GLOBAL DRUG FACILITY (GDF) STRATEGIC PLAN 2006- 2010









THE GLOBAL DRUG FACILITY STOP TB PARTNERSHIP Geneva



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The Global Drug Facility (GDF) is one of the success stories in the fight against TB. Formally established at the Stop TB Partners Forum in Washington in October 2001, the GDF has developed a radically new approach to providing access to drugs for a disease that is spiralling out of control in many parts of the world – fuelled by HIV/AIDS and the spread of multidrug-resistant tuberculosis (TB).

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

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

Achievements 2001 - 2005

▼ The GDF has procured 5 million life-saving TB drug treatments and made deliveries to more than 60 countries in its first 5 years of operation.

By guaranteeing a regular, uninterrupted supply of quality TB drugs to some of the 8 million people who contract TB every year, the GDF is helping to save lives. The GDF accomplishes this by providing three services: 1) a Grant Service for 1st line drugs; (2) a Direct Procurement Service; and 3) a TB Prequalification Service.

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

The GDF established a series of mechanisms to guarantee the quality of the TB drugs it supplies. The GDF buys only from manufacturers whose products have passed stringent manufacturing standards set by the World Health Organization (WHO). The GDF has also been able to achieve a remarkable reduction in drug prices, through standardization of products, pooled procurement, competitive bidding and prompt payment policies.

✓ The GDF mobilizes a wide network of partners.

The GDF benefits from the Stop TB Partnership's broad alliance of national governments, funding agencies, foundations, national and international non-governmental organizations (NGOs), and the private sector, which provide invaluable technical assistance, monitoring support, TB and drug management technical expertise and funding.







The GDF is building the capacity of procurement systems.

With a dedicated team at the Stop TB Partnership Secretariat coordinating procurement activities and several contractual agents managing supply, logistics and freight, the GDF is able to deliver life-saving drugs on time and on budget. The GDF procurement services include a web based mechanism that enables countries and organizations to place order requests for TB drugs and trace their progress through the manufacturing, quality control and delivery stages. Moreover, the GDF implements, together with partners such as WHO, Management Sciences for Health and John Snow Inc., drug management workshops for consultants in different world regions. The objective of these workshops is to train regionally based consultants in the area of drug management.

The GDF promotes standardization and innovation in TB drug products.

One of the biggest barriers to effective TB treatment has been the large numbers of products and regimens available to national TB control programmes as well as conflicting international recommendations on treatment. For this reason, the GDF is supporting standardized WHO recommended regimens underpinned by the use of fixed-dose combination (FDC) products, which have several advantages over conventional formulations. The GDF promotes blister packaging as opposed to traditional bulk packaging, which offers numerous advantages, including better hygiene and protection of the drugs. The GDF has also developed "Patient kits" that contain all the drugs needed to treat one, middleweight patient for six months.

▼ The GDF monitors grant performance to ensure real impact.

The GDF monitors country performance at every step of the grant and procurement process to ensure that this "bundled approach" achieves results. Provision of grants is therefore dependant on a performance based system that is fundamental to the GDF's focus on tangible results.

▼ The GDF has contributed to placing TB control back on the global public health agenda.

As part of the Stop TB Partnership, the GDF has been able to raise awareness of TB as a public health risk. It has succeeded in this not only through marketing of the GDF's core business and products but also with strong advocacy work carried out by its partners and in-country monitoring missions.

✓ The GDF has catalysed global DOTS expansion.

The GDF is widely regarded as an innovative and effective tool for supporting global DOTS expansion. Only governments and NGOs that adhere to effective diagnostic, treatment and disease monitoring practices encompassed in DOTS are eligible for GDF grants. DOTS expansion leads to significantly fewer TB patients, lower health care costs and the social and economic benefits of improved public health.

✓ The GDF always looks to the future.

The GDF encourages countries to take increasing responsibility to fund their TB control programmes, while maintaining uninterrupted access to standardized, quality and competitively priced TB drugs -- thus ensuring that any "gains" made through GDF grants are secured. This approach is illustrated in the GDF "Sustaining the gains" strategy, issued in October 2005. The strategy is firmly based on the principle of additionality.







