additional second line anti-TB drugs according to suggestions made from Global Drug Facility and Stop TB Department related to new strengths and/or new finished pharmaceutical products.

In 2009, two new second line anti-TB drugs were prequalified:

Table 8: Second line Anti-TB drugs prequalified in 2009

Drug	Formulation	Manufacturer	Packing	Date of Prequalification
Cycloserine	Capsules 250mg	Aspen Pharmacare Limited	HDPE bottle 100	2009-Jun-19
Para-amino salicylate sodium	Delayed release granules 60% w/w	Macleods Pharmaceuticals Ltd	LDPE bag placed in triple laminated Alu/PET/Alu/LLDPE sachet further packed in HDPE container 100g	2009-Dec-14

New dossiers were submitted in 2009 to WHO PQP for the following products:

- Amikacin 100 mg/2ml injection
- Amikacin 250 mg/2ml injection
- Amikacin 500 mg/2ml injection
- Capreomycin 1g injection
- Ofloxacin 200 mg tablets
- Ofloxacin 400 mg tablets
- Levofloxacin tablets 250 mg
- Levofloxacin tablets 500 mg
- Kanamycin injection 1.0 g
- Kanamycin injection 0.5 g
- Moxifloxacin tablets 400 mg
- Ethionamide tablets 250 mg
- Cycloserine tablets 250 mg



GDF expects more dossiers will be submitted and accepted for assessment by WHO PQP and/or SNRA in 2010.

Procurement of Second Line Medicines

Grants

In July 2007, UNITAID agreed to fund a joint project with the Global Drug Facility and the Global Fund to fight against multidrug resistant tuberculosis (MDR-TB) called the MDR-TB Scale-up Initiative. The aim of this joint project is to increase access to quality-assured second line anti-TB drugs to treat patients with MDR-TB in eligible countries and positively impact the dynamics of the MDR-TB drug market. The successful implementation of this project will allow for MDR-TB patient treatments to be delivered to 17 countries from 2007 to 2011.

Since project inception, fifteen (15) of the seventeen (17) approved countries have placed orders. In 2009, twelve (12) countries placed orders valuing US\$4,203,670. Thirteen (13) countries¹² received deliveries totaling US\$ 5,688,264 in 2009.

Direct Procurement

GDF continued to see a steady increase in the volumes of second line anti-TB medicines procured through its direct procurement service. In 2009, 38 countries purchased anti-TB second line medicines through direct procurement, an increase compared to the 33 countries who procured through direct procurement in 2008. The value of medicines procured also increased from US\$ 17,562,399 in 2008 to US \$22,349,833 in 2009.

Strategic Rotating Stockpile for MDR-TB

In November 2008, UNITAID signed a Letter of Agreement (LoA) with the Stop TB Partnership initiating the "MDR-TB Acceleration of Access project: strategic rotating stockpile", building on the original MDR-TB scale up initiative under which an original stockpile was approved for 800 patient treatments. The primary objective of the project is to increase the current stockpile level from 800 patient treatments to 5,800 patient treatments. This increase is expected to allow for improved and accelerated service to patients enrolled under GLC approved country projects/programmes.

The Strategic Rotating Stockpile for MDR-TB drugs was fully operational in 2009 and serviced thirty-nine (39) countries. For the majority of anti-TB medicines in the stockpile, target volumes had been reached with the exception of Capreomycin and Kanamycin. GDF has taken action to remedy this in 2010.

Key Partnership - Innovative Initiative in New Diagnostics for detection of MDR-TB

In 2009, UNITAID approved and provided funding for a project to accelerate access to diagnostics for patients at risk of multidrug-resistant tuberculosis in twenty-seven (27) countries. The EXPAND-TB (Expanding Access to New Diagnostics for TB) Project is a collaboration between the World Health Organization (WHO), the Global Laboratory

¹² Includes countries that placed orders in 2008

Initiative (GLI), the Foundation for Innovative New Diagnostics (FIND) and the Stop TB Partnership's Global Drug Facility (GDF).

The overall goal of the five-year Project is to narrow the huge diagnostic gap in MDR-TB control by expanding and accelerating access to new and rapid diagnostic technologies within appropriate laboratory services at country level, accompanied by the necessary know-how for technology transfer, and ensuring these new technologies are properly integrated within TB control programmes.

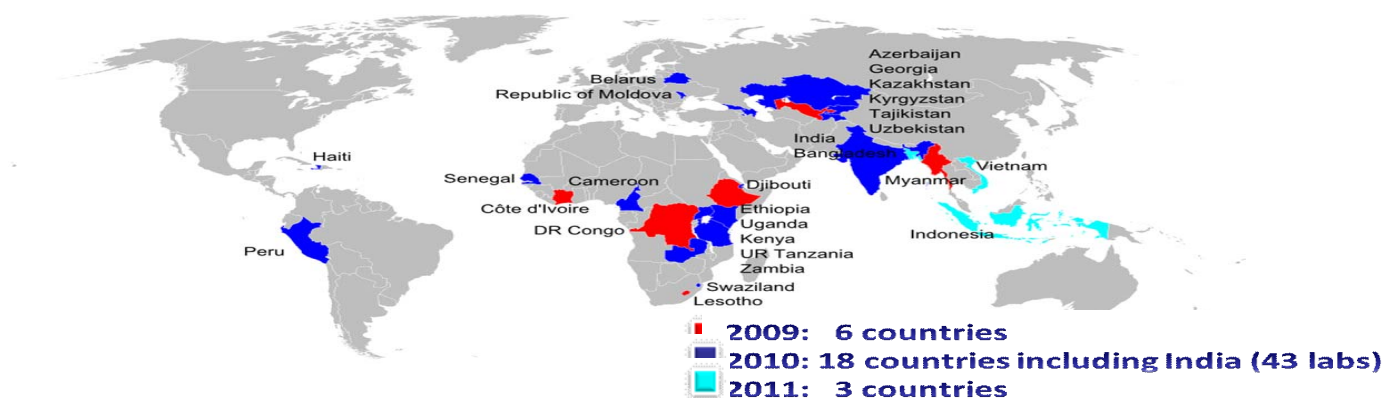
During the first year of EXPAND-TB a wide range of activities has been initiated in countries, including the crucial components of laboratory needs assessment and preparedness, upgrade of infrastructure, and training of staff. Technology transfer has subsequently started, paving the way for accelerated patient diagnosis and eventual routine surveillance of drug resistance at country level.

