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The Global TB Drug Facility: innovative global procurement

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SUMMARY

The Global TB Drug Facility (GDF) is a new initiative to increase access to high quality tuberculosis drugs. The GDF, a project of the Global Partnership to Stop TB, is managed by its secretariat, in the World Health Organization (WHO), Geneva. It aims to provide tuberculosis drugs to treat up to 11.6 million patients over the next 5 years and to assist countries to reach the WHO global TB control targets by 2005. The GDF was launched on 24 March 2001. Six rounds of applications have been completed, with 46 countries and non-governmental organisations (NGOs) approved for support. The GDF is not a traditional procurement mechanism. It has adopted an innovative approach to the supply of drugs, by linking demand for drugs to supply and monitoring, using partners to provide services, using product packaging to simplify drug management and linking grants to TB programme performance. This paper describes the GDF operational procedures and experience gained so far. Key achievements to date are also outlined, including the creation of a flexible supply system to meet differing programme needs, rapid establishment of procedures, reduction in TB drug prices—a catalyst for DOTS expansion in countries, standardisation of products, and collaboration with partners. The GDF is flexible enough to meet the needs of countries with a TB burden. The GDF experience could be used as an example for global procurement of drugs and commodities for other diseases, such as HIV/AIDS and malaria. In the future it is likely that the GDF will expand to include second-line drugs and diagnostic materials for TB and could assist other partnerships to develop similar mechanisms and facilities to meet country needs.

KEY WORDS: tuberculosis; procurement; drug management; tuberculosis, drug therapy; partnership; DOTS

TUBERCULOSIS (TB) is the world's leading curable infectious killer. Every day, nearly 25 000 people develop active TB and 5000 die from the disease. Without treatment, 50–70% of people with infectious TB will die. If left untreated, a single person with infectious TB can infect between 10 and 15 people a year. The global TB epidemic is increasing by 3% every year, largely because of the epidemic of the human immunodeficiency virus (HIV) and the acquired immunedeficiency syndrome (AIDS), affecting many African countries.[1] If these trends continue, 10.2 million new cases of TB per year are expected by 2005.

The continued growth of this epidemic is completely avoidable. DOTS, the internationally recommended control strategy for TB control, has long been proven to cure patients, save lives and reduce the transmission of the disease. Progress in expanding DOTS, however, remains inadequate. The World Health Organization (WHO) estimates that in 2001 only 32% of people with infectious TB were diagnosed and treated in DOTS programmes. Without a rapid acceleration of DOTS expansion, the WHO global targets of detecting 70% of people with infectious TB and curing 85% of those detected will not be met until 2012.[2]

A significant barrier to rapid DOTS expansion is drug shortages, which are frequent and serious in many parts of the world, and often caused by financial constraints, inefficient drug procurement systems, and poor management. In 1998, at an ad hoc meeting in London, a committee of TB experts identified drug supply as one of the key impediments to DOTS expansion.[3] A continuous supply of drugs is one of the foundations of the DOTS strategy. While poor drug supply is not unique to TB control, its impact may be especially severe. Erratic supplies severely undermine a TB control programme, contributing to the emergence of multidrug-resistant TB (MDR-TB).[4]

Recognising the urgent need to overcome this serious constraint to rapid DOTS expansion, 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.'[5] The Global TB Drug Facility (GDF) was developed by the Global Partnership to Stop TB in response to this call, with the aim of

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increasing and securing access to high quality TB drugs. A prospectus for the GDF was developed and endorsed at the Stop TB Interim Co-ordinating Board meeting in February 2001, and the GDF was formally launched on 24 March 2001.[6]

The goal of the GDF is to: 1) ensure uninterrupted access to high quality TB drugs for DOTS implementation; and thereby 2) catalyse rapid DOTS expansion in order to achieve the WHO global targets for TB control; 3) stimulate political and public support in countries worldwide for public funding of TB drug supplies; and 4) secure sustainable global TB control and eventual elimination of TB.

The GDF fulfils its mission through the following elements: providing grants to countries that qualify for support, procuring drugs through bulk purchasing, and mobilising Stop TB partners for technical assistance to National TB Programmes (NTPs). The unique aspect of the GDF is that these elements are combined under one operating entity.

