Stop TB Partnership

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DRAFT

Global TB Drug Facility

Strategic Plan 2002-2005

Stop TB Partnership Secretariat
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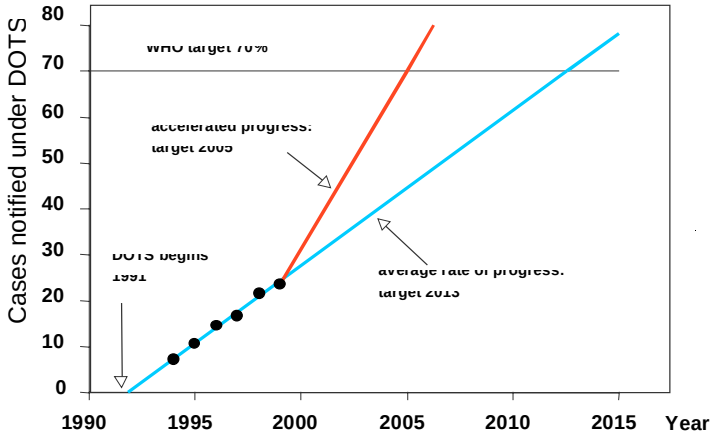
Contents

Background

It is clear that with current rates of DOTS expansion – approximately 3% per year – the global targets will not be reached by 2005. Failure to reach this target condemns millions more people to die from a disease that has been treatable for over 50 years.



Recognising the urgent need to overcome a serious constraint to rapid DOTS expansion – frequent shortages of quality drugs – countries attending the Ministerial Conference on TB and Sustainable Development held in Amsterdam in March 2000 adopted a declaration calling on the global community to 'build new international approaches towards ensuring universal access to, and efficient national systems of, procurement and distribution of tuberculosis drugs.'[1]

The Global TB Drug Facility (GDF) has been developed by the Global Partnership to Stop TB in response to this call, with the aim of increasing and securing access to high quality TB drugs. A prospectus[2] for the GDF was developed by a Core Technical Group (CTG) of Stop TB partners, and endorsed at the Stop TB interim Coordinating Board meeting in February 2001. Launched in March 2001 with a grant from the Canadian government, the GDF has already had a significant impact. Two rounds of applications have been reviewed, with 25 countries submitting applications. Of these, 16 have been approved for support.

Pooled procurement, standardisation of products, and international competitive bidding has also had a profound impact on drug prices, with a six-month course of daily treatment now costing less than $10 – one third lower than previous international prices.

This strategic plan builds on the GDF prospectus and the experience gained through the first year of activities, outlining the steps the GDF will take to accelerate progress towards reaching the global targets by 2005. Over the next four years, the GDF aims to provide grants of drugs to treat 11.9 million patients, with an additional 3.7 million treated with drugs made available through the GDF direct procurement mechanism. The GDF will also increase access to second line drugs and will provide diagnostics to support increased case detection. The total investment required over this period is US$ 224 million – less than $20 per patient diagnosed and treated.

Scope

Beneficiaries

The main beneficiaries of GDF grants are low income and lower middle income countries (per capita GNP < $2,995), that are able to fulfill the GDF conditions of support (see annex 2).[3] The priority countries for the GDF are those where GDF support is likely to have the greatest effect in accelerating progress in DOTS expansion, ie those facing the most serious resource constraints, and having the greatest burden of unreported patients. Thirty six countries each have more than 20,000 unreported people with TB – together accounting for nearly 90% of the global total of unreported cases (see annex 1).

[1] Amsterdam Declaration to Stop TB. March 2000
[2] World Health Organization. Global TB Drug Facility Prospectus. WHO/CDS/STB/2001.10a, Geneva, 2001
[3] These countries are also eligible to use the GDF direct procurement mechanism, utilising their own resources (or those from donors) through the GDF.

NGOs are also eligible for GDF support. In order to ensure efficiency and avoid the possibility of reduced government commitment to TB, NGOs will be encouraged to form coalitions,[4] providing evidence of government approval for the application.

In countries with a federal system of government, the GDF can accept applications from states or provinces within a country. In such a situation, the normal criteria and conditions for support apply, and the application must be supported by the central government.

Products and Services

The primary role of the GDF is to provide first line line TB drugs, with a focus on fixed dose combination tablets (FDCs). Two drug FDCs are already supplied, and the GDF has recently added a 4-drug FDC (in accordance with the WHO model essential drugs list). Providing a complete range of TB drugs, to include all formulations used by countries fulfils the principle of responsiveness, but make procurement processes complex and inefficient, and leads to prescription errors. Further standardisation of treatment regimens, formulations and packaging, based on FDCs, will be of considerable benefit to patients, health workers, and TB programmes.

The Green Light Committee (GLC) has been most successful in establishing a pooled procurement mechanism for second line TB drugs. Several of the GLC processes have parallels with those of the GDF, for example, applications, technical review, prequalification, procurement and monitoring. There are significant differences; the GLC has not provided grants, and second line drugs are restricted to projects of operational research, as the DOTS Plus strategy is still in development. The GDF and GLC will explore ways of building on each others strengths and experiences, with the aim of combining functions in the future.