EXPAND-TB has full ownership by the Ministries of Health of the recipient countries and works on a model of best-practices, learning-by-doing, and optimizing resources for laboratory strengthening at country level.

The EXPAND-TB Project aims to diagnose at least 129 000 patients with multidrug-resistant TB. Specific operational objectives are to:

- expand and accelerate access to quality-assured new diagnostic technologies, endorsed by WHO, which currently include commercial liquid culture, rapid speciation by immuno-chromatography and molecular line probe assay;
- impact market dynamics to leverage price reductions for diagnostic tools, instruments, reagents, and supplies and to stimulate a greater number of suppliers of new TB diagnostics;
- improve case detection and management of TB and MDR-TB by ensuring that the new TB diagnostic tools are taken up and appropriately used in National TB Control Programmes.

Table 10: Recipient Countries Expand-TB Project



GDF is the partner charged with the procurement of MDR diagnostic commodities under the Expand-TB project. In 2009, GDF delivered new diagnostic commodities valuing US\$ 966,298.90 to five countries.

5.0 Technical Assistance

Key Partner - Collaboration with TB Team for improved provision of Technical Assistance

Reflecting GDF's continued commitment to provide technical assistance to countries, GDF increased its collaboration in 2009 with the TBTEAM (Stop TB Partnership TB Technical Assistance Mechanism housed in WHO's Stop TB Department), with GDF's Capacity Building Officer joined the TBTEAM to assist with increasing coordination between GDF and other services providing technical assistance in countries.

TBTEAM provides a platform for technical assistance coordination, encourages collaboration among partners, promotes available quality expertise and facilitates planning for technical assistance according to country needs. TBTEAM promotes local ownership of planning for and accessing technical assistance based on sound technical discussion by existing TB coordination mechanisms.

The TBTEAM web site provides on-line tools to facilitate access to and coordination of technical assistance, including:

- Stop TB missions and events
- Stop TB experts
- Stop TB partner mapping

As not all technical assistance needs can be anticipated, TBTEAM helps countries identify on an ad-hoc basis consultants within a large pool of qualified experts and technical partners. Most of these are drawn from the TBTEAM roster of experts to which consultants must apply according to their technical expertise. Where necessary, TBTEAM also provides funding for ad-hoc missions, although funding is limited.

884 missions and events, including eighty-eight (88) missions organized by GDF were recorded in the TBTEAM online tools in 2009.

TB Control

Technical Assistance through GDF Missions

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 programme 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 (capacity building in procurement and supply management) missions also covering: training, information regarding services etc.

Summary of GDF Missions and Workshops for 2009

In 2009, GDF performed eighty-eight (88) missions to sixty-four (64) different countries in all six WHO Regions (See Table 11 for more information). Of these eighty-eight (88) missions, eighteen (18) were combined missions¹³ allowing for more efficient use of time and country resources. Of these, one (1) was a pre-delivery country visits, forty-two (42) were grant monitoring missions, thirty-three (33) were DP technical support missions and twelve (12) were technical assistance missions.

The increase in missions in 2009 (88) as compared to 2008 (76) illustrates GDF's continued commitment to increase awareness at the country level of the importance of effective drug management while helping alleviating immediate bottlenecks during in-country missions. However, GDF recognizes that financing for technical assistance in drug management needs to be made available to countries to achieve long-term impact. As such, GDF will continue its efforts to help identifying the needs in this area and matching with them the support from technical assistance providers, through the TBTEAM mechanism.

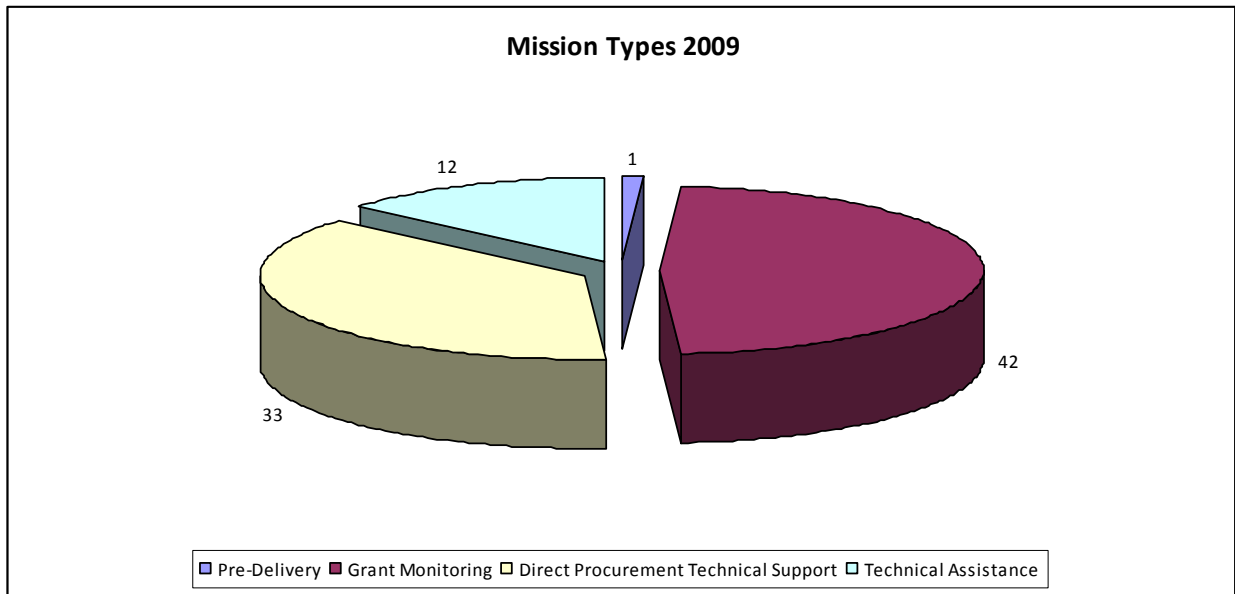
In addition to the missions performed in country in 2009, GDF also performed six (6) workshops (Bangladesh, Belarus, Brazil, Pakistan, Tunisia and Uganda) focusing on drug management capacity building for first and second line medicines.