OPERATIONS

The GDF is structured as a lean partnership. It has a small, dedicated secretariat that provides administrative support (and ensures alignment in decision making and execution of grants), manages procurement, and mobilises partners for technical assistance; these elements are delivered through the GDF's contractual and collaborative partners.

The GDF was established by the Stop TB Coordinating Board as an 'embedded legal identity housed in WHO'.[6] It has a unique governance model that balances the roles of 1) WHO, which provides the legal identity for GDF, facilitates access to WHO's country and regional offices, coordinates with the DOTS Expansion working group and ensures administrative support, 2) the Stop TB Partnership, which provides funding and technical assistance through partners, and 3) the Coordinating Board, which provides oversight in reviewing annual work plans and Technical Review Committee (TRC) recommendations in relation to grants.

The GDF has four core donors—the Canadian International Development Agency (CIDA), the Government of the Netherlands, the United States Agency for International Development (USAID) and the World Bank. Responsibility for resource mobilisation for the GDF lies with the Stop TB Coordinating Board. The Board has successfully mobilised funds to date for all countries approved for GDF grants for their first year. The GDF Secretariat and the Board are actively seeking new donors to ensure that the resources required for 2004 to 2005 are met.

The grant making process of the GDF is described in four operational areas—applications, review, supply, and monitoring.

Applications

The application process of the GDF is simple and relies on information that the country should already have: 1) a multi-year DOTS expansion plan and budget; 2) national technical and operational guidelines for TB control; 3) annual reports on DOTS performance (WHO TB data collection form), including case finding and treatment, and 4) the most recent independent monitoring report.

Annex 1 lists the terms and conditions to be fulfilled for countries to be eligible for GDF grant support. Eligible countries should provide information on the estimated patients to be treated each year to reach the global targets, the proportion of patients requiring support from the GDF, evidence of agreement with terms and conditions of GDF support, and consignee details. Countries and NGOs can access and submit application forms from the GDF website in four United Nations languages: English, French, Spanish and Russian.*

Review

All applications for GDF support are screened by the Secretariat for completeness and then submitted to the TRC, a group of independent experts in TB control, drug management and TB programme management from around the world. The TRC reviews applications three times a year, and makes recommendations to approve, place under consideration or not to approve applications.

Guidelines for prioritising GDF applications were developed through a consultative process involving Stop TB partners and technical experts. Priority is given to those countries where GDF support is likely to have the greatest effect in accelerating DOTS programmes, and is based on the following criteria: 1) drug shortage as the main problem for DOTS expansion; 2) potential contribution to DOTS implementation and expansion; and 3) evidence of high-level commitment from government, including financing for TB control.

All countries that are accepted or placed under consideration by the TRC undergo country assessment visits. The objectives of these visits are: 1) to provide a briefing on the GDF, including the conditions of support and reporting requirements; 2) to assist countries to provide the additional information requested by the TRC; 3) to verify the patient numbers, product specifications, quantities and delivery schedule; 4) to assess the drug management and distribution system to be used for TB drugs; and 5) to prepare a draft of the GDF grant agreement.

The GDF Secretariat organises these visits, with the support of Stop TB partners who provide technical assistance. Following the country visit, the GDF Secretariat prepares the official grant agreement, which

* www.globaldrugfacility.org

specifies the number of patients to be treated and consignee information. Once signed by the grantee, the drug order is placed with the procurement agent.

Supply

The GDF has appointed a procurement agent, currently the Inter-Agency Procurement Services Office (IAPSO) of the United Nations Development Programme (UNDP), through a process of competitive bidding, to manage the supply process. IAPSO coordinates the services of other selected agents for preshipment inspection, laboratory analysis, freight and insurance. The drugs, specified and quantified by the GDF, are tendered through Limited International Competitive Bidding (LICB) of prequalified suppliers and purchased for direct shipment to the recipient country. IAPSO provides an internet-based system for the tracking of orders.* Up-to-date reports on progress at every step in the supply chain, including delivery, are available to the recipient country and the GDF Secretariat.