Many countries face difficulties in sustaining uninterrupted supplies of diagnostic equipment and consumables, such as microscopes, slides, sputum containers and reagents. The GDF will be able to offer similar advantages in terms of pooled procurement to reduce cost, improve quality, and secure uninterrupted supplies.

The GDF will explore opportunities for convergence with other pooled procurement facilities that are established to increase access to related products, such as drugs for HIV/AIDS, and antimalarials.

Adequate levels of technical assistance are essential to assist countries introduce and expand the DOTS strategy, and make effective use of the resources available to them (particularly when loans or donor funds are involved). This is usually provided as international staff posted to the country, visits by consultants, monitoring missions, and assistance in preparation of plans, technical guidelines, and reviews. The cost of technical assistance is usually equivalent to at least 15% of expenditure on TB control.

The GDF Technical Review Committee (TRC) frequently makes recommendations on increased need for technical assistance, particularly when countries lack a recent independent review of NTP performance, or do not yet have a national multi-year plan for DOTS expansion to reach the global targets. As the GDF does not fund this activity, the GDF secretariat and countries concerned must then contact appropriate technical agencies (such as IUATLD, KNCV and WHO), requesting technical assistance. As resources are limited, and many technical agencies have already defined their priorities and plans, it is not always possible to rapidly mobilise partners and resources to provide the technical assistance required.

The GDF will work with the Stop TB DOTS Expansion Working Group to facilitate and expand technical assistance to countries, and could potentially act as a conduit for funding to technical agencies.

[4] The minimum number of patients for an NGO application is 5,000

Mechanisms of Support

The primary mechanism of support from the GDF is in the form of 'grants in kind' of TB drugs and other commodities. The quantity provided is calculated on the basis of the number of additional patients to be treated in accordance with a national DOTS expansion plan to reach the global targets by 2005. As resource constraints for TB control extend beyond budgets for drugs, the GDF can further catalyse DOTS expansion by enabling countries to reallocate of budgets for TB drugs to other aspects of DOTS expansion. This ensures the principle of additionality is upheld, at the same as enabling countries to free up more resources for DOTS expansion. The Global DOTS Expansion Plan[5] estimates that for every dollar spent on drugs, an additional $2-9 is needed for non-drug aspects of DOTS, such as diagnostic equipment and consumables, training, supervision, drug supply, monitoring etc. Inefficient procurement mechanisms mean that many countries pay 3 to 4 times the prices obtained by the GDF. Support from the GDF, combined with reallocation of TB drug budgets, will free up a substantial resource for DOTS expansion. However, it is essential that the governments have mechanisms in place to demonstrate that funds freed up in this way are actually used for DOTS expansion, and not diverted elsewhere.

In addition to grants in kind, the GDF direct procurement can support countries which have adequate funds for drugs, but lack efficient mechanisms for procurement and quality assurance. Such a system will also be attractive to donors which provide funds or grants in kind to countries for TB control, and to NGOs that lack their own procurement mechanisms.

Principles

The specific principles which determine the manner in which operations of the facility are carried out include independence, transparency, accountability, flexibility, rapidity and responsiveness, additionality, equity and confidentiality. These principles are applied to all operations of the GDF, and are described in detail in annex 2.

Operations

Oversight

The GDF is managed by a secretariat based in WHO Stop TB department, with oversight from a working committee of the Stop TB Coordinating Board. The nature of the relationship between the secretariat, WHO and the Stop TB Coordinating Board is defined in a memorandum of understanding (see annex 4).

Applications, Review and Monitoring

The GDF application process is simple, relying on information that the country will already have ready to hand, including:

(a) Multi-year DOTS expansion plan and budget
(b) National technical and operational guidelines for TB control
(c) Annual report on DOTS performance (WHO TB data collection form) including case finding and treatment
(d) Most recent independent monitoring report

To complete the application, the country provides information on the estimated patients to be treated each year to reach the global targets, and the proportion requiring support from the GDF, evidence of agreement with terms and conditions of GDF support, and consignee details.

The Stop TB partnership has established a technical review committee (TRC) for the GDF, comprising about 30 members, of which two thirds are from regions and countries, and one third are

[5] World Health Organization. Global DOTS Expansion Plan: Progress in TB control in high-burden countries, 2001. WHO/CDS/STB/2001.11 Geneva, Switzerland.

international technical experts. Members are selected for their individual skills and experience, and not as representatives of countries or organizations. The TRC meets in six regional subgroups of 8-10 members, comprising the members from the relevant region, 2-3 from another region and 2-3 technical experts.