Table 11: GDF Missions for 1 January - 31 December, 2009

Mission Type	2009	2008
Pre-Delivery	1	5
Grant Monitoring	42	41
Direct Procurement Technical Support	33	22
Technical Assistance	12	8
Total Missions:	88	76
Combined Missions:	18	13
Total Unique missions:	76	63
Workshops	6	n/a
Total Missions and Workshops	94	n/a
Number of Countries	64	63

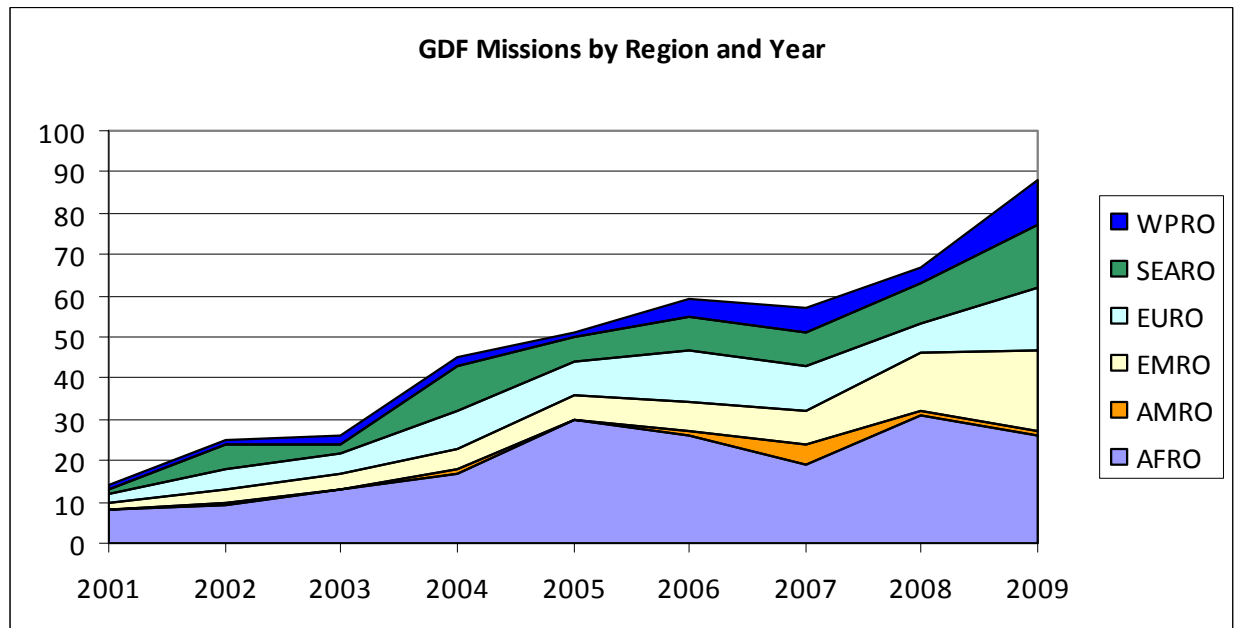
¹³ Combined missions: Missions where multiple mission types (i.e. Grant and Direct Procurement Monitoring) occur during the same country visit.

Table 12: Mission Types 2009



Since 2001, GDF has provided a total of four hundred and thirty two (432) missions in GDF supported countries. The graph below shows the breakdown of missions per WHO region since the inception of GDF in 2001.

Table 13: Breakdown of GDF Missions by Region and Year: 2001 - 2008



Technical Assistance through GDF Regional Support Officers (RSOs)

GDF began placing RSOs in the regions in 2004. In 2009, GDF Regional Support Officers (RSOs) played a key support role in the regions. Currently GDF has an RSO placed in AFRO, EMRO and SEARO.

In 2009, Regional Support Officers activities included the following:



- Participated in Pharmaceutical Management for Tuberculosis workshop in Uganda, the focus of which was to improve knowledge and develop skills on specific managerial issues regarding first line DOTS and second line MDR-TB drug supply management.
- Established communication with WHO Essential Medicines Programme (EMP)/EMRO discussing a policy to limit anti-TB medicines in the private market. A survey was performed in 2009, with GDF's RSO participating in the writing of the report of findings.
- Continued working with WHO/EMP to increase number of WHO pre-qualified suppliers
- Conducted survey in EMRO to determine potential causes of medicine shortages and bottlenecks to lead times.
- Conducted trainings on Pharmaceutical and Supply Management for first and second line medicines in Bangladesh, Fiji and Nepal.
- Led GDF monitoring and technical assistance missions to Democratic Peoples Republic of Korea, Liberia, Nepal and Sri Lanka and participated in the joint external review mission in India.
- Conducted two day workshop in Sri Lanka on proper planning and use of Global Funds monies.
- Conducted trainings on Pharmaceutical and Supply Management for first and second line medicines in Tunisia
- Conducted GDF technical and monitoring missions to Eritrea, Ghana, Kenya, Liberia, Nigeria and Tanzania.
- Provided technical support to four (4) countries to strengthen procurement and supply management systems for TB medicines (Eritrea, Ghana, Liberia and Nigeria).
- Co-organized and participated in a regional drug management workshop attended by participants from nine (9) countries (Angola, Ethiopia, Eritrea, Ghana, Liberia, Nigeria, Sierra Leone, Uganda and Zimbabwe) aimed at improving knowledge and developing skills on specific managerial issues regarding first line and second line anti-TB drug supply management. Participants were assisted in developing a TB drug management improvement plan for implementation in their country's national tuberculosis programme upon return.