GDF Vision and Mission

The GDF strategic vision and mission is part and parcel of the overall strategic vision of the Stop TB Partnership, which is to "create a TB-free world by 2050" through "the full and active contribution of all partners to TB control and poverty reduction."

The mission of the GDF stemming from this vision is reflected in the GDF mission statement:

The GDF is committed to continuously improve the quality of its services so as to provide quality-assured TB drugs and commodities to countries at affordable prices in a timely manner and to meet all agreed legal and regulatory requirements as they relate to WHO and relevant international standards.

The GDF will hereby meet the needs and expectations of the customers it serves and contribute to the fulfilment of broader health objectives as embodied in the strategic goals of the Global Partnership to Stop TB and the United Nations' Millennium Development Goals.

The GDF will achieve this vision and mission through:

- ▼ The GDF Grant Service whereby 1st line TB drugs are granted to approved countries and NGOs to support DOTS expansion and sustainability of nationwide coverage in countries that are donor-dependent for their drug needs.
- The GDF Direct Procurement Service for countries, donors and NGOs to purchase drugs for use in DOTS programmes in countries that have sufficient finances but lack adequate procurement capacity including a robust quality assurance system.
- ✓ The TB Prequalification Service which results in a list of prequalified quality TB drugs, for countries that have sufficient finances and good procurement mechanisms with the exception of a robust quality assurance system. The GDF is a principal contributor of funds for this service and identifies political support for it. The service is coordinated by WHO's Department of Medicines Policy and Standards.
- ✓ **Technical Support Services:** the GDF operates a unique "bundled" model of services that combines grant and direct procurement services for TB drugs with technical assistance for in-country management and TB drug monitoring. This holistic approach to TB control allows the GDF to maximize the impact of each patient treatment and strengthen global DOTS expansion efforts. The model is underpinned by the support and contributions of collaborative partners in the Global Partnership to Stop TB.







Strategic Plan 2006-2010: Overview

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

Drug supply is a critical partnership resource underpinning the assumptions of the Global Plan to Stop TB (2006-2015). An important part of the Secretariat's strategic vision is therefore the evolution of the GDF to ensure access to quality, affordable TB drugs in all countries where there is need. By 2007, the supply of TB drugs through the GDF will meet the biennial target of patient treatments to be delivered globally, as identified by DOTS Expansion Working Group.

Though the focus of the GDF within the Secretariat will remain on the **provision** of 1st line TB treatment, the GDF will expand the availability of products in the GDF catalogue, to introduce diagnostic kits, paediatric TB drugs, single TB drug formulations for patients experiencing the side effects of currently available fixed dose combination formulations and 2nd line TB drugs (following a merger by 2007 with the Green Light Committee - the supply mechanism for 2nd line TB drugs). Moreover, in view of the close relationship between TB and HIV infection, the GDF will be prepared for the harmonized supply of TB-HIV preventative therapies by 2007 and possibly other TB-HIV treatment therapies by 2009.

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

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





Strategic Plan 2006-2010: Objectives, Targets and Indicators

Table 1: Targets and Indicators for Strategic Objective 1, Supply of low cost, quality TB drugs through grant and direct procurement services in a timely and demand driven manner to all countries needing GDF support.