Monitoring

GDF support is provided, in principle, for a 3-year period, subject to annual independent monitoring, satisfactory compliance with GDF conditions of support and availability of resources. All grant recipients of first-line tuberculosis drugs from the GDF agree to regular assessments of: 1) adherence to GDF terms and conditions of support; 2) programme management (including case detection and treatment outcome), financial management and drug management; 3) estimated drug needs for each year of GDF support; and 4) follow-up on recommendations made by the TRC.

The international agency or institution that normally provides technical support to the National TB Programme (NTP), monitors the use of the GDF drugs and assesses the above as part of their regular monitoring mission. The country submits this monitoring mission report, together with information on GDF drug arrival, customs clearance, drug registration, quarterly reports on case finding and treatment outcomes and annual WHO TB data collection forms to the Stop TB Secretariat. This information, known as a monitoring dossier, is then sent to the desk auditors.

The desk auditors for the GDF, currently Management Sciences for Health (MSH) and the German Leprosy Relief Association (GLRA), were appointed through a competitive process in October 2002. The role of the desk auditor is to review the monitoring dossier for completeness, consistency and credibility, and to determine whether the information included is sufficient to enable the GDF TRC to make an assessment of whether the GDF terms and conditions of support have been met.

Monitoring reports cleared through the desk audit are submitted to the TRC, which makes recommendations on continued GDF support to the relevant grantees. The TRC decides on either of the two options for the second year of support—a green light that signifies that support can continue, or an orange light that signifies that there are problems. Unless these problems are rectified in the second year, a red light could be given for the third year, meaning that the country will not receive GDF support.

To date, nine countries have been monitored and approved for second year support (Moldova, DPR Korea, Kenya, Myanmar, Tajikistan, Sudan, Somalia, Djibouti and DR Congo).

ACHIEVEMENTS

In 2001, the first year of operation, the main activities of the GDF were to: 1) set up systems and processes for applications, review, procurement and monitoring for supply of drugs; 2) develop a web-based e-procurement mechanism, enabling the GDF Secretariat and countries to place orders for drugs, and trace progress in manufacturing, quality control and delivery; and 3) process the drug orders of the initial countries approved for support.

In 2002, the second year of operations, these systems and processes were finalised and the GDF moved from an interim to a robust procurement mechanism. In addition, GDF established systems for: 4) buying drugs through a direct procurement mechanism; 5) assessing and identifying suppliers of quality assured TB products; and 6) monitoring countries that had received drugs 8 months previously.

A number of key achievements within the first 2 years of GDF operations are of note.

Patient treatments

In the first 2 years of operations, the GDF reviewed applications for grants of TB drugs from 65 countries, two NGOs, one federal state, and one public-private partnership initiative. Of these, 46 applications have been approved for support (Annex 2).

Of the 46 countries approved for support, the majority applied to initiate or expand DOTS and a few to maintain DOTS. The reasons for applying were manifold: lack of finances to buy drugs due to financial crises, lack of foreign currency to procure drugs, inefficient or slow procurement mechanisms, drug quality concerns, increased demand for drugs due to the HIV/AIDS epidemics, deteriorating health structures, socioeconomic changes, war, loss of donor support, etc. Eleven of the approved countries applied for one-off emergency support as a stopgap measure due to irregular procurement practices, late deliveries, changes in regular donor support and weak forecasting of needs. GDF grants are usually made for 3 years and include a 100% buffer of drugs to prevent stock outs.

* www.stoptb.unwebbuy.org

Table Overview of GDF grant activities

Activity	Cumulative (as of January 2003)
Rounds of applications and review	6
Number of applications for GDF support	69
Number of applications approved for support	46
Number of applications monitored for repeat support	9
Number of applications accepted for repeat support	8
Total value of grants (including buffer)	US$23 404 434
Number of patient treatments approved (including buffer)	1 911 451
Average cost per patient (including freight and insurance)	$12
Drug orders placed	37
Number of applicants who have received drug deliveries	27

GDF = Global TB Drug Facility.

The majority of the countries approved for support are from Africa, and all countries have a gross national product (GNP) of under $1000. The Secretariat has received few applications from the Latin American Region.

Thirty-seven countries have more than 20 000 unreported people with TB: together they account for nearly 90% of the global total of unreported cases. The GDF encourages applications from these countries. Twenty-two in this list have applied for GDF support, and 18 have been approved (Annex 3).