- Participated in the Mozambique mid-term review of the National Tuberculosis Control Programme Strategic Plan 2008-2012

The overall outcome of the RSOs activities in the region led to effective and improved collaboration and coordination of pharmaceuticals and commodities procurement at various levels. The RSO regular and continuous support significantly contributed to strengthening countries' capacity for improving drug management practices.

GDF Drug Management Technical Support for MDR-TB Programmes

In 2009, GDF organized, assisted with or participated in many support interventions for programs accessing second line anti-TB medicines along with the GLC Initiative including:

- Participated and presented at the MSH Workshop: Practical Approaches to Ensuring Equitable Access to TB medicines at the International Union against Tuberculosis and Lung Disease (UNION) meeting in Cancun, Mexico, December 2009.
- Participated in the Eli Lilly Summit for manufacturing partners to engage suppliers (Cancun, Mexico, December 2009).
- Presented and participated in the monitoring and evaluation mission in Ecuador, November 2009.
- Participated in the first Green Light Committee Forum held in Geneva in October 2009.
- Attended Interagency Pharmaceutical Coordination (IPC) meeting in Vienna in May 2009. The Interagency Pharmaceutical Coordination (IPC) Group consists of the senior pharmaceutical advisers of the World Health Organization, World Bank, UNAIDS, UNFPA, Global Fund, UNICEF, UNIDO.



- Participated in the technical support mission to Moscow 2009 with the aim to assess existing obstacles in the procurement of second line drugs (SLD).
- Participated in the procurement and supply management mission to Santo Domingo, Dominican Republic, July 2009 to assess: implementation of the program, identify gaps and achievements; assess the needs and readiness for TB program expansion; collect data of patients on treatment and identify challenges in the management of patients.
- Facilitated the Drug Management module of the VI International Course - Manejo Clínico y Operativo de la Tuberculosis con Resistencia a Farmacos (Clinical and Operational Management of MDRTB). Dominican Republic, July 2009.
- Attended Stakeholders Meeting organized by the Global Fund, Kuala Lumpur, Malaysia, December 2009.

For more information regarding technical support provided for MDR programmes see the GLC annual report to be located at:

<http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/index.html>

6.0 GDF OPERATIONS

Developments to Management and Operational Functions 2009

GDF further developed its management and operational functions in 2009:

- GDF continued developing its Order Management System (OMS) to include an improved reporting component allowing for increased ease and flexibility.
- GDF divided its procurement team into two sub-teams: one focusing on first line and diagnostics and the second focusing on MDR-TB. In Q4 2009 GDF recruited a new team leader for the MDR-TB team to allow for increased focus on this growing area.
- To address a key bottleneck, a Procurement Officer was recruited to focus on assisting with registration issues for both first and second line products.
- GDF has continued to increase its collaboration with the Green Light Committee through improved communication and joint mechanisms.
- Illustrating its commitment to quality management, GDF further divided its Business Advisory Committee subgroups to include a sub-group devoted to Quality Management. This sub-group performed two management reviews in line with ISO 9001:2000 requirements.
- GDF's Procurement team held a key stakeholder meeting in Brazil in March 2009 that addressed key bottleneck issues with service providers and manufacturers.

- GDF participated in the 3rd Stop TB Partnership's Partner's Forum in Rio de Janeiro, Brazil allowing for critical communications and relationship building.
- GDF participated in two high-level meetings regarding MDR-TB in Beijing and Seattle to ensure country commitment to the MDR-TB Scale Up.
- GDF began issuing quarterly forecasts to manufacturers to increase manufacturer commitment.

External Advisory Committee focused on GDF Operational and Strategic Issues

Business Advisory Committee (BAC)

As GDF takes on further challenges, with the supply of diagnostic kits, paediatric formulations, second line anti-TB medicines and diagnostics and increased involvement in country drug management capacity building, 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.

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

In 2009 the BAC held its 5th and 6th meetings which continued the format of plenary sessions plus individual subgroup sessions. Subgroups continued to be focus on issues raised in a particular area: 1) Business Operations, 2) Marketing and Procurement and 3) Country Support. Following BAC 5 an additional subgroup was created using the Chairs of the individual subgroups with a specific mandate to focus on Quality Management.

In 2009 some of the key areas identified for which recommendations were made are:

- Building a sustainable financing model for GDF direct procurement activities
- Improving monitoring mechanisms of external providers
- Addressing challenges presented by the pending MDR-TB Scale-Up
- Further alignment with GLC to improve data collection and forecasting mechanisms
- Evaluating extent of GDF's involvement in drug registration process
- Recommendations for paediatric tendering process

- Effective tool for capturing feedback on technical assistance provided through GDF and TBTEAM
- Addressing any bottlenecks relating to Pre-Qualification
- Recommendations regarding percentage of compensation for quality assured products in competitive tenders
- Determining key action steps following Beijing meeting in March 2009

The BAC also performed two (2) Management Reviews as per ISO 9001:2000 requirements.