Every year, the regional TRC subgroup 'audits' eligible countries in the region, reviewing the documents listed above. The TRC subgroup makes recommendations to the country on proposed programmatic changes, to countries and partners on needs for technical and financial assistance, and to GDF for GDF support. These recommendations are immediately fed into the regional interagency coordinating committee, to ensure they are acted upon appropriately.

Independent monitoring is carried out by the technical agencies that usually provide support to the country, in accordance with standardised indicators and guidelines develop for this purpose.

Procurement and Supply

The GDF is developing a white list of manufacturers and products meeting international quality standards, through a standardised prequalification process. This process is based on document review, GMP inspection, and quality control, with requalification on a regular basis (every 2-3 years). The white list of manufacturers and products will be published, enabling agencies and countries procuring TB drugs to identify sources of products of assured quality.

Through a process of limited international competitive bidding (LICB), the GDF has appointed UNDP Interagency Procurement Services Office (IAPSO) as the procurement agent for the GDF. The GDF provides the procurement agent with the list of approved manufacturers and products, and IAPSO manages the LICB to identify the GDF supplier(s). IAPSO also manages GDF contracts with the quality assurance agent (SGS Global Solutions) and the freight agents (Kuhne & Nagel, and Mahe).

The GDF secretariat provides IAPSO with details of consignees in each country, products, quantities and preferred time and port of delivery. This information is provided online to IAPSO by the GDF secretariat through the 'webbuy' system at www.stoptb.unwebbuy.org. IAPSO issues purchase orders on behalf of the consignee to the GDF supplier(s), and provides the consignee with a username and password to access the online Track and Trace system.

Preshipment inspection and batch analysis in accordance with the relevant pharmacopeial standards is carried out by the GDF quality assurance agent, before release to the freight forwarding agent.

Communications

Effective communications strategies are essential to support the advocacy and resource mobilization strategies The GDF has three main services to offer countries, and will develop a marketing strategy to promote these services:

(a) Grants in kind of TB drugs and diagnostics
(b) A direct procurement mechanism for countries wishing to use their own resources
(c) A white list of products and manufacturers for countries wishing to use their own procurement mechanisms and resources

The GDF requires a substantial investment of resources over the period of this plan, and will require a resource mobilization strategy to support this.

All advocacy and resource mobilization efforts for the GDF will be closely coordinated with similar initiatives in support of the Global DOTS Expansion Plan and the Global Plan to Stop TB.

Management

The GDF is managed by a small team in the Stop TB secretariat. The GDF has a core group of staff dedicated to GDF activities, but also benefits from support from other staff in the Stop TB secretariat, and from the two technical units of the WHO Stop TB department. Meetings of the Working Committee of the GDF are normally held by teleconference.

Most GDF services are contracted out by the GDF secretariat to prequalified agencies though a limited international competitive bidding (LICB) process. Contracts are usually issued for a period of up to two years.

The GDF submits annual plans and budgets, and 6-monthly performance reports and financial statements to the Stop TB Coordinating Board and donors. A continuous internal monitoring system to improve performance is being developed.

Logical Framework

Narrative Summary	Indicators	Means of Verification	Assumptions/Risks
1 Goal 1.1 Reduce the burden of TB (deaths and prevalence) by half by 2010	(a) Estimated prevalence of tuberculosis (all forms) in 2010 (compared with 2000 estimates) (b) Estimated TB related deaths in 2010 (compared with 2000 estimates)	▪ WHO published estimates for 2000 and 2010	Achieving the case detection and treatment outcome objectives by 2005 will lead to lead to a reduction in deaths and prevalence
2 Purpose 2.1 Ensure uninterrupted access to quality TB drugs for DOTS implementation. 2.2 Catalyze rapid DOTS expansion in order to achieve global TB targets 2.3 Stimulate political and popular support in countries worldwide for public funding of TB drug supplies 2.4 Secure sustainable global TB control and eventual elimination	(a) Global population coverage with DOTS strategy end 2005 (b) Global DOTS case detection rate for 2005 (c) Global DOTS treatment success rate for 2005 (d) Trends in global funding for TB control 2001-2005	▪ WHO annual report on Global TB epidemic 2007 ▪ WHO annual report on Global TB epidemic 2008	Drug shortages are a major constraint to accelerated DOTS expansion Support from the GDF will catalyse additional resources for non-drug related aspects of DOTS expansion
3 Objectives 3.1 Provide grants for treatment of at least 10 million people with TB by the year 2010 3.2 Increase the proportion of patients treated with products of known quality from prequalified manufacturers 3.3 Reduce the proportion of patients treated with non standard products 3.4 Develop a regular, independent, objective and standardised process for assessing TB programme performance, in order to assist countries achieve the global targets for TB control, identifying opportunities for technical and financial assistance, including GDF support.	(a) Number of people treated with drugs supplied by GDF (b) Proportion of global market for TB drugs produced by prequalified manufacturers (c) Proportion of DOTS patients treated with products on GDF product list (d) Proportion of countries having an independent annual audit of TB programme performance	▪ GDF annual reports ▪ GDF survey of TB drug market	Countries have capacity to absorb and utilise TB drugs effectively Poor quality products are widespread, and pose a major threat to TB control Standardisation of products will increase the efficiency of procurement, and the effectiveness of treatment
4 Outputs *4.1 Oversight* 4.1.1 Meetings of Stop TB Coordinating Board Working Committee	(a) Numbers of meetings and conferences of the STB CB WC	▪ Minutes of STB CB WC meetings	