The TRC did not approve a number of countries for support for the following reasons: 1) incomplete application dossier; 2) weak DOTS expansion plans; 3) poor budgetary or financial information in the DOTS expansion plan; 4) no obvious need for drugs; 5) concerns about in-country drug management; 6) lack of political commitment from the Ministry of Health (MOH) or other partners; and 7) the request included single drugs or formulations not recommended by the WHO.

A total of 1 911 451 free patient treatments have been approved in the first 2 years of operations (see Table). It is too early to quantify the impact of the GDF, in terms of actual patients treated/cured and progress towards the global targets. This is due to the fact that only a few countries are in the second year of the grant. Yet we can make some predictions. Of the 1.9 million treatments approved so far, 1 327 539 constitute drugs for new patients and 583 912 buffer stocks for patients. Assuming 85% cure rate in those patients diagnosed and commencing treatment, this means 1 128 408 additional patients will have been cured through GDF support to date.

Access to high quality drugs

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, good manufacturing practices (GMP) inspection, and quality control. The white list of manufacturers and products will be published on the GDF website, enabling agencies and countries procuring TB drugs to identify sources of quality assured drugs.

The Société Générale de Surveillance (SGS), Nederland BV, won a limited international competitive bid to carry out the initial screening of potential manufacturers. Over 70 expressions of interest were received. The WHO Department of Essential Drugs and Medicines is conducting the prequalification process for TB drug manufacturers that passed the initial screening by SGS, based on the process established for prequalification of manufacturers of HIV/AIDS-related drugs. The first white list of pre-qualified TB manufacturers is expected to be published in 2003.

Reduction in TB drug prices

In 2000, the Global Alliance for TB Drug Development reported that the world spent $470 million on TB drugs. An estimated $140 million was in the public/tender market, and $60 million in international donor assistance. Countries were paying $7 to $797 for drugs for a new smear-positive case in the public sector.[7]

As the GDF combines centralised, pooled procurement with a grant making function, it is able to guarantee a minimum demand and negotiate prices with drug manufacturers. This has meant that GDF prices are, on average, a third less than previous international tenders. The GDF secretariat is currently collating information from grantees to determine the impact that the GDF is having on the global antituberculosis drug market.

Catalysing rapid DOTS expansion

The GDF has a catalytic impact on DOTS expansion that goes beyond the provision of drugs. More countries are developing DOTS expansion plans and introducing policies based on the DOTS strategy, as part of the GDF application process. In addition, plans are being developed for improving drug management, and in several countries, new partners are providing additional technical and financial assistance for DOTS. Moldova and Myanmar, two countries with a similar GNP (circa $300 per capita) illustrate the role of the GDF as a DOTS catalyst. In Moldova, the GDF was the catalyst to introduce DOTS and in Myanmar to expand DOTS. The following case studies describe the DOTS expansion in these countries.

Case Study

MYANMAR When the DOTS strategy was officially introduced in Myanmar, in 1997, the NTP faced severe shortages of drugs. As a result, it switched to a fully intermittent regimen with drug intake three times per week.

Although drugs were provided to all smear-positive cases, the shortage of drugs made it necessary to limit the percentage of smear-negative cases treated with short course chemotherapy (SCC) to 10% of the total caseload. By 2001, 80% of the population was covered by DOTS. However, maintaining and expanding DOTS beyond 80% proved to be a major challenge despite Myanmar's high level of political commitment to TB and strong health infrastructure with trained health workers. The missing link was a consistent supply of TB drugs. The irregular drug supply prompted the national drug store to retain stocks of expired drugs because they did not know when they might receive another shipment. The country had never been able to maintain a buffer stock. Myanmar applied to the GDF to tackle this problem and received the grant in 2001. By August 2002, DOTS coverage had increased to 90%. With the assistance of new donors and technical partners providing diagnostic equipment and the government's commitment to building better drug storage facilities, Myanmar aimed to achieve 100% DOTS coverage by the end of 2003.

Case Study

MOLDOVA In October 2001, the first shipment of TB drugs from the GDF arrived in Moldova, a former Soviet Republic and newly independent country struggling with the difficulties of a transition economy. Moldova was the first country to receive a GDF grant of drugs, within 6 months of the establishment of the facility.