7.0 CHALLENGES AND OPPORTUNITIES FOR 2010

- **STRATEGIC PLAN 2011-2015:** Boston Consulting Group consultancy: considering GDF achievements in the past 9 years and the changing TB landscape, the consultancy will review and analyse future strategic directions for GDF and make recommendations to ensure that GDF continues to play an essential role in continuing to provide value added quality service to countries in need.
- **MDR-TB SCALE UP:** In anticipation of a significant increase in countries procuring SLD, GDF is ramping up its engagement with 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 future introduction of new paediatric formulations following the new WHO recommendations for TB treatment in children, GDF will continue to closely interact with country programmes and suppliers to ensure that adequate drugs are provided during the transition phase.
- **HUMAN RESOURCES:** Recruitment of a new General Manager for GDF as well as three new staff for the MDR-TB team that will support the scale up of MDR-TB patients expected to be diagnosed and treated in 2011 and beyond.
- **FORECASTING:** To continue building on improvements to existing forecasting mechanisms needed to allow for greater manufacturer engagement.
- **GLOBAL FUND COLLABORATION:** Ensuring effective implementation of the renewed Stop TB Partnership-Global Fund Memorandum of Understanding: key outcomes would be complete alignment of GDF and Global Fund Quality Assurance policies as well as a 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).
- **FINANCING:** following completion of BCG consultancy translate Stop TB Partnership Coordinating Board accepted recommendations into a business and financing plan that will inform donors support to GDF as well resource mobilization efforts where needed for sustainable financing for medicines and operations.

- **DIRECT PROCUREMENT:** As the volume of direct procurement service increases development of a sustainable financing model will be essential - enhanced marketing and branding is required to demonstrate the value added and GDF comparative advantages.

In 2010 as GDF further develops its business model and services it will continue to offer complete, high quality services to countries procuring TB medicines and commodities while, always striving to remain the most cost effective service available. GDF will remain a key contributor in the fight to reduce the burden of TB worldwide.

Annex 1: GDF performance, process and impact indicators

GDF core functions	Indicator	2009	2008
	Orders Placed		
Funding	Funds raised for GDF Operations, in US \$'000 (includes contributions in kind) ¹⁴	\$57,584	\$63,786
FLD Patient Treatments delivered	Number of patient treatments supplied via GDF Grant and Direct Procurement Services ¹⁵	2,454,274 ¹⁶	2,778,879
Countries receiving Deliveries	Number of countries that received First line Grant deliveries	28	35
	Number of countries that received First line Direct Procurement deliveries	57	44
	Number of countries that received Paediatric Treatments	45	44
	Number of countries that received FLD Diagnostic Kits	15	7
	Number of countries that received Second line Grant deliveries	13	12
	Number of countries that received Second line Direct Procurement deliveries	43	33
	Number of countries that received MDR New Diagnostic Deliveries	5	n/a

GDF core functions	Indicator	2009	2008	Cumulative (2001 -2009)
First line Grant/Direct Procurement applications approved by the TRC	No. of rounds of grant application and review	2	2	21
	No. of new applications submitted	7	25	224
	Value of TRC approvals, in US\$ '000**			
	Total	\$24,881	\$25,097	\$182,688
	Number of applications approved**			
	Adult	20	23	144
	Paediatric	42	14	104
	Total	62	37	248
	Number of patient treatments approved via TRC			
	Adult	283,871	876,028	7,827,382
	Paediatric	121,086	23,605	314,800
	Direct Procurement	376,899	40,000	416,899
	Total	781,856	939,633	8,559,081

¹⁴ Figure does not contain funds received for Direct Procurement orders as in reports issued prior to Progress Report 13.

¹⁵ Patient treatments calculated using pill count methodology and based on total order quantities for orders that received first shipment of medicines within reporting period.

¹⁶ Includes paediatric prophylaxis treatments (not included in previous reports)

GDF core functions	Indicator ¹⁷	2009	2008
	Orders Placed		
FLD Adult Grant Services ¹⁸	Number of Orders Placed	59	75
	Cost of Products ¹⁹	\$15,608,721	\$37,412,236
	Freight and Insurance Costs orders placed	\$844,511	\$2,093,278
	Procurement Agent Fee	\$534,321	\$1,212,157
	Quality Control ²⁰	\$923,112	\$1,635,954
	Order Cost Fluctuation Buffer ²¹	\$245,771	\$504,267
	Total Value of all orders placed (all inclusive)	\$18,156,435	\$42,857,892
	Number of Countries placing orders	18	29
	Products Delivered²²		
	Cost of Products	\$26,247,037	\$34,983,742
	Freight and Insurance Costs	\$1,215,291	\$2,165,213
	Quality Control	\$1,346,320	\$1,335,792
	Procurement Agent Fee	\$848,984	\$1,133,599
	Order Cost Fluctuation Buffer	\$340,826	\$360,868
	Total Value of all shipments delivered (all inclusive)	\$29,998,458	\$39,979,215
	Number of Countries receiving Deliveries ²³	28	35
	Patient Treatments/Lead Times		
	Number of patient treatments delivered	1,212,466	1,744,557
	Average lead time ²⁴	111	93
	Median Lead Time	107	79

¹⁷ All order values are based on estimates provided at time of order placement. Final value available only after payment of all invoices.

¹⁸ Does not include grants for Paediatric Medicines

¹⁹ Includes Cost of Products Exworks Manufacturer

²⁰ Includes Cost of Quality Control and Cost PSI

²¹ The order cost fluctuation buffer is a buffer to cover for any unforeseen costs related to the estimated costs and other associated costs for an order. The buffer is calculated as 30% of the estimated freight costs. Any unspent buffer will - after payment of invoices - be returned to UNITAID funds ceiling. For DP orders the clients will be re-imbursed the balance of the total order after payment of invoices.