4.2 Application, Review and Monitoring 4.2.1 List of countries with a well functioning DOTS programme, 'prequalified' for GDF support (and other funding mechansims, eg GFATM) 4.2.2 Standardised methods for reviewing DOTS expansion plans, technical and operational guidelines, and monitoring reports 4.2.3 Establish Stop TB Technical Review Committee 4.2.4 Guidelines for standardised method of monitoring mission 4.2.5 Annual monitoring missions to all countries	(b) Number of countries prequalified for GDF support (c) Publication of tools to assess DOTS plans, technical guidelines and monitoring reports (d) Number of meetings of Technical Review Committee (e) Publication of guidelines for DOTS monitoring mission (f) Number of monitoring missions to eligible countries	▪ GDF annual reports ▪ WHO published tools and guidelines ▪ Technical Review Committee minutes	
4.3 Procurement and Supply 4.3.1 A whitelist of prequalified manufacturers of quality products 4.3.2 Provision of drugs to treat at least 10 million patients in DOTS programmes by 2005 4.3.3 Provision of drugs to treat at least 80,000 patients with second line drugs by 2005 4.3.4 Provision of equipment and consumables to diagnose at least 10 million patients in DOTS programmes by 2005 4.3.5 Direct procurement mechanism 4.3.6 An efficient web based ordering and track and trace mechanism	(g) Number of prequalified products and manufacturers (h) Number of patients diagnosed and treated with grants of GDF products, and quantity of products supplied (i) Number of patients diagnosed and treated and quantity of products supplied through GDF direct procurement mechanism (j) Number of countries placing and tracking orders through the web (k) Average lead time from application to supply of products	▪ GDF published whitelist of products and manufacturers ▪ GDF annual reports ▪ GDF internal monitoring system	
4.4 Advocacy and Resource Mobilization 4.4.1 Plan for advocacy and resource mobilization as part of the Stop TB advocacy and communications strategic plan 4.4.2 Marketing strategy for GDF services 4.4.3 GDF website 4.4.4 GDF advocacy tools 4.4.5 GDF newsletter	(l) Publication of strategic plan (m) Uptake of GDF services – numbers of countries and NGOs applying for support (n) Value of resources flows to GDF	▪ Stop TB Strategic Plan for advocacy and communications ▪ GDF annual reports ▪ GDF publications ▪ GDF website	
4.5 Management 4.5.1 Annual plans and budgets for GDF activities	(o) Timely production of accurate		

4.5.2 6-monthly reports and financial statements on GDF performance and progress 4.5.3 Information management for performance improvement 4.5.4 External evaluation of GDF 4.5.5 Financing mechanism for GDF	plans and budgets, reports and statements (p) Performance indicators (q) Establishment of financing mechanism	▪ GDF plans and reports ▪ Internal monitoring database ▪ Report of external evaluation of GDF	
5 Cost Areas See attached spreadsheets	**6 Inputs** See attached spreadsheets		

Summary Resource needs

Cost Area	2002	%	2003	%	2004	%	2005	%	Total	%
Applications,review and monitoring	870,000	5%	915,000	2%	840,000	1%	840,000	1%	3,465,000	2%
Drugs	10,930,881	57%	36,618,988	69%	50,726,390	76%	66,015,552	78%	164,291,813	73%
Diagnostics	4,004,618	21%	10,969,643	21%	10,760,616	16%	13,134,003	15%	38,868,880	17%
Procurement, supply and quality control	768,887	4%	2,106,171	4%	2,066,038	3%	2,521,728	3%	7,462,825	3%
Prequalification of manufacturers	540,000	3%	370,000	1%	680,000	1%	520,000	1%	2,110,000	1%
Advocacy and Resource Mobilization	792,000	4%	792,000	1%	792,000	1%	792,000	1%	3,168,000	1%
Administration	1,213,765	*6%*	1,326,215	*2%*	1,326,215	*2%*	1,326,215	*2%*	5,192,410	2%
Total	**19,120,150**		**53,098,018**		**67,191,260**		**85,149,498**		**224,558,926**	