The country's TB rates had increased throughout the 1990s, and by 2002 Moldova had one of the highest TB rates in Europe. The NTP lacked funds, resulting in chronic drug shortages. Drugs provided by the GDF to Moldova stimulated the introduction of DOTS as the counry's national control strategy. Three weeks after a visit by the GDF, the Ministry of Health formally adopted DOTS, beginning several pilot projects and reaching 28% DOTS coverage in 2001 and 70% by 2002. In March 2003, The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) provided Moldova with $5 257 941 for joint TB and HIV activities, of which $880 000 have been disbursed. The Government of Moldova has increased the TB budget from $88 000 in 2001 to $163 000 in 2003. GDF has also facilitated technical support from partners (MSH, USAID, KNCV) to the TB control programme.

Encouraging proper drug use and standardisation of products

By linking demand for drugs to supply and monitoring, the GDF ensures that drugs are used in accordance with WHO-recommended treatment and control strategies. An assessment of the drug distribution system is carried out as part of the GDF country visit, and recommendations are provided to the NTP and its technical partners. These recommendations are followed up during the annual monitoring visits.

One of the goals of the GDF is to promote standardised treatment regimens and products, to support DOTS and encourage effective TB control. As a result, the GDF offers a limited, WHO-approved catalogue of TB drugs and formulations, which is designed to promote the use of fixed-dose combination tablets (FDCs), and in particular, the four drug fixed-dose combination tablet (4FDC).[8] The emphasis on FDCs is in response to the lack of product standardisation in TB programmes and the clear benefits of FDCs over single drugs.[9,10] The following case study illustrates the benefits of 4FDCs to the NTP of DR Congo.

Case Study

DR CONGO The Democratic People's Republic of Congo is a current recipient of GDF support, having been approved for a 3-year grant of TB drugs, including 4FDCs, in November 2001.

DR Congo is one of the world's 22 high-burden TB countries. The Government formally adopted the DOTS strategy in 1995. The NTP is managed by NGOs, and current DOTS coverage is 70%.

DR Congo applied for assistance from the GDF because the NTP did not have enough drugs to treat TB patients. The country had lacked buffer stocks for 10 years, some regions had no drugs, and the NTP's funding partners were unable to increase their budgets for drugs. As a result of periodic shortages, DOTS could not be maintained or extended throughout the country even though the NTP was generally good. The NTP decided to shift to 4FDCs because of a need for simplified drug management and compatibility with the existing TB drug treatment regimens.

The provision of the 4FDC drugs in the country has made it possible to improve the drug management skills of the TB personnel and primary health care workers who are responsible for the diagnosis and treatment of TB. The introduction of 4FDCs has greatly simplified drug ordering, stocking and distribution, reduced complex prescriptions and minimised the potential for error. With a consistent drug supply in place, the NTP plans to expand DOTS to all provinces in the country.

Using partnerships to provide the most efficient services

The GDF has provided timely, cost-effective and high quality services through the involvement of partners. The review, supply and monitoring functions of the GDF are carried out by competent partners, selected on a competitive basis, and engaged on contractual (fee-based) or collaborative (non-fee-based) arrangements. Quality of services is frequently evaluated by regular meetings of the partners, indicating the commitment of the partners to the joint cause.

THE FUTURE

One of the biggest concerns related to GDF grants is over-dependence. Sceptics insisted that countries would discontinue budget lines for TB drugs if they received grants. However, through the monitoring operation, the GDF ensures that grants are truly additional to the system. All grant agreements carry, as

one condition of support, that 'public sector funding for TB control activities will not be reduced as a consequence of, or during the period that GDF grants are received'. This statement takes into consideration the fact that many countries do not have a specific budget line item for TB drugs, but a budget for overall TB activities.

The GDF strongly discourages NTPs from deleting the line item for TB drugs. During country visits, prior to signing grant agreements, this issue is discussed at length with NTPs and the MOH. The GDF has not provided 100% of all drug needs for a country; in most cases its support is in addition to government provision, while in others it is additional to donor support. In a few instances, perhaps due to the fact that drugs that were previously purchased were of poor quality or high cost, it is preferable to reallocate this money to other aspects of DOTS, while at the same time keeping a budget for paediatric drugs or single drugs (for side effects), which are not provided by the GDF.