²² In 2009 GDF modified its method for calculating products delivered. Prior to 2009 total order value was included in the calendar year of first shipment. Current methodology includes values only of shipments delivered within the calendar year. (Note: orders can often have multiple shipments)

²³ Includes countries that placed orders in 2008

²⁴ Lead time is calculated from date firm order is placed with procurement agent until first shipment received in country.

GDF core functions	Indicator	2009	2008
	Orders Placed		
FLD Direct Procurement Service (includes FLD Diagnostic orders)	Number of Orders Placed	87	60
	Cost of Products	\$20,105,473	\$14,034,998
	Freight and Insurance Costs	\$2,868,261	\$2,023,764
	Procurement Agent Fee	\$780,579	\$491,877
	Quality Control	\$1,042,901	\$648,377
	Order Cost Fluctuation Buffer	\$831,753	\$516,615
	Total Value of all orders placed (all inclusive)	\$25,628,967	\$17,715,632
	Number of Countries placing orders	52	41
	Products Delivered		
	Cost of Products	\$21,003,360	\$13,815,269
	Freight and Insurance Costs	\$3,014,411	\$1,560,700
	Quality Control	\$1,014,994	\$548,440
	Procurement Agent Fee	\$748,280	\$468,588
	Order Cost Fluctuation Buffer	\$818,860	\$256,610
	Total Value of all shipments delivered (all inclusive)	\$26,599,905	\$16,649,606
	Number of Countries receiving Deliveries	57	44
	Patient Treatments/Lead Times		
	Number of patient treatments delivered	867,848	878,569
	Average lead time	83	118
	Median Lead Time	79	109

GDF core functions	Indicator	2009	2008
	Orders Placed		
FLD Grant Service - Paediatric medicines	Number of Orders Placed	53	34
	Cost of Products	\$2,102,739	\$446,821
	Freight and Insurance Costs	\$303,140	\$142,016
	Procurement Agent Fee	\$78,975	\$19,803
	Quality Control	\$264,567	\$83,802
	Order Cost Fluctuation Buffer	\$96,750	\$47,142
	Total Value of all orders placed (all inclusive)	\$2,846,172	\$739,583
	Number of Countries placing orders	42	31
	Products Delivered		
	Cost of Products	\$2,290,403	\$934,993
	Freight and Insurance Costs	\$342,082	\$248,457
	Quality Control	\$275,139	\$134,963
	Procurement Agent Fee	\$85,770	\$38,784
	Order Cost Fluctuation Buffer	\$108,287	\$35,672
	Total Value of all shipments delivered (all inclusive)	\$3,101,682	\$1,392,868
	Number of Countries receiving Deliveries	45	44
	Patient Treatments/Lead Times		
	Number of patient treatments	145,691	155,753 ²⁵
	curative prophylaxis	228,269	91,995
	Average lead time	87	105
	Median Lead Time	85	97

²⁵ Includes patient treatments delivered through UNITAID Paediatric Project and treatments delivered to India

GDF core functions	Indicator	2009	2008
	Orders Placed		
FLD Diagnostics Orders	Number of Orders Placed	18	9
	Cost of Products	\$822,340	\$529,345
	Freight and Insurance Costs	\$326,599	\$241,179
	Procurement Agent Fee	\$35,237	\$22,854
	Quality Control (orders placed)	\$16,050	\$5,900
	Order Cost Fluctuation Buffer	\$91,583	\$59,844
	Total Value of all orders placed (all inclusive)	\$1,291,809	\$859,123
	Number of Countries placing orders	15	7
	Products Delivered		
	Cost of Products	\$1,030,805	\$522,571
	Freight and Insurance Costs	\$473,611	\$160,961
	Quality Control	\$16,972	\$7,650
	Procurement Agent Fee	\$45,197	\$20,330
	Order Cost Fluctuation Buffer	\$131,704	\$11,210
	Total Value of all shipments delivered (all inclusive)	\$1,698,288	\$722,722
	Number of Countries receiving Deliveries	15	7
	Lead Times		
	Average lead time	99	162
	Median Lead Time	91	154

	Indicator	2009	2008
	Orders Placed		
Second line Grant Service	Number of Orders Placed	29	30
	Cost of Products ²⁶	\$3,730,734	\$3,703,160
	Freight and Insurance Costs	\$191,165	\$203,441
	Procurement Agent Fee	\$198,571	\$197,104
	Quality Control ²⁷	\$83,200	\$82,592
	Total Value of all orders placed (all inclusive)	\$4,203,670	\$4,186,296
	Number of Countries placing orders	12	12
	Products Delivered		
	Cost of Products	\$5,038,828	\$1,967,172
	Freight and Insurance Costs	\$269,207	\$106,258
	Quality Control	\$112,034	\$43,362
	Procurement Agent Fee	\$268,196	\$105,667
	Total Value of all shipments delivered (all inclusive)	\$5,688,264	\$2,222,460
	Number of Countries receiving Deliveries	13	12
	Lead Times		
	Average lead time	100	113
	Median Lead Time	59	80

²⁶ Includes Cost of Product Exworks and Cost of Freight to Consolidator

²⁷ Includes Cost of Pre-Shipment Inspection, Cost Quality Assurance and Cost Quality Control

GDF core functions	Indicator	2009	2008
	Orders Placed		
Second Line Direct Procurement Service	Number of Orders Placed	84	77
	Cost of Products	\$20,236,742	\$15,810,109
	Freight and Insurance Costs	\$589,986	\$561,235
	Procurement Agent Fee	\$1,077,117	\$841,506
	Quality Control	\$445,988	\$349,549
	Total Value of all orders placed (all inclusive)	\$22,349,833	\$17,562,399
	Number of Countries placing orders	38	33
	Products Delivered		
	Cost of Products	\$22,303,837	\$7,997,260
	Freight and Insurance Costs	\$687,095	\$486,665
	Quality Control	\$491,109	\$178,263
	Procurement Agent Fee	\$1,187,140	\$425,661
	Total Value of all shipments delivered (all inclusive)	\$24,669,181	\$9,087,848
	Number of Countries receiving Deliveries	43	33
	Lead Times		
	Average lead time	103	111
	Median Lead Time	64	75