Patient Estimates

	2001	2002	2003	2004	2005	Total
Estimated incidence of TB						
New patients	9,026,115	9,342,633	9,687,563	10,064,760	10,478,659	48,599,730
Retreatment patients	1,805,223	1,868,527	1,937,513	2,012,952	2,095,732	9,719,946
MDR patients	90,261	93,426	96,876	100,648	104,787	485,997
Estimated DOTS Coverage	30%	35%	50%	60%	70%	
Proportion treated with GDF grants	5%	9%	21%	28%	35%	
Proportion treated with GDF direct procurement	0%	3%	6%	9%	12%	
Patients treated with GDF grants						
New patients	451,306	840,837	2,034,388	2,818,133	3,667,531	9,812,194
Retreatment patients	90,261	168,167	406,878	563,627	733,506	1,962,439
MDR patients	-	-	20,344	28,181	36,675	85,201
Total	**541,567**	**1,009,004**	**2,461,610**	**3,409,941**	**4,437,712**	**11,859,834**
Patients treated with GDF direct procurement						
New patients	-	280,279	581,254	905,828	1,257,439	3,024,800
Retreatment patients	-	56,056	116,251	181,166	251,488	604,960
MDR patients	-	2,803	5,813	9,058	12,574	30,248
Total	**-**	**339,138**	**703,317**	**1,096,052**	**1,521,501**	**3,660,008**

Annex

Annex 1: Countries with more than 20,000 unreported cases

Country	*Estimated TB cases (all forms) 2000*	*Reported TB cases (all forms) DOTS 2000*	*Reported TB cases (non DOTS) all forms, 2000*	*Unreported TB cases (all forms) 2000*
China	1,375,382	348,436	114,937	912,009
India	1,885,967	211,751	903,967	770,249
Indonesia	602,397	67,949	-	534,448
Nigeria	356,743	25,821	-	330,922
Bangladesh	339,330	59,669	15,689	263,972
Pakistan	253,008	11,050	-	241,958
Ethiopia	255,609	91,101	-	164,508
Philippines	254,275	96,371	32,124	125,780
DR Congo	154,940	60,627	-	94,313
Kenya	151,605	58,067	6,092	87,446
United Republic of Tanzania	129,140	54,442	-	74,698
Afghanistan	72,125	7,107	-	65,018
Viet Nam	149,687	89,792	-	59,895
Mozambique	80,667	21,158	-	59,509
Cambodia	76,845	18,891	-	57,954
Uganda	84,316	30,372	-	53,944
Russian Federation	191,444	8,288	129,309	53,847
Côte d'Ivoire	63,660	12,943	-	50,717
Myanmar	81,245	30,840	-	50,405
Cameroon	51,801	4,754	497	46,550
Ghana	56,370	10,325	608	45,437
Madagascar	41,830	-	-	41,830
Sudan	61,250	16,479	8,328	36,443
Burkina Faso	38,357	2,310	-	36,047
Malawi	51,716	23,606	-	28,110
Mali	31,190	3,845	371	26,974
Somalia	33,000	5,686	-	27,314
Burundi	26,411	-	-	26,411
Rwanda	32,170	6,093	-	26,077
Iran	37,792	11,828	22	25,942
Senegal	25,247	-	-	25,247
Niger	28,712	4,292	-	24,420
Zimbabwe	75,012	51,918	-	23,094
Guinea	22,369	-	-	22,369
Chad	22,253	-	-	22,253
Iraq	31,051	9,697	-	21,354
Angola	37,163	-	16,062	21,101
Total	***7,262,079***	***1,455,508***	***1,228,006***	***4,578,565***
Global Total	**8,810,818**	**2,023,833**	**1,630,164**	**5,136,793**

Annex 2: GDF Principles In Practice

The GDF prospectus identifies several key principles which will be applied to the operations of the facility. In some cases these are described in detail, for example, sustainability, but for others it is unclear what is meant, or how they should be applied. The following describes the way the Stop TB Partnership secretariat has interpreted and applied these principles to the operations of the interim GDF, and also identifies additional principles of importance not included in the prospectus, such as equity and confidentiality.

Independence

1. As the GDF is managed by WHO, it benefits from the administrative and technical support provided by the Organisation. However, it is not a core activity of the host agency, and according to the GDF prospectus, *"…the GDF management team and contractors will follow the directives of the stakeholders."* As an initiative of the Global Partnership to Stop TB, the GDF is therefore managed by the Partnership secretariat. The nature and terms of the relationship between WHO and the GDF stakeholders, represented by the Stop TB Coordinating Board (STB CB), are described in a Memorandum of Understanding, signed by the Director General of WHO and the chair of the Stop TB Coordinating Board.

2. The GDF views 'entitlement' (non-competitive allocation of roles and contracts) as poor business practice, and detrimental to the independence and transparency of the Facility. GDF technical functions are contracted (on a competitive basis where possible) to prequalified agencies. These functions include prequalification and quality assurance of drug manufacturers, procurement, (including preshipment inspection and laboratory analysis, shipping, and insurance), technical assistance, and monitoring.

3. GDF applications are assessed by an independent technical review committee, (TRC) comprising participants from high burden countries, together with experts in TB control and drug management.

4. *"The GDF will ensure independent appraisal and monitoring of GDF treatment standards, drug supply, management and verifiable outcome indicators…"* Routine annual monitoring reports from recipient countries and technical agencies are reviewed by an independent agency to ensure GDF conditions continue to be met.