l	TARGETS*	INDICATORS			
	Cumulative supply of approx. 10 million patient treatments by 2007 and 15 - 17 million patient treatments by 2010 via the Grant and Direct Procurement Services.	Affordable, quality patient treatments supplied where and when they are needed within specified timeframe (2005 Baseline: 5 million patient treatments supplied).			
J	Direct Procurement accounts for approx. 45% of cumulative number of treatments supplied by 2010.	45% of all patient treatments supplied are via the Direct Procurement Service (2005 Baseline: 20% of all patient treatments supplied).			
	50% of GDF grant supported countries transition to using the Direct procurement Service to secure all or part of their TB drug needs by 2010.	50% of countries under Grant support transition to using the Direct Procurement Service thereby Sustaining the Gains in quality, affordability and service delivery secured via GDF Grant support.			
	15% of GDF Direct Procurement Supported Countries successfully transition to managing their own procurement processes, limiting procurement to the list of products prequalified via the TB Prequalification Service.	15% of GDF Direct Procurement Supported Countries develop sufficient capacity to procure on their own low cost, quality assured, standardized TB drugs in a timely manner for their National TB Programmes.			
	Strategy developed by 2007, in collaboration with interested partners, to enhance local manufacturing capacity.	Strategy development task force established from among partners, coordinated by GDF Secretariat and mandated by the Coordinating board.			
	GDF responds to and secures at least 2 tender awards for the supply of TB drugs per year from 2006-2010.	GDF succeeds in positioning itself to respond to tenders and successfully secures 10 contract awards by 2010.			
	Convergence of procurement functionality (Phase I of convergence) with Green Light Committee resulting in supply of US\$ 10 million worth of 2nd line drugs by 2007 through Direct Procurement. Buffer stock of focus 2nd line drug(s) established and functioning.	2 nd line treatment courses valued at US\$ 10 million procured and supplied to eligible countries/projects by end 2007. Buffer stock of focus 2 nd line drug(s) established and functioning. Procurement agent contracted and manufacturers secured under Long Term Agreements.			
	Supply of paediatric formulations and mono-therapies to treat side-effects of 1st line FDCs, introduced in 2006.	Limited international competitive bidding process conducted for paediatric formulations and mono-therapies to treat side-effects of 1st line FDCs and resultant contract awards allow for these medicines to be added to GDF catalogue.			
	Supply of Diagnostic Kits introduced via the Direct Procurement Service by 2006 and via the Grant Service by 2007.	Limited international competitive bidding process conducted for Diagnostic Kits and resultant contract awards allow for these products to be added to GDF catalogue; GDF Diagnostics Application and Review Process in place.			
	Supply of preventative TB-HIV therapies such as Isoniazid and Co-trimoxazole introduced by end 2007,	Limited international competitive bidding process for prequalified TB-HIV preventative therapies conducted and contract awards result in therapies added to GDF catalogue.			
	GDF systems prepared for the introduction of new drugs and diagnostics by end 2010.	Concessional prices negotiated and/or supply contracts established, client markets identified and national regulatory requirements met for the introduction of new drugs and diagnostics in a phased manner and in line with international technical and quality recommendations/guidelines.			
	75% of 1st line adult TB formulations and 25% of the paediatric formulations supplied by GDF are prequalified and have at least 2 suppliers by 2007. 100% of 1st line adult and paediatric formulations supplied via GDF are prequalified and have at least 2 suppliers by 2010.	The specified percentage of prequalified products among those in the GDF catalogue have at least 2 suppliers by the target dates indicated (as assessed under the TB Prequalification Project).			
	At least 1 source for Active Pharmaceutical Ingredients (API) for Rifampicin, Isoniazid, Ethambutol, Pyrazinamide, Streptomycin, Capreomycin, Cyclocerin and PAS prequalified, by 2010.	API sources for specified 1st and 2nd line medicines prequalified under the TB Prequalification Project.			
	100% of 2 nd line TB drug formulations supplied via GDF/GLC are prequalified and have at least 2 suppliers by 2010 (Target source countries: China, India, Russian Federation and South Africa).	The specified percentage of prequalified products among those in the GDF/GLC catalogue have at least 2 suppliers by the target dates indicated (as assessed under the TB Prequalification Project).			
	To ensure that 100% of the countries supported by GDF use FDCs as per the regimens recommended by WHO, preferably in blister packs or Patient Kits.	All GDF supported countries using FDCs as per the regimens recommended by WHO; NTP programmes fully trained on the introduction of FDCs and aware of the advantages.			

^{*} These targets are estimates and will be monitored and revised as appropriate during the period 2006-2010.





GDF Grant and Direct Procurement (DP) Projections 2006-2010

Patient Treatments provided through GDF Grant & Direct Procurement (DP) Services Cumulative, millions of patient treatments