Sustainability in the international development arena is often understood to mean that countries receiving external assistance (in this case grants) should not become dependent on resources long term. Projects use a variety of mechanisms to ensure sustainability over the long term: cost sharing, capacity building, phase out plans, etc. The GDF offers three core services at the moment—grants, direct procurement and a white list of quality TB drugs. The last two services are attempts to strengthen overall drug procurement and quality assurance systems in countries, and to reduce dependency on the grant. The GDF encourages countries receiving grants to use direct procurement as a cost-sharing exercise.

The direct procurement mechanism was established in 2002, to enable governments, NGOs and donors to realise these cost savings. Organisations and countries buying drugs through the GDF direct procurement mechanism must make a clear commitment to follow WHO-approved treatment regimens in DOTS programmes and provide the drugs free of charge to patients. The advantages of purchasing drugs through the GDF include the following:

- competitive prices, which free up resources for other aspects of DOTS expansion;
- quality control, bought from prequalified manufacturers; all TB drugs manufactured for the GDF are subject to pre-shipment inspection and independent laboratory analysis;
- standardised TB drugs and formulations, approved by the WHO;
- flexible choice of loose or blister packed tablets with user-friendly packaging and clear labelling;
- a web-based tracking system for tracing the order;
- a 'value-added' service of ongoing technical support and an annual monitoring mission to all clients.

In 2002, the GFATM was set up with the purpose of attracting, managing and disbursing additional resources for AIDS, TB and Malaria through a new public-private partnership. The secretariats of GFATM and GDF meet regularly to ensure collaboration, to share knowledge and to ensure complementary work. In addition, the GDF secretariat is actively working with the GFATM secretariat to encourage recipients of GFATM funds to use the GDF for procurement of TB drugs where appropriate.

Given the early positive effects of the GDF, there is a growing interest in expanding GDF to second-line drugs[11] and diagnostic materials for TB and to other diseases such as HIV/AIDS and malaria. The recent GDF evaluation recommended that the GDF mechanism could be a model for other diseases where rational use of drugs is critical and where there is an economic case for providing free drugs and commodities.

CONCLUSIONS

The concept of pooled procurement in public health is not new; for instance, PAHO's revolving fund for vaccine procurement has existed since the late 1970s. There are many examples of bulk purchasing, ranging from global initiatives such as GAVI,* to regional initiatives such as the Eastern Caribbean Drug Service† and national initiatives such as The Delhi Society for the Rational Use of Drugs.‡ The GDF is not a traditional procurement mechanism; it was established rapidly, and the experience gained so far is shaping its future operations. The following lessons from the GDF may be useful for similar initiatives:

1 focused mandate: the GDF was set up to address a key constraint to reaching the WHO global targets for TB, namely drug supply;
2 single operating entity combining grants, procurement and technical assistance: a separate or unlinked system will not have the same impact as the GDF because it would not encourage standardisation of products and price reductions through bulk procurement;
3 supportive operating environment: a supportive partnership environment is key to mobilising technical support to countries, donor support and strategic guidance to the GDF;
4 'virtual organisation': outsourcing services on a collaborative and contractual basis ensures a lean secretariat and draws on the relative strengths of partners. Competitive bidding, to identify organisations that provide efficient, quality and low cost services, creates an effective partnership chain.

* www.vaccinealliance.org
† www.caribisles.org
‡ www.dsprud.org

5 rational drug use and standardised product packaging: linking demand for drugs to supply and monitoring of TB programme performance ensures rational use. Providing a limited, standardised list of products and using product packaging (blisters and patient packs) simplifies drug management in countries.
6 diverse funding base: sustainability of funds is ensured through the direct procurement mechanism where countries and NGOs use their own resources, through donors/lending agencies (e.g., World Bank/GFATM) and drug donations.

References

1 De Cock K M, Soro B, Coulibaly I M, Lucas S B. Tuberculosis and HIV infection in sub-Saharan Africa. JAMA 1992; 268: 1581–1587.
2 World Health Organization. WHO Report 2003. Global Tuberculosis control: Surveillance, Planning, Financing. WHO/CDS/TB/2003.316. Geneva, Switzerland: WHO, 2003.
3 World Health Organization. Report of the ad hoc committee on the tuberculosis epidemic. WHO/TB/98.245. Geneva, Switzerland: WHO, 1998.
4 Raviglione M C, Gupta R, Dye C M, Espinal M A. The burden of drug resistant tuberculosis and mechanisms for its control. Ann NY Acad Sci 2001; 953: 88–97.
5 World Health Organization. Global Partnership to Stop TB. Washington Commitment to Stop TB. WHO/CDS/STB/2001.14a. Geneva, Switzerland: WHO, 2001.
6 World Health Organization. Global TB Drug Facility: A global mechanism to ensure uninterrupted access to quality TB drugs for DOTS implementation. WHO/CDS/STB/2001.10a. Geneva, Switzerland: WHO, 2001.
7 Global Alliance for TB Drug Development. The economics of TB drug development. New York, NY: The Global Alliance for TB Drug Development, 2001.
8 World Health Organization. Frequently asked questions about the 4-drug fixed-dose combination tablet recommended by the World Health Organization for treating tuberculosis. WHO/CDS/STB/2002.18. Geneva, Switzerland: WHO, 2002.
9 Blomberg B, Spinaci S, Fourie B, Laing R. The rationale for recommending fixed-dose combination tablets for treatment of tuberculosis. Bull World Health Organ 2001; 79: 61–68.
10 World Health Organization. Fixed-dose combination tablets for the treatment of tuberculosis. WHO/CDS/TB/99.267. Geneva, Switzerland: WHO, 1999.
11 Gupta R, Cegielski J P, Espinal M A, et al. Increasing transparency in partnerships for health—introducing the Green Light Committee. Trop Med Intern Health 2002; 7: 970–976.

Annex 1 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 NTP 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:
  1 A regular annual report on NTP performance in accordance with WHO guidelines;
  2 Quarterly reports on case finding, smear conversion and treatment outcomes;
  3 Date of arrival of GDF drugs at port;
  4 Time taken to register drugs (if applicable);
  5 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).

GDF = Global TB Drug Facility; NTP = National Tuberculosis Programme; WHO =World Health Organization.

Annex 2 Countries approved for GDF support

No, TRC approved country	Total annual grant value	No, TRC approved country	Total annual grant value	No, TRC approved country	Total annual grant value
TRC 1–March 2001		TRC 3–April 2002		TRC 5–Oct 2002	
1 Kenya	256 091	17 Kyrgyzstan	—	36 Kosovo (Yugoslavia)	44 889
2 Myanmar	266 668	18 Niger	64 395	37 Rwanda	167 622
3 Rep. of Moldova	59 420	19 The Gambia	29 067	38 Cameroon	140 625
4 Somalia	70 906	20 Central African Rep	54 033	39 Bosnia/Herzego.	83 947
5 Tajikistan	33 947	21 Zambia	530 530	40 Azerbaijan	46 843
		22 Armenia	1 150	41 Eritrea	191 836
TRC 2–August 2001		23 Bangladesh	764 509		
6 Congo	129 406	24 Uzbekistan	228 260	TRC 6–March 2003	
7 DPR Korea	513 247	25 India	2 050 309	42 Benin	64 800
8 Liberia	152 719			43 Mali	127 680
9 Pakistan	2 327 464	TRC 4–July 2002		44 Egypt	212 016
10 Sudan	74 956	26 Cote d'Ivoire	399 754	45 Yemen	549 348
11 Togo	40 663	27 Burundi	52 978	46 Madagascar	668 052
12 Yemen	67 195	28 Haiti	351 876		
13 Djibouti	32 410	29 Mauritania	578		
14 DR Congo	132 122	30 India (Orissa State)	668 310		
15 Nigeria	816 499	31 Indonesia	1 741 324		
16 Uganda	627 390	32 Angola	250 778		
		33 Philippines	858 852		
		34 Philippines PPP	121 622		
		35 Sierra Leone	125 359		

* Includes cost of drugs, freight, insurance, laboratory tests, preshipment inspection costs and procurement fees.
TRC = Technical Review Committee.

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

N = No; Y = Yes.

RÉSUMÉ

La Global TB Drug Facility (GDF) est une nouvelle initiative visant à améliorer l'accès à des médicaments antituberculeux de haute qualité. Le GDF, un projet du Partenariat Mondial Stop TB, est dirigé par son secrétariat, au sein de l'Organisation Mondiale de la Santé (OMS) à Genève. Il vise à fournir des médicaments antituberculeux pour traiter jusqu'à 11,6 millions de patients au cours des 5 années à venir et pour aider les pays à atteindre d'ici 2005 les objectifs mondiaux de l'OMS pour la lutte antituberculeuse. Le GDF a été lancé le 24 mars 2001. Six séries de demandes ont été conduites à terme et 46 pays et organisations non-gouvernementales (ONG) ont été approuvés en vue d'un soutien. Le GDF n'est pas un mécanisme traditionnel de fourniture. Il a adopté une approche innovatrice dans la fourniture de médicaments, en liant le besoin de médicaments à leur fourniture et à leur suivi, en utilisant des partenaires pour assurer des services, en utilisant l'empaquetage des produits pour simplifier la gestion des médicaments et en liant les subventions aux performances du programme antituberculeux. Cet article décrit les procédures opérationnelles du GDF et l'expérience accumulée jusqu'ici. On souligne également les réalisations-clé à ce jour, y compris la création d'un système flexible de fourniture pour rencontrer les besoins différents des programmes, l'élaboration rapide des procédures, une réduction des prix des médicaments TB, ce qui catalyse l'expansion du DOT dans les pays, la standardisation des produits et la collaboration avec des partenaires. Le GDF est suffisamment flexible pour rencontrer les besoins des pays lourdement affectés par la tuberculose. L'expérience du GDF pourrait être utilisée comme un exemple pour la fourniture mondiale de médicaments et de produits pour d'autres maladies comme le VIH/SIDA et le paludisme. A l'avenir, il est probable que le GDF va s'élargir pour y inclure des médicaments de deuxième ligne, ainsi que des produits de diagnostic pour la TB, et qu'il pourrait soutenir d'autres partenariats pour développer des mécanismes et des institutions similaires pour répondre aux besoins des pays.

RESUMEN

La Global TB Drug Facility (GDF) es una nueva iniciativa para aumentar el acceso a los medicamentos antituberculosos de alta calidad. La GDF, un proyecto de la Colaboración Mundial para Detener la TB, es dirigida por su Secretaría, en la Organización Mundial de la Salud (OMS), en Ginebra. Se propone proveer los medicamentos antituberculosos para tratar hasta 11,6 millones de pacientes, durante los 5 próximos años y asistir a los países para alcanzar las metas de la OMS de control mundial de la TB de aquí al año 2005. La GDF fue lanzada el 24 de marzo de 2001. Se han llevado a cabo seis tandas de candidaturas, habiéndose aprobado el apoyo a 46 países y organizaciones no gubernamentales (ONG). La GDF no constituye un mecanismo tradicional de aprovisionamiento. Ha adoptado un en-foque innovador para el abastecimiento de medicamentos, vinculando la solicitud de medicamentos al abastecimiento y control, utilizando colaboradores para prestar servicios, usando el embalaje de los productos para simplificar el manejo de los medicamentos y vinculando las donaciones al rendimiento del programa TB. Este artículo describe los procedimientos operacionales de la GDF y la experiencia obtenida hasta aquí. Se subrayan los logros clave realizados hasta esta fecha, incluyendo la creación de un sistema flexible de aprovisionamiento para satisfacer las diferentes necesidades de los programas, el establecimiento rápido de los procedimientos, la reducción de los precios de los medicamentos antituberculosos, la catálisis para la expansión del DOTS en los países, la estandarización de los productos y la cooperación con los organismos colaboradores. La GDF es suficientemente flexible como para satisfacer las necesidades de los países con prevalencia elevada de TB. La experiencia de la GDF podrá ser usada como ejemplo para un aprovisionamiento, a nivel mundial, de medicamentos y otros productos para otras enfermedades como VIH/SIDA y malaria. Es probable que en el futuro, la GDF extienda su acción para incluir medicamentos de segunda línea y material de diagnóstico para la TB y que ayude a otros organismos colaboradores a desarrollar mecanismos similares y recursos para satisfacer las necesidades de los países.