Transparency

1. Avoidance of conflict of interest. This includes the following measures:
   (a) Agencies preparing terms of reference for a contract are disqualified from bidding for implementation of the contract
   (b) The organisation(s) acting as procurement agent(s) for the GDF cannot also be a supplier/manufacturer of TB drugs for the GDF
   (c) Members of technical review committee and other advisory groups are required to declare any conflict of interest in writing, as per WHO policy

2. Transparent and equitable bidding and contracting processes.
   (a) Bidding processes and criteria are developed or reviewed by stakeholders
   (b) Criteria for prequalification are explicit and developed in advance of inviting bids for contracts
   (c) Criteria for adjudication of bids are explicit and developed in advance of opening bids for contracts
   (d) Bidders are invited to be present at opening of bids
   (e) Detailed description of all functions, activities, and standards or performance is required in development of requests for proposals and contracts

3. Minutes of meetings are circulated to all participants for review and revision prior to wider circulation

4. Countries are encouraged to develop applications together with their donor and technical partners, to ensure that partners support such applications

5. The GDF publishes details of prequalified suppliers and their products, specifications and costs on the GDF website.

Accountability

1. **Accountability to the Stop TB Partnership**. The GDF is an initiative of the Global Partnership to Stop TB, and is accountable to the Partnership. Oversight is provided by the STB CB. A Working Committee of the STB CB provides regular support and counsel to the GDF secretariat, and receives regular reports on activities. The GDF secretariat reports to the STB CB twice a year.

2. **Accountability to the host agency.** The STB CB has no independent legal personality, and the GDF therefore borrows its legal identity from WHO as the host organisation. The GDF secretariat is therefore accountable to WHO for all administrative functions, and all contracts and agreements concerning the GDF are developed and implemented in accordance with WHO polices and regulations. The GDF is managed by the Stop TB Partnership Secretariat within the Stop TB Department, and WHO staff working on the GDF are subject to WHO staff rules and regulations. The relationship between WHO and the STB CB concerning the GDF is described in a Memorandum of Understanding.

3. **Accountability to beneficiaries.** The purpose of the GDF is to support countries expand DOTS. Accountability to countries is maintained through representation of regions and high burden countries on the STB CB and the GDF Technical Review Committee.

4. **Accountability to donors.** The GDF reports to donors through WHO reporting mechanisms, as per specific agreements between donors and WHO for resources provided to the GDF (including financial grants and secondments of staff).

Flexibility

Flexibility is essential to ensure the GDF remains responsive to the needs of people with TB, and effectively supports rapid and sustainable DOTS expansion.

Rapidity and Responsiveness

Recognising that drug shortages pose a serious threat to public health and the lives of individuals with TB, the GDF aims to respond quickly and efficiently to the needs of countries. Procurement of drugs is often held up by administrative delays, which can be substantially reduced with efficient management systems, and close working relationships between organizations involved in the supply chain.

The principle of responsiveness indicates that GDF support should be ‘demand driven’, ie responding to the expressed needs of countries. This necessitates an application process, which must be simple, easily understood, and objective.

The following steps have been taken to ensure the GDF remains responsive to country needs:

1. **Rapid operationalisation of the GDF.** Launched in March 2001, the GDF was able to rapidly establish a limited set of operations, with interim processes for applications, review and procurement. As a result, the first countries were supplied within a few months of applications being processed.

2. **Continuous application and review process.** The interim GDF has used a time limited application process, with applications only accepted up to set deadlines. Meetings of the GDF TRC are held three times a year. This system puts pressure on countries to meet these deadlines, often resulting in incomplete information in applications. It also means the GDF secretariat and TRC must process many applications simultaneously. The GDF is therefore changing to a continuous application and review process.

3. **Use of the internet** to promote wider and more rapid communication:
   (a) The GDF application form and notes will be available on the GDF website, with the possibility for making an application on line
   (b) Email, teleconferences and video conferences will be increasingly used to supplement meetings of the GDF TRC
   (c) The GDF places orders with the GDF procurement agent through its website (http://stoptb.unwebbuy.org). Applicant countries can also track and trace their orders through the same website.

Additionality

1. *"All GDF assistance must represent new resources for TB control…".* In practice this means that:
   (a) Countries applying for GDF grants must demonstrate that GDF support will not displace funding for TB control from national governments or donors.
   (b) Countries are encouraged to develop applications together with their donor and technical partners, to ensure that partners are able to mobilise additional resources required to support DOTS expansion

2. This principle also applies to stakeholders in the GDF and means that GDF resources have not been used to subsidise core functions of Stop TB partners, such as policy development, ongoing technical assistance to countries, routine monitoring and surveillance.