	Indicator	2009	2008
	Products Delivered		
MDR New Diagnostics	Equipment Cost	\$811,026	N/A
	Consumables and reagents	\$101,709	N/A
	Essential Supplies (Biosafety)	\$53,564	N/A
	Freight and Insurance	\$37,719	N/A
	Procurement Fee and Fixed costs ²⁸	\$224,570	N/A

	Indicator	2009	2008
	Mission Type		
First line Monitoring and Evaluation Missions and Workshops	Pre-Delivery	1	5
	Grant Monitoring	42	41
	Direct Procurement Technical Support	33	22
	Technical Assistance	12	8
	Total Missions:	88	76
	Combined Missions:	18	13
	Total Unique missions:	76	63
	Number of Countries	64	63
	Workshops	6	n/a
	Total Missions and Workshops	94	n/a

²⁸ Shared between FIND and GDF

	Indicator	2009	2008
Cure Rates/Treatment Costs	Estimated number of patients that will be cured with drugs supplied via GDF Grants ²⁹	1,348,462	1,992,305
	Estimated number of TB patients that will be cured with drugs supplied via GDF Direct Procurement ³⁰	737,670	746,784
	Total Estimated number of TB patients that will be cured (Grants and Direct Procurement)	2,086,133	2,362,042
	Average Cost per treatment in US dollars		
		18.65 ³¹	18.65
	<i>Adult First Line</i>	34.95 ³²	34.95
	<i>Paediatric</i>	14.37 ³³ 1.28 ³⁴	16.80 n/a
	<i>Adult Second Line</i>	2,349.00 ³⁵ 5,286.60 ³⁶	1584.47 4920.84

²⁹ Number does not include patients who received MDR medicines through GDF. Estimated 85% Cure rate.

³⁰ Number does not include patients who received MDR medicines through GDF. Estimated 85% Cure rate.

³¹ Cat. I & III - 2(RHZE)/4(RH)

³² Cat. II - 2S(RHZE)/1(RHZE)/5(RHE)

³³ 2(RHZ)/4(RH)

³⁴ 6H (5mg/kg)

³⁵ Example of low end-of-range cost calculation for one country

³⁶ Example of high end-of-range cost calculation for one country

Annex II: Statement of Income, contribution received for Direct Procurement and Expenditures

Stop TB Partnership Global TB Drug Facility Financial Management Report Statement of Income, contribution received for Direct Procurement and Expenditures For the year ending 31 December 2009 (US\$'000)			
	Notes	2008	2009
Income			
Government and their Agencies - specified	1	39,200	32,976
Multi lateral institutions	2	22,832	23,174
In kind contribution for drugs from Novartis	3	1,033	1,690
Contribution for direct procurement	4	15,463	47,979
Other income	5	227	30
Total Income		78,755	105,849
Expenditure			
Grant procurement of Anti TB drugs		52,098	22,134
Direct procurements		15,463	47,979
Quality assurance and prequalification		140	469
Technical assistance, Monitoring and Salaries		3,068	4,123
Advocacy and Communications & management		231	448
Indirect costs	6	982	764
Total Expenditure		71,982	75,917
Funds transferred to GLI	7	-	1,126
Total of expenditures and fund transfers		71,982	77,043
Balance of income over expenditure		6,773	28,806

Balance of income over expenditure contains US\$ 15 Million disbursement from USAID received only in November 2009. Additionally balance contains funds received in 2009 for multi-year projects including \$ 9.6 million received in Q3 for the Expand-TB project, all these funds have been allocated for spending in 2010. Remaining balance can be attributed to deviation in delivery target for MDR-TB treatments.

Annex III: Approval Status First line adult and paediatric medicines provided through GDF

Product and packaging	Supplier	Approval Status
E-400 Bulk	Macleods	Prequalified
E-400-Blister	Macleods	Prequalified
H300 Bulk	Macleods	Prequalified
H300-Blister	Macleods	Prequalified
Z-400-Blister	Macleods	Interim Review
Z-400 Bulk	Macleods	Prequalified
EH-400/150 Bulk	Macleods	Prequalified
EH-400/150-Blister	Macleods	Prequalified
E-400 Bulk	Lupin	Interim review
E-400 Blister	Lupin	Interim review
EH-400/150 Bulk	Lupin	Interim review
EH-400/150- Blister	Lupin	Interim review
RH-150/75 - Bulk	Lupin	Prequalified
RH-150/75- Blister	Lupin	Prequalified
2-FDC RH150/150 - Bulk	Lupin	Interim review
2-FDC RH150/150- Blister	Lupin	Interim review
E-400 Bulk	Cadila	Prequalified
E-400 - Blister	Cadila	Prequalified
H300 Bulk	Cadila	Interim Review
H300 - Blister	Cadila	Interim Review
Z-400 Bulk	Cadila	Prequalified
Z-400-Blister	Cadila	Prequalified
EH-400/150 Bulk	Cadila	Interim Review
EH-400/150 Blister	Cadila	Interim Review
E-400 Bulk	Svizera	Interim Review
E-400 - Blister	Svizera	Interim Review
H300 Bulk	Svizera	Interim Review
H300 - Blister	Svizera	Interim Review
EH-400/150 Bulk	Svizera	Interim Review
EH-400/150-Blister	Svizera	Interim Review
RH-150/75-Blister	Svizera	Interim Review
4FDC RHZE-Blister	Svizera	Interim Review
Z-400 Bulk	Strides-Arcolab	Interim Review
H100-B	Fatol	SRA
S 1	Panpharma	SRA
4FDC-RHZE Bulk	Sandoz	Prequalified
4FDC-RHZE - Blister	Sandoz	Prequalified
RH-150/75 Bulk	Sandoz	Prequalified
RH-150/75-Blister	Sandoz	Prequalified

Approval Status for GDF's Paediatric Products

Product	Packaging	Supplier	Approval Status
Rifampicin 60mg/Isoniazid 30mg/Pyrazinamide 150mg	Blister	Lupin	Interim
		Macleods	Product(PQ)/ Packaging (Interim)
Rifampicin 60mg/Isoniazid 30mg	Blister	Lupin	Interim
		Macleods	Product(PQ)/ Packaging (Interim)
Rifampicin 60mg/Isoniazid 60mg	Blister	Macleods	Product (PQ)/ Packaging (Interim)
Pyrazinamide 150mg	Blister	Lupin	Interim
Pyrazinamide 150mg	Jar	Lupin	Interim
Isoniazid 100mg	Blister	Lupin	Interim
		Cadila**	Interim
		Macleods	PQ*
Isoniazid 100mg	Jar	Lupin	Interim
		Cadila**	Interim
Isoniazid 50mg	Blister	Lupin	Interim
		Macleods	Interim
Isoniazid 50mg	Jar	Lupin	Interim
Ethambutol 100mg	Blister	Fatol	SNRA
Ethambutol 100mg	Jar	Labatech	SNRA

*PQ currently waiting for some outstanding updated information.

** As an outcome of the product dossier assessment (GDF EoI 2008) during 2009, Cadila was not found eligible as supplier for the H-100mg formulation.

Drug code / drug group	INN	MANUFACTURER			
			Basis for product approval	Strength	Dosage Unit
Group 2: Injectable	Amikacin (Am)	Medochemie	SRA	500mg/2ml inj	Vial
Group 2: Injectable	Amikacin (Am)	Mylan	SRA	500 mg powder for injection	Vial
Group 2: Injectable	Capreomycin (Cm)	Eli Lilly	SRA	1g powder for inj	Vial
Group 2: Injectable	Capreomycin (Cm)	Cipla	Interim Review	1 g (Lyophilized powder for injection i.v. & i.m.)	Vial
Group 3: Fluoro-quinolones	Ofloxacin (Ofx) 200	Macleods	Interim Review	200 mg	Tablet
Group 3: Fluoro-quinolones	Ofloxacin (Ofx) 400	Macleods	Interim Review	400 mg	Tablet
Group 3: Fluoro-quinolones	Ofloxacin (Ofx) 400	Microlabs	Interim Review	400 mg	Tablet
Group 3: Fluoro-quinolones	Levofloxacin (Lfx) 250	Macleods	Interim Review	250 mg	Tablet
Group 3: Fluoro-quinolones	Levofloxacin (Lfx) 250	Microlabs	Interim Review	250 mg	Tablet
Group 3: Fluoro-quinolones	Levofloxacin (Lfx) 250	Cipla	Interim Review	250mg	Tablet
Group 3: Fluoro-quinolones	Levofloxacin (Lfx) 500	Macleods	Interim Review	500mg	Tablet
Group 3: Fluoro-quinolones	Levofloxacin (Lfx) 500	Microlabs	Interim Review	500 mg	Tablet
Group 3: Fluoro-quinolones	Levofloxacin (Lfx) 500	Cipla	Interim Review	500mg	Tablet
Group 3: Fluoro-quinolones	Levofloxacin (Lfx) 750	Macleods	Interim Review	750 mg	Tablet
Group 3: Fluoro-quinolones	Moxifloxacin (Mfx)	Bayer	SRA	400 mg	Tablet
Group 3: Fluoro-quinolones	Moxifloxacin (Mfx)	Cipla	Interim Review	400 mg	Tablet
Group 4: Oral bacteriostatic	Cycloserine (Cs)	Macleods	Prequalified by WHO PQP TB 154	250 mg	Capsule
Group 4: Oral bacteriostatic	Cycloserine (Cs)	Aspen	Prequalified by WHO PQP TB 166	250 mg	Capsule

Group 4: Oral bacteriostatic	Cycloserine (Cs)	Chao Center	SRA	250 mg	Capsule
Group 4: Oral bacteriostatic	Ethionamide (Eto)	Macleods	Prequalified by WHO PQP TB 133	250 mg	Tablet
Group 4: Oral bacteriostatic	Ethionamide (Eto)	Lupin	Interim Review	250 mg	Tablet
Group 4: Oral bacteriostatic	Prothionamide (Pto)	Fatol	SRA	250 mg, film coated	Tablet
Group 4: Oral bacteriostatic	Terizidone (Trd)	Fatol	SRA	250 mg, film coated	Capsule
Group 4: Oral bacteriostatic	p- amynosalicylic acid (PAS)	Jacobus	SRA	4 g aminosalicylic acid	Sachet containing delayed-release granules
Group 4: Oral bacteriostatic	PAS Sodium Granules	Macleods	WHO Prequalified TB156	60% w/w	sachet, containing delayed-release granules
Group 4: Oral bacteriostatic	Pas Sodium Podwer for oral solution	Olainfarm	SRA	powder 5.52 g (4 g para-aminosalicylic)	Sachet containing 5.52 g
Group 5: Anti-TB agents with unclear efficacy	Amoxicillin/ Clavunate (Amx/Clv)	Microlabs	Interim Review	625 mg	Tablet
Group 5: Anti-TB agents with unclear efficacy	Amoxicillin/ Clavunate (Amx/Clv)	Microlabs	Interim Review	125/31.25mg/5ml and 250/62.5mg/5ml dry syrups	suspension (for reconstitution)