Source: GDF Secretariat

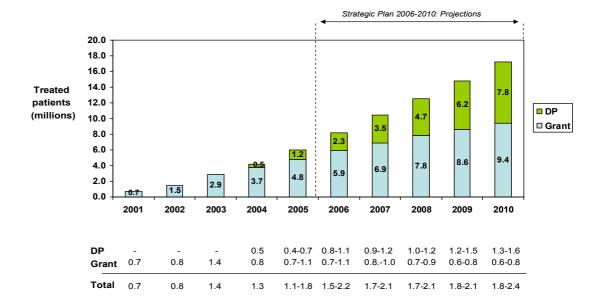
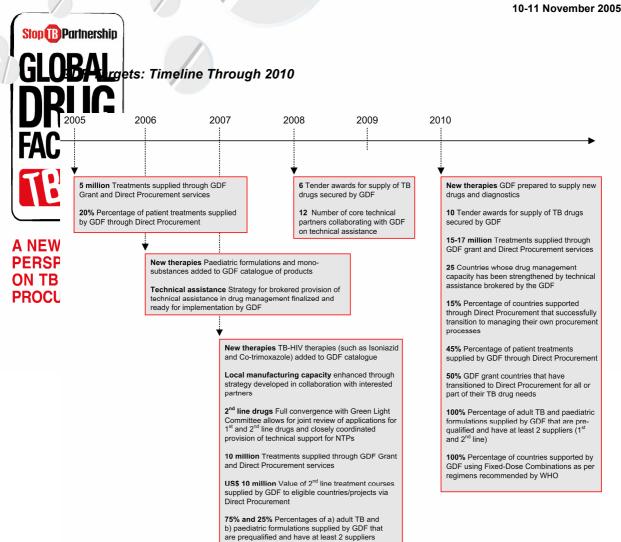


Table 2: Targets and indicators for Strategic Objective 2, Implementation of an efficient global mechanism ensuring access to life saving TB drugs and provision of technical assistance either directly or via partners for building capacity in TB programme management with a particular focus on drug management

TARGETS	INDICATORS
Strategy for formal provision of Technical Assistance in Drug Management brokered via the GDF finalized and ready for implementation by end 2006.	Strategy finalized in close collaboration with DOTS Expansion Working Group and GDF Technical Review Committee (TRC); strategy endorsed by Coordinating Board; funding needs identified in strategy for activities and human resource focal point secured.
25 countries with weak drug management systems have capacity strengthened via GDF brokered support by 2010.	Measurable, long-term strengthening of capacity as relates to one or more aspects of the drug management cycle.
Number of core technical partners collaborating with GDF on technical assistance increased to 12 by 2008.	Additional core technical partners identified and agreements/memoranda of understanding concluded for provision of technical assistance, particularly in Drug Management, to GDF supported countries at cost, subsidized or as in-kind contribution to the Stop TB Partnership/GDF (baseline 6 core technical assistance partners).
Full convergence with the GLC by 2007 allows for joint technical review of applications for supply of 1st and 2nd line TB drugs and closely coordinated provision of technical support for National TB Programmes.	GDF and GLC converged as a single entity within the Stop TB Partnership Secretariat structure, and referred to as GDF. Jointly constituted TRC in place and SOPs for closely coordinated technical support missions finalized and in place.













Monitoring and Evaluation

Country Progress

- **A.** All countries supported via the GDF Grant and Direct Procurement services receive an annual monitoring/technical support mission to:
- Assess adherence to GDF terms and conditions of support.
- Assess program management (including case finding and treatment outcomes), financial management and drug management.
- Determine drug needs for the next year of GDF support.
- Follow up on recommendations made by the GDF TRC.
- Follow up on issues raised in previous missions.

These monitoring/technical support missions are integrated into regular DOTS monitoring visits conducted by Stop TB Partners to the greatest extent possible. Moreover, they are undertaken in collaboration with WHO regional and country offices

In the period 2001 - 2005 (June) the GDF conducted 132 monitoring/technical support missions to over 60 countries.

B. The GDF TRC also relies on the annual WHO report: *Global Tuberculosis Control: surveillance, planning and financing* to evaluate progress in TB control in GDF supported countries.

GDF Impact

- **A.** The GDF together with the Stop TB Department of WHO and other interested partners will conduct an in-depth study in 2006-2007 to assess the impact of GDF support to countries during the first 5 years of GDF operations. The study will focus primarily on impact from an epidemiological and drug management perspective.
- **B.** As a follow up to the independent external evaluation of the GDF conducted by McKinsey & Company in 2003, a second external evaluation of the Stop TB Partnership including the GDF, will be commissioned during 2007-2008, subject to the endorsement of the Coordinating Board.