Equity

The main measure of success for the GDF is the number of additional people with TB cured of their disease. The GDF is also 'demand' driven, responding to the needs of countries, rather than supply driven. These two principles could potentially lead to inequitable allocation of GDF resources, for the following reasons:

(a) Countries with limited capacity to prepare applications to the GDF would be less likely to seek support
(b) Countries with weak planning and reporting systems would be less likely to have their applications approved.
(c) Countries with a relatively weak health service infrastructure will only be able to provide care for a proportion of their population

Successful countries with extensive technical assistance from Stop TB partners would therefore be more likely to receive support than poorly performing countries with limited assistance.

The GDF seeks to redress this potential imbalance in the following ways:

1. **Prequalification of countries.** In close collaboration with the Stop TB DOTS Expansion Working Group the GDF will identify and prioritise the eligible countries which would most benefit from technical and financial assistance to enable them to meet the global targets

2. **Simple application process.** Countries are invited to express interest in receiving GDF support. Information required to initiate an application is limited. Following an expression of interest, the GDF will encourage Stop TB partners to assist the country prepare a full application, including a country visit if necessary.

3. **Catalyse increased technical and financial assistance to countries.** The GDF will encourage Stop TB partners to provide resources to increase technical and financial assistance for countries where needed. This may be needed for performance reviews, preparation of long term plans for DOTS expansion, and funding TB control activities.

4. **Encourage applications from other service providers, eg NGOs.** Support to NGOs will enable the GDF to provide drugs for some patients who would otherwise not receive care. In so doing, the GDF will also facilitate greater cooperation between countries and NGOs, and encourage completeness of reporting.

Confidentiality

The principle of transparency may at times be at odds with the need to maintain appropriate levels of confidentiality. The GDF will develop principles of disclosure of information to third parties in relation to:

(a) content of application forms from countries
(b) minutes of meetings of the GDF TRC
(c) content of materials provided by manufacturers for registration of products
(d) results of quality assurance assessments, including but not limited to site visits to manufacturers, preshipment inspection reports, and laboratory analyses
(e) content of country monitoring reports
(f) disclosure of contents of bids
(g) disclosure of potential conflict of interest

Annex 3: GDF Conditions of Support

1. All drugs supplied by the Global TB Drug Facility (GDF) will ONLY be used:
    a. For treatment of TB patients.
    b. Free of charge to patients.
    c. In treatment regimens following WHO guidelines.
    d. In programmes following national guidelines for DOTS implementation.
    e. In accordance with a multi-year plan for DOTS expansion to reach global targets by 2005

2. The applicant is responsible for the drugs beyond the agreed point of delivery. The applicant will make arrangements for the payment or waiver of any import duty or tax, storage fees or insurance levied on drugs supplied by the GDF in a timely fashion so that the drugs are released from customs and supplied for programmatic needs as required. The applicant is responsible for the in-country distribution and monitoring of drugs provided by the GDF.

3. Where registration is required, GDF drugs will be expeditiously registered and the applicant will facilitate this process, so that drugs are released from registration and supplied for programmatic needs as required.

4. Regular assessments of the National TB Programme performance, including TB drug management, will be carried out by an independent technical agency, and the complete assessment report provided to the GDF. The applicant will also provide the following reports to the Stop TB secretariat:
    a. A regular annual report on TB programme performance in accordance with WHO guidelines;
    b. Quarterly reports on case finding, smear conversion and treatment outcomes;
    c. Date of arrival of GDF drugs at port;
    d. Time taken to register drugs (if applicable);
    e. Date drugs received in central drugs store.

5. Public sector funding for TB control activities will not be reduced as a consequence of, or during the period that GDF grants are received.

6. Co-financing and technical co-operation are available from other governments/donors for non-drug aspects of the multi-year plan (including DOTS expansion).

Annex 4: GDF Memorandum of Understanding

Memorandum of Understanding
between the
Stop Tuberculosis Partnership Coordinating Board
and the
World Health Organization
on the
Administration, Operations, and Financing
of the
Global Tuberculosis Drug Facility

1. Introduction

1.1. The following is a memorandum of understanding (MOU) between the Stop TB Partnership Coordinating Board (STBCB) and the World Health Organization (WHO) concerning the establishment and functioning of the Global Tuberculosis Drug Facility (GDF).[*]

1.2. The GDF is a new initiative with the aim of increasing access to quality TB drugs worldwide. It is being established in response to a call from high-burden countries at the Amsterdam conference on TB and Sustainable Development in March 2000. It is intended that the GDF will mobilize funds for drug supply, review requests from countries for drugs through a Technical Review Committee (TRC), procure quality drugs via a competitive bidding process, and ensure monitoring and evaluation for proper use of GDF drugs.

1.3. WHO will carry out the functions of the GDF as generally described above and in accordance with the provisions of this MOU set forth below.

1.4. WHO will manage the GDF for an initial period of two years. WHO will be financially and otherwise responsible legally for the GDF, but will seek and pay due respect to the recommendations concerning the management of the GDF made to it by the STBCB, as an advisory body.