GDF Operations

A. To support its efforts to continuously improve the efficiency, sustainability, and quality of GDF services, the GDF Secretariat has installed an electronic system and a model for GDF services that tracks planned GDF staff efforts and alerts responsible staff to probable next steps, reducing response lead-time and promoting adherence to standard operating procedures.

In addition, by automatically capturing business critical information from these efforts, this system facilitates timely and consistent reporting to donors and interested parties, and allows GDF performance indicators to be easily generated.

Combining information about on-going GDF efforts with the tools required to maintain and learn from these efforts in a shared web-interface increases the efficiency of the secretariat and promotes team collaboration.







Lastly, by including records from previous GDF efforts and consolidated demographic, financial, health, and procurement information within this shared web-interface, the GDF Management System enhances the resources for effective decision-making. The system will be further enhanced to meet the strict qualifications required to meet ISO certification.

B. The GDF applied for and is expected to receive ISO 9001 certification in 2005. The processes and procedures put in place and the training of staff effected to attain ISO certification will allow a documented and audited *Quality Management System* to be routinely implemented, increasing GDF transparency, accountability, efficiency and credibility.

A NEW PERSPECTIVE ON TB DRUG PROCUREMENT

Key Risk Factors*

r.	Risk	Potential Impact
	Deterioration of the global TB situation and continued misuse of TB drugs	Without effective scale-up and enhancement of DOTS and DOTS Plus by all health care providers diagnosing and treating TB (including private practitioners) there is a risk of the creation and circulation of TB strains resistant to all known TB drugs. In addition, without urgent and effective attention to the joint impact of HIV and TB/MDR-TB the positive contribution of the GDF to effective TB control could be seriously undermined.
	Lack of political will at the National/Global level:	 Lack of national leadership to enhance DOTS and to engage all health care providers could present threats to the global TB control.
		 The GFATM must secure the funding it requires and disburse the same effectively. Countries will need to be prepared for efficient absorption and use of the funds.
		 The future success of the GDF will depend on the political commitment and stability of countries, the donor community (for multi-year funding) and technical agencies to scale up and strengthen DOTS/DOTS plus programmes. Political commitment is critical for any DOTS/DOTS Plus programme and must translate into human and financial resources.
	Lack of global coordination efforts	At global level the enhancement of DOTS/DOTS Plus requires resources for monitoring the global TB/MDR-TB epidemic and programme performance, together with continued policy development and dissemination of guidelines.
	Inadequate attention to Drug Management	Human and financial resources are needed to provide technical assistance and capacity building, particularly in Drug Management. The availability of affordable, quality assured TB drugs does not necessarily guarantee broad access and use where there are weak procurement systems, regulatory hurdles and unreliable distribution/storage systems.
	Lack of availability of quality assured Active Pharmaceutical Ingredients (APIs) and finished	WHO must secure the funding it requires to scale up and accelerate the implementation of the TB Prequalification Project otherwise the increase in the number of quality assured TB drugs will be undermined.
	dosage forms of TB drugs	Manufacturers of TB drugs must be provided the incentive to maintain their business focus, increase capacity for the production of quality assured APIs and/or the number of API manufacturers must increase to meet the growing demand for TB drugs.
	Creation of dependency	The GDF, GFATM and other entities supporting countries in TB control with in-kind or monetary contributions for TB drug procurement will need to be vigilant about the pursuit of "additionality" and policies that support long term self-sufficiency. Moreover there will need to be close collaboration to avoid duplication or "cancelling out" of each others' efforts in this regard. Business as usual is not an option if the cycles of dependency created in the past through international "aid" are to be avoided.

^{*}Incorporates Risk Factors outlined in section of Working Group on DOTS-Plus for MDR-TB in the Global Plan to Stop TB 2006-2015







Sustainability

The GDF regular grant is in principle for a three-year period and subject to satisfactory compliance with GDF terms and conditions of support, annual independent monitoring and availability of resources. However, the funding situation for TB drug procurement in many countries remains such that continuous external assistance is still required. For many of these countries, the GDF is the only source to support such assistance. In addition, there are concerns that GDF grant cessation will result in a loss of the gains achieved by the country during the grant period, including expansion or maintenance of the internationally recommended strategy for TB control (DOTS), availability of quality drugs and advances made in drug management.

For these reasons, the GDF "Sustaining the gains" strategy was developed, in close consultation with the TRC, Stop TB Partnership Secretariat, Coordinating Board and the Stop TB Department of WHO. The strategy is an integral part of this Strategic Plan: 2006-2010 and can be accessed on the GDF website at: www.stoptb.org/gdf/.

The objectives of the GDF second-term grant strategy are: (a) to encourage countries to take increasing responsibility to fund their TB control programmes; (b) to ensure uninterrupted access to standardized, quality and competitively priced TB drugs; and (c) to ensure that any "gains" made through the GDF grant are secured.

In close collaboration with the Stop TB partners, the GDF will ensure monitoring, evaluation and problem solving for effective drug delivery and deployment, through capacity building and assistance in drug management, as well as through direct technical feedback to countries, partners and others concerned. The GDF will also encourage the local production of quality TB drugs by identifying political and financial support for the WHO TB Prequalification Project.

Due to the importance of financial sustainability in national TB programmes (NTPs), the GDF Grant Service was always envisaged to be time limited so as not to create long-term dependency on grants. The objective of the GDF Grant Service is to overcome problems of drug shortage and dubious quality drugs for DOTS sustainability and national coverage of quality TB drugs in the short to medium term. To achieve this, one of the key conditions to receive a GDF grant is that it should be an "additional" resource for the NTP, i.e. that government TB budget lines should not be reduced or removed as a consequence of a GDF grant during the grant period.

The Direct Procurement Service and TB Prequalification Service are, in part, GDF's approaches to reduce the dependency on grants. In addition, the GDF encourages grant receiving countries to use the Direct Procurement Service as a cost-sharing exercise. The GDF works closely with partners and technical agencies including WHO, which houses the GDF, to strengthen sustainable national procurement, drug management capacity and national quality assurance mechanisms.

While financial self-sufficiency is the ultimate goal, considering the realities of the funding situation in resource limited countries, "sustainable financing" for TB control is considered a more realistic goal in the short term.







The GDF definition of sustainability is:

Financial self-sufficiency must be the ultimate goal. However, in the nearer term, sustainable financing for TB control is defined as a country's ability to mobilize and efficiently use governmental and supplementary external resources to achieve TB control targets and the Millennium Development Goals. Sustainable National TB Programme financing must be a shared concern and is the responsibility of both governments and their partners.

Therefore, the following guiding principles will apply:

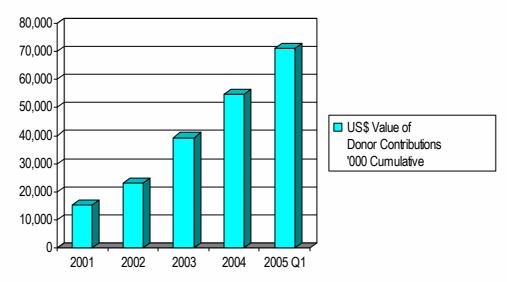
- I. GDF grant termination must not hamper DOTS coverage.
- 2. GDF grant termination should not have negative effects on advances made in access, standardization, quality and cost for TB drugs.
- The GDF should continue to facilitate strengthening of national TB drug management systems (procurement, distribution, and quality assurance, including quality control) by advocating technical assistance for capacity building and by engaging donors.
- **4.** The GDF should ensure, where needed, uninterrupted supply of TB drugs through the Direct Procurement Service when GDF grants are no longer required.



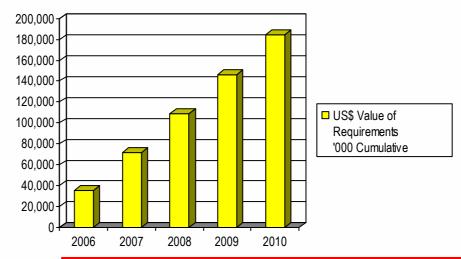


Budget Requirements

2001-2005 (Q1) Cumulative Contributions



Projected Budget Requirements 2006-2010



Activity	Costs	% of total
Drugs, freight, Quality Control and insurance	160,000,000	88.39
Contractual services	8,500,000	4.70
Staff costs	8,000,000	4.42
Workshops, training, meetings	2,000,000	1.10
Professional service charges levied by WHO	2,000,000	1.10
Advocacy, Branding and Communications	270,000	0.15
Travel	240,000	0.13
Total	181,010,000	100