1.5. This MOU will be valid for the period from the date of signature by the parties concerned to 31 July 2003. Amendments to this Memorandum of Understanding may be proposed by WHO and the STBCB for consideration by both parties.

2. Administration

2.1. WHO will provide secretariat functions for the GDF, by forming a distinct unit called the "GDF Secretariat" to manage the GDF operations and by utilizing its administrative and technical services to otherwise implement, administer and support the activities of the GDF.

[*] The GDF will comprise a Secretariat and a Technical Review Committee (TRC), and will work in co-ordination with the STBCB and its Working Committee:
GDF Secretariat: The Secretariat is the administrative component of the GDF.
TRC: The TRC will be responsible for reviewing grant applications for the GDF. It will make recommendations on grants to the GDF Secretariat and the STBCB. Its members will be technical experts serving in their individual capacities.
STBCB: The STBCB represents and acts on behalf of the Stop TB Partnership. Its composition reflects both the major groupings and the diversity of the Stop TB Partnership.
Working Committee: The Working Committee is a sub-group of the STBCB that guides and evaluates the operations of the GDF Secretariat.

2.2. The STBCB will create a Working Committee from among its members to guide and evaluate management of the GDF. The GDF Secretariat will cooperate with the Working Committee to enable it to fulfil its functions effectively.

2.3. The GDF Secretariat will communicate on a regular basis with the Working Committee. The STBCB or the Working Committee may direct queries to the GDF Secretariat at any time, and will promptly receive an appropriate response. Any major changes or enhancements proposed in the mandate and management of the GDF will be agreed by WHO and the STBCB.

2.4. The Working Committee will collaborate with the GDF Secretariat in the preparation of an annual work plan, to be submitted for approval by the STBCB and WHO. The GDF Secretariat will be responsible for implementation of the plan.

2.5. The GDF Secretariat will make formal reports on its operations, including advocacy and fundraising, to the STBCB at each of the latter's biannual meetings. In addition, WHO will report, as necessary, on any related issues in managing the GDF.

2.6. WHO will establish a Technical Review Committee (TRC) composed of up to 15 experts to review applications for GDF support. Its detailed terms of reference will be drawn up in consultation with the STBCB. Recommendations of the TRC on GDF applications will be submitted to the Working Committee for consideration. The Working Committee will submit its recommendations to WHO. With the approval of both the Working Committee and WHO, the recommendations of the TRC on applications for GDF drug supply will be implemented by WHO through the GDF secretariat. Copies of the recommendations will be made available to the STBCB. The STBCB will provide comments or recommendations in the event of there being no unanimous recommendation on an application.

2.7. The STBCB will monitor and evaluate the performance of the GDF, including output, impact and process. The STBCB will organize an independent review of the GDF after two years of operation (by mid 2003). The STBCB will make recommendations to its constituent members, others in the Stop TB partnership and donor organizations on any proposed changes to the structure, management and location of the Global TB Drug Facility following the independent review.

3. Operations and staffing of the GDF Secretariat

3.1. WHO rules and regulations, in particular those for its administrative, financial and human resource management, will apply to the GDF Secretariat and its operations. There may, however, be a need to make adaptations to its rules and practices in order to meet particular needs of the GDF. WHO will consider justified requests for any such adaptations, provided they are consistent with its Financial and Staff Regulations and Rules and any other requirements established by its governing bodies. Any such adaptations or exceptions must be expressly approved by an authorized official of the WHO, and will be recorded by WHO in a "Log of Administrative adaptations for the GDF Secretariat."

3.2. WHO will develop terms of reference for the GDF Manager in consultation with the STBCB. After consultation with, and advice from the STBCB, WHO will appoint or assign a GDF Manager who will head the GDF Secretariat. WHO will also appoint or assign all other personnel of the GDF Secretariat. The GDF Manager will consult the STBCB, through its Working Committee, on terms of reference for any other senior (P5 or above) staff to be selected. All appointments and assignments of GDF personnel will be time limited until mid-2003, and made in accordance with the WHO's policies, regulations, rules and procedures. Nevertheless, staff may be seconded from other organizations to the GDF secretariat, subject to the conclusion in each case of an agreement covering the terms of secondment between such other organization and WHO.

3.3. Once appointed, the GDF Manager will report to the Director-General of WHO or to a senior manager chosen by the Director-General.

3.4. WHO will contract, in accordance with its rules, for procurement, quality control and monitoring/evaluation functions with suitably pre-qualified agencies based on an ongoing assessment of the most advantageous sources of supply.

4. Financing

4.1. The financing of GDF will be provided by donors and the funds received will be recorded as Trust Funds in WHO accounts. These funds will be administered in accordance with WHO Financial Regulations and Financial Rules, financial procedures and practices. They will be reported in the WHO's Financial Report and Audited Financial Statements; separate financial statements of income and expenditure will be provided.

Signed:

Gro Harlem Brundtland
Director-General
World Health Organization

Ernest Loevinsohn
Chair
Stop TB Coordinating Board

Date: