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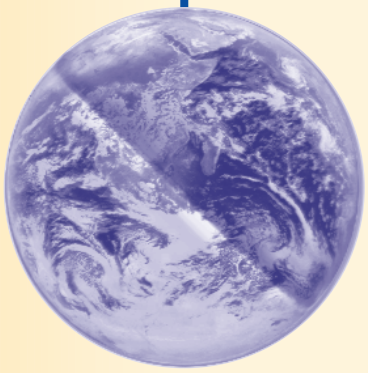
Prospectus

GLOBAL TB DRUG FACILITY

A global mechanism to ensure uninterrupted access to quality TB drugs for DOTS implementation



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Preface

The establishment of the Global TB Drug Facility (GDF) is one of the most important activities of the Stop TB Initiative. In March 2000, Ministers of Health, Finance and Development Planning from twenty of the highest TB burden countries endorsed the "Amsterdam Declaration to Stop TB", committing themselves to reaching global DOTS targets by 2005 and calling upon international partners to increase their support to "new international approaches towards ensuring universal access to and efficient national systems for procurement and distribution of tuberculosis drugs." In May, the World Health Assembly encouraged all Member States to endorse the Amsterdam Declaration. In response, many countries have prepared or are preparing national plans of action to accelerate DOTS expansion. A major contribution from the global community will be the GDF, which will facilitate country efforts to rapidly expand access to DOTS and save lives.

The Stop TB Initiative and its partners, especially the Rockefeller Foundation, have made significant progress on the development of the GDF. Beginning in December 1999, a range of experts from Stop TB partner organizations began consulting on a variety of technical issues surrounding the establishment of a Global TB Drug Facility. This Prospectus has emerged from that work, and is a result of significant effort by these experts and by the GDF Writing Committee, composed of experts from the Rockefeller Foundation, the World Bank, WHO and the Stop TB Secretariat. Contributions were also received from a wider group of people, as listed in the acknowledgements. Several additional supporting documents and other information on to the GDF are in preparation and available from the STB Partnership Secretariat.

This Prospectus was presented in draft form in November 2000 at a meeting of the Working Group on DOTS Expansion. We received valuable input at that meeting from a wide variety of Stop TB partners—donors, representatives from TB high-burden countries, UN agencies, NGOs and foundations. As part of the DOTS Expansion meeting, a planning meeting for the GDF was held. At this meeting, a core technical group for the GDF was created that had the following terms of reference: to finalize the prospectus, to resolve remaining issues, and to develop final recommendations for the form, strategies, objectives and governance of the GDF. These recommendations were presented to the Stop TB Coordinating Committee at its meeting in Bellagio in February of this year.

As the Coordinator of the GDF Prospectus writing group, as well as co-chair of the GDF Core Technical Group, I would like to thank the members for their excellent work and the time they devoted to make this happen. I also appreciate the useful comments and contributions that were received from the many persons on this or previous versions of the Prospectus. There were a number of views and diverse opinions to take into account, and I take the responsibility for final editing of the document. A great effort was made to incorporate as much of the input as possible.

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Executive summary

Globally, tuberculosis (TB) is the leading curable cause of infectious death. A cure has been available for more than 50 years, and yet nearly two million people die from tuberculosis every year. Although there has been significant progress in combating the global tuberculosis epidemic over the past ten years, advances in some parts of the world have been offset by increases in TB due to HIV and by the widespread emergence and spread of multidrug-resistant strains of TB.

A comprehensive public health strategy to control tuberculosis, known as DOTS, reliably increases cure rates by 20%–50%, decreases the proportion of patients who die by 10%–30%, and prevents the further emergence of drug resistance. Despite this, less than one in four patients receive the benefits of this strategy today.

In March 2000, the Stop TB Initiative convened a Ministerial Conference on "Tuberculosis and Sustainable Development" for representatives from 20 countries comprising 80% of the global TB burden. The resulting Amsterdam Declaration to Stop TB called for the establishment of a Global Fund for Tuberculosis to mobilize new additional resources to support "new international approaches towards ensuring universal access to, and efficient national systems of, procurement and distribution of tuberculosis drugs." In May 2000, the 53rd World Health Assembly endorsed this declaration and requested the WHO Director-General to act appropriately on the recommendations of the Ministerial Conference.

Shortage of TB drugs is frequent and serious. Causes include resource constraints, inefficient and ineffective procurement, short-term political, managerial, logistic and financial crises, and failures of health system management. Even where drugs are available, quality is often a problem. Ensuring uninterrupted supply of quality drugs will increase the human and financial resources available for the planning, training, management, service delivery, supervision and other services that are essential for effective TB control.

The Global Drug Facility (GDF) will expand access to, and availability of, high quality TB drugs and will thereby facilitate DOTS expansion. It will make a significant contribution to worldwide efforts to reach WHO's global targets for TB control by 2005, and the GDF can also help slow the spread of drug resistant disease. There are no replacements or appropriate substitutes for rifampicin and isoniazid, the principal first-line TB drugs, if resistance to them continues to spread. If they become ineffective, the costs of TB control would increase enormously and the epidemic could spiral out of control. Hence, improving the supply, quality and administration of first-line TB drugs is vitally important.

By supplying uninterrupted access to quality TB drugs for qualifying DOTS programmes, the GDF will contribute to the success of national TB control programmes and can thereby stimulate political and popular support throughout the world for effective, publicly funded TB control. In stimulating DOTS expansion, the GDF hopes to strengthen national TB programmes and help them eventually to become self-sustaining. The fruits of DOTS expansion will be significantly fewer TB patients, lower health care costs and the social and economic benefits of improved public health. Each of these is likely to increase national commitment to TB control.

The GDF is part of and will complement other international and national actions to improve the coverage and quality of TB control. Its key functions will be to finance the purchase and provision for grants of quality TB drugs to qualifying countries and organizations that conclude agreements with the GDF. It will also provide pooled procurement services for countries, and their partner organizations, that finance their own TB drugs. Its functions will include procurement-related services, arrangements for buffer stocks, and services for quality control/inspection. The GDF will call on its Stop TB partners to ensure monitoring, evaluation

and trouble-shooting for effective drug delivery, increased coverage, and successful treatment. Independent reviews will evaluate progress and programme results and will contribute to decisions on continued supply of drugs.

The GDF will operate on the principles of independence, transparency, accountability, flexibility, rapidity, and responsiveness. It will draw on the positive attributes of the private sector such as independence, flexibility and responsiveness, while building on the strengths of the public sector such as sustainability and credibility with national governments. Independence of operations will be key, with the ability to say "no" to governments and manufacturers as necessary.

GDF management will ensure that GDF assistance does not replace existing TB or health financing initiatives. Countries receiving GDF assistance will be required to keep budget lines open for TB control activities, including TB drug procurement, and will be encouraged to increase their budgets for TB control. At a minimum, governments will be expected to sustain TB control budgets at current levels by reapplying resources from drug procurement to TB control activities that would be under-funded in the absence of GDF assistance. In sum, the GDF will act as a catalyst for DOTS expansion, providing drugs required for effective TB control and to supplement those made available by governments and organizations assisting them in TB control. GDF assistance will in no cases duplicate or replace existing TB control assistance from specialized agencies such as WHO, IUATLD, KNCV, etc. Rather, in all cases, GDF assistance will be designed to respect the existing mandates and responsibilities of these organizations, and the GDF will call upon these organizations for appraisal and technical evaluation in its assistance.

The GDF will catalyze the sustainability of TB control programmes. The minimum required time horizon for the Facility would be 10–15 years. After at least ten years of successful implementation (including meeting global targets) in all countries, it is expected that there will be a significant decrease in the number of patients requiring treatment and subsequently a lower level of resource requirements. In addition, the GDF will have catalysed increased national commitments for DOTS expansion, as the number of patients treated will have tripled during this time.

Even if the GDF were to cease operating after 10–15 years, it would leave sustainable improvements in return for investments made. These would involve large numbers of trained staff, increased national budgets for TB control and improved diagnostic, treatment, monitoring and supervision capacity and practices. More importantly, GDF-supported programmes would reduce disease burden both in absolute numbers and in number of drug-resistant cases, so that low-income countries would have to support treatment of less than half of the pre-GDF caseload.

The GDF is likely to require an estimated annual investment of US$ 47 million for each of the next five years. Yet this estimate is subject to important uncertainties. The major determinants of GDF needs will be the ability and speed with which countries can successfully expand DOTS programmes, and thus the number of patients in qualifying programmes to be treated with GDF drugs. Unit costs per patient will also be a determinant of cost, but it is neither a goal nor an expectation of the GDF that it will have a significant impact on the prevailing major market prices for TB drugs. Operating and contracting costs are expected to be US$ 6 million per year, on average. If the global DOTS expansion targets are achieved by 2007, the total GDF resource needs will be around US$ 220–US$ 240 million for 2001–2005 (assuming average drug prices).

If the global targets are reached by 2005, the GDF will have contributed to the treatment of approximately 10 million patients in five years and a total of 45 million patients over a ten-year period. By maintaining these achievements in subsequent years, TB incidence and prevalence will be reduced by 50% and more than 75% by 2020.

Goals of the GDF

Ensure uninterrupted access to quality TB drugs for DOTS implementation.

Catalyze rapid DOTS expansion in order to achieve global TB cure and coverage targets.

Stimulate political and popular support in countries throughout the world for public funding of TB drug supplies.

Lay the foundation for sustainable global TB control and eventual elimination.

Functions of the GDF

Mobilize financing for drug procurement and supply for countries implementing or expanding successful DOTS programmes.

Entertain requests from countries or organizations, that meet DOTS planning and implementation requirements and develop grant agreements with recipients.

Procure drugs via transparent, competitive bidding using procurement agents and pre-qualified suppliers for direct distribution to grantees.

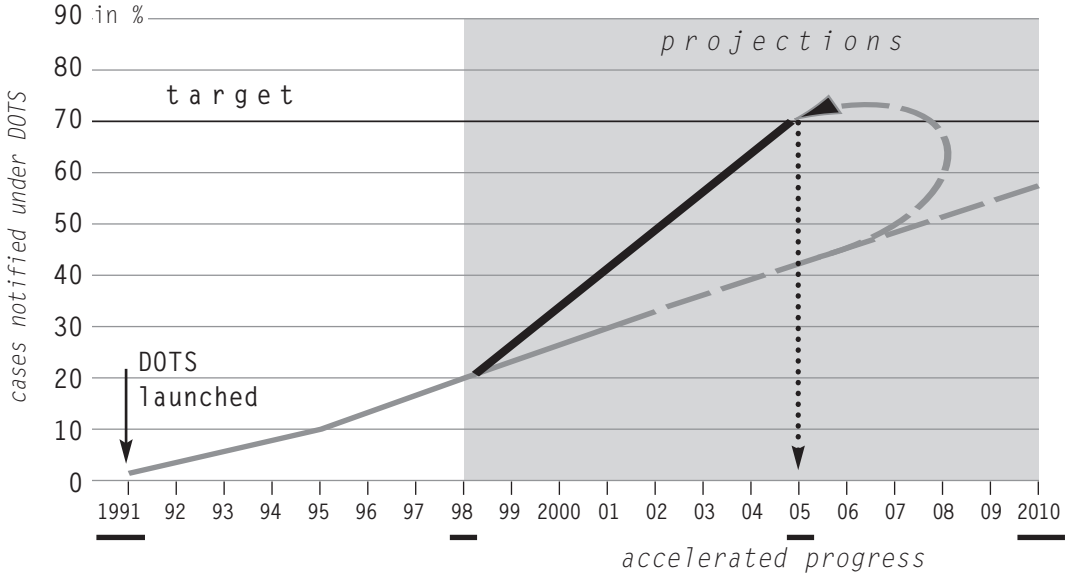
Providing procurement services for governments, and their partner organizations, that finance their own TB drug purchases.

Work with Stop TB partners to ensure monitoring, evaluation and problem solving for effective drug delivery and deployment.

Background

1. **The epidemic**—Tuberculosis is a disease caused by *Mycobacterium tuberculosis* and is curable with an inexpensive course of antibiotics. Still, every day, 20 000 people develop TB and 5 000 die from it. There are 7 to 8 million new cases and nearly two million deaths per year. TB's economic costs are more than US$ 12 billion per year, mostly affecting the poor, and its social consequences are tremendous. The spread of HIV is now accelerating and amplifying the TB epidemic, as is multidrug TB resistance, which is largely due to inadequate or inappropriate TB control efforts.
2. **If the world fails to act,** it faces a tuberculosis epidemic that could spiral out of control in many parts of the world, fuelled by the AIDS epidemic, the spread of multidrug-resistant (MDR) strains of disease, or both. If TB is not effectively treated, HIV can increase TB cases four-fold and TB drug resistance could result in a disease that is at best expensive, and at worst impossible to treat. Drug-resistant TB will then spread rapidly and inevitably across borders and become a significant problem in nations in which TB is not now a public health threat.
3. **Adopting a control approach**—The WHO-recommended control strategy for tuberculosis (DOTS—Directly Observed Therapy, Short-course), is among the most cost-effective health interventions available, and has proven to be successful on a national scale in diverse low-income developing nations. A full course of therapy can be provided for less than US$ 10. The costs of DOTS delivery are low given use of the primary health care infrastructure, as well as active involvement of community volunteers in many countries. When fully applied, DOTS can increase TB cure rates by 20%–50%, can decrease TB mortality by 10%–30%, and prevent the emergence of drug resistance.
4. **Slow progress towards targets**—The World Health Assembly has set year 2005 TB control targets of detecting at least 70% of patients who develop infectious tuberculosis and successfully treating at least 85% of them. While over 120 countries had adopted DOTS as of the end of 1999, less than 25% of infectious TB patients globally are being treated under the strategy due to obstacles in expanding coverage. If efforts were made to accelerate DOTS expansion, coverage could reach levels shown in Figure 1 in the next few years. *Further information on the status of DOTS expansion worldwide is provided in Annex C.*

Figure 1: Potential for expanded coverage under DOTS



5. **Coordinating and accelerating response**—In response to the global TB emergency and slow expansion of DOTS, the Stop TB Initiative was launched as a global partnership in 1998. It involves governments, UN, bilateral and multilateral agencies, nongovernmental and private organizations, and research institutions working together to accelerate action to reverse the TB epidemic. The mission statement of Stop TB is to: i) raise TB as a key issue across social, economic, and human rights agendas; ii) mobilize demand for TB services; iii) ensure global access to TB drugs; and iv) accelerate research for new tools.

6. **A call from high TB burden nations**—In March 2000, Stop TB convened a Ministerial Conference on "Tuberculosis and Sustainable Development" in Amsterdam. Ministerial representatives of Health, Finance and Planning from 20 countries that carry 80% of the global TB burden participated along with high-level representatives of Stop TB partner organizations. The "Amsterdam Declaration to Stop TB" endorsed by the delegates called for urgent global action to stop TB, including the establishment of "new international approaches towards ensuring universal access" to TB drugs. The 2000 World Health Assembly subsequently endorsed the Amsterdam Declaration.

7. **New environment for global action on diseases of the poor**—Since Amsterdam, there has been a dramatic increase in global attention focused on the worsening epidemics of HIV/AIDS, TB, and malaria as well as other health problems of the poor. Resolutions of the G8 Summit in Okinawa, the European Commission Roundtable in Brussels, and the UN Millennium Summit in New York this year have set new targets to reduce morbidity and mortality due to these communicable diseases and have committed nations to increase spending to reach these targets. Major foundations have also launched new commitments to public health. The efforts to devise poverty reduction strategies and plans for increased investment in health as part of the debt relief plans for the Heavily-Indebted Poor Countries (HIPC) have also opened the windows for increasing national resources for priority health problems and for strengthening primary care infrastructures. Coordinated global action against diseases of the poor is advancing, and the Global DOTS Expansion Plan to combat TB is a prime example. Yet while the environment for DOTS expansion is improving, innovative mechanisms are still needed to make best use of newly available resources and to reach the greatest number of those of TB patients.

8. **Financing for TB control**—In 1990, estimated commitments of foreign assistance for TB control in developing nations totalled approximately US$ 16 million. In 1996, WHO estimated that assistance had risen to roughly US$ 50 million. A survey of bilateral, multilateral, and non-governmental partners suggests that support had grown to more than US$ 175 million by year 2000 and that the increasing trend is likely to continue. These are conservative estimates, given support for disease control also provided through broad sectoral financing in some countries. There is far less complete information available on national and local commitments for TB control. Given the worsening epidemic, the resource gap is still great.

9. **Improving drug supply matters**—Insecure financing and shortages of TB drugs are frequent and serious in many parts of the world and have been a major obstacle to DOTS expansion. While poor drug supply is not unique to TB control, the impact may be especially severe. Drugs are essential to TB prevention and cure. Inadequate and erratic supply can contribute to the emergence of drug resistant strains of the disease. Reasons for the shortages include absolute resource constraints, increased demand for drugs in high TB/HIV settings, limited technical capacity, inefficient and ineffective procurement mechanisms, financial crises, and health system failures. Even where drugs are procured in adequate quantity and at reasonable cost, quality assurance may be absent. There has been progress in the last decade in TB drug supply, such as improved forecasting and distribution systems, the adoption of standardized treatment regimens and some significant price reductions in TB drugs in international markets. Annex D provides information from a recent WHO survey on TB drug supply in member states and information on prices obtained in public tenders for TB drugs. Ensuring uninterrupted supply of quality drugs with new financing and mechanisms could free human and financial resources to address management, service delivery, training, supervision, and other services essential for scaling up DOTS.

In 2000, WHO pursued a survey of National Tuberculosis Programmes in low and middle-income Member States on their TB drug supply experiences in 1999–2000. The objective was to inform various initiatives including DOTS expansion, the development of a global TB facility and the Global Alliance for TB Drug Development. A final report will be produced when several outstanding responses are translated and incorporated. Seventy-three countries have responded to date, representing more than 50% of the population in each region, and include 17 of the 22 high TB burden nations. The interim results are reported in Annex D and some of the key findings are summarized here:

a) Seventy-one per cent of respondents are responsible for calculation of drug needs and over 50% are involved in definition of drug budgets and therefore are well-prepared to develop drug need proposal should a facility be developed;

b) Over two-thirds of respondents are using fixed-dose combinations and 28% are using blister-packaged capsules or tablets;

c) A disturbingly high proportion of respondents were uncertain about financing for drugs needs in 2001—especially in Africa and Europe;

d) Of US$ 77 million in reported spending for TB drugs in 2000, 74% came from national sources (not all provided spending information);

e) Well under half of respondents are utilizing international tenders, and some are spending at least four times more than average prices received by international agencies procuring on the international market (drug price information is still being reviewed);

f) The number reporting national level drug stock-outs of single or multiple drugs in 1999 was also of concern, and especially high in Africa;

g) A surprisingly high proportion of countries (65%) reported that patients were charged for TB drugs—and this figure being 58% in Africa (the drug facility might offer a means to promote enforcement of free provision of drugs;

h) Only 61% of countries reported having access locally to drug quality laboratories, and no standards were offered to ensure that those reporting access can ensure the technical quality of product examination.

10. **Global interventions for global impact**—Controlling tuberculosis and preventing the spread of TB drug resistance are global public goods—no country alone can eliminate these threats. As follow-up to the Amsterdam Conference, the 20 highest TB burden countries developed DOTS expansion plans. These plans were reviewed and compiled into a Global DOTS Expansion Plan (GDEP), and then presented and discussed at a Cairo Meeting (November 2000) by Stop TB partners, donors and National TB Programme Directors from high-burden countries. The GDEP is built upon each of those national plans and the country specific partnerships that have been arranged to help achieve global DOTS targets by 2005.

The GDF is a crucial element in most of these plans. Without it, many countries will fail to reach their targets. Together, the Global Plan for DOTS expansion and the GDF have the potential to help reverse this epidemic and advance global public health by catalyzing expanded TB control efforts.

Overview

of the proposed Global TB Drug Facility (GDF)

Operating principles

11. **The GDF** will be independent, transparent, accountable, flexible, rapid, and responsive.
12. **The GDF** will aim to achieve substantial economies of scale through pooled demand forecasting, standardization of regimens, manufacturer pre-qualification, bulk purchasing, and reduced transaction costs.
13. **Drug supply** via the GDF will not support maintenance of non-DOTS efforts. Only governments and nongovernmental organizations (NGOs) that adhere to proven effective diagnostic, treatment, and disease monitoring practices encompassed in the DOTS strategy will be eligible to receive grants of TB drugs from the GDF.
14. **The GDF** will expect national DOTS expansion plans to achieve clear, measurable TB control results (people cured, lives saved). The country-specific results of GDF contributions and the associated TB control programme achievements will be published in an annual report and made available to the general public.
15. **Operations** will seek to minimize the burden placed on governments or other applicants in preparing GDF applications and complying with conditions of GDF grants. This is consistent with the expectation that the facilities would decrease current drug procurement inefficiencies, not add to them.
16. **Additionality:** all GDF assistance must represent new resources for TB control in countries receiving a GDF grant. The GDF will ensure that its assistance does not replace existing health care financing from national or international sources. Rather, the GDF will expect that any national or international resources or assistance made available through its grants be re-applied from drug procurement to other under-funded components of TB control activities. Further-more, the GDF will not duplicate or replace the mandates of existing organizations.
17. **Some governments** procure high-quality TB drugs through their own drug supply programmes or with financing provided by other donors. The GDF will offer assistance to these programmes in tendering and bulk purchasing, if this assistance is requested and appropriate.
18. **The GDF** will provide grants of drugs-in-kind with resources mobilized by and for the GDF. Responsiveness to the reasonable requests of high TB burden countries, or donors acting in their relationship with these countries, will be emphasized. This may mean that those governing the GDF will need to further consider the benefits and risks of opening windows to procure drugs for specific countries with resources other than those directly mobilized by the GDF. This may be difficult in the first years of GDF operations.
19. **The GDF** will extend access to high quality first-line* TB drugs for countries implementing or expanding effective DOTS treatment programmes. By increasing availability, quality assurance, efficient procurement and standardization, the GDF will address two significant obstacles to TB control—insufficient treatment of active TB patient and the spread of drug resistance.

* *First-line TB drugs are those used for the initial treatment of patients with tuberculosis. They are relatively inexpensive and with low toxicity. Second-line TB drugs are used for the treatment of drug-resistant disease. They are more expensive and their use requires more intensive clinical management.*

20. **The GDF** will catalyze national commitment and public support for rapid DOTS expansion. By providing significant assistance with drug supply, the GDF will provide incentive and assistance to policy-makers, and it will free up limited human and financial capacity in TB burdened countries for the difficult, patient work of DOTS expansion. If countries are to meet their TB control targets, governments will need to increase outlays for clinical services, training, supervision, monitoring, and other activities, because the number of patients to be treated will nearly triple. In the context of these burdens on developing country budgets for health, GDF assistance is obviously critical.

21. **The GDF** will catalyze increased national commitment for public funding of TB drugs procurement. Drug costs account for less than half of total treatment cost of treating TB patients. GDF assistance will be supplied with the intent of increasing capacity and public support in recipient countries for TB drug funding. Successful DOTS expansion will result in increased efficiency and cure rates, and decreased TB transmission. The GDF goal anticipates that healthier populations, lowered TB transmission and burden, and the consequent social and economic benefits will increase national resolve to assume responsibility for sustaining effective TB control. *See the section on "Benefits" as well as Annex C.*

22. **The GDF** will be time-limited, with an expected life of 10–15 years. As such, the GDF does not intend to create dependency or to reduce existing local drug procurement capacities. Rather, it will work with partners in the health and development community to ensure that there is ongoing support for the strengthening of overall drug procurement systems and quality assurance mechanisms in low-income nations. Creating a consolidated and identifiable market for TB drugs with transparent and competitive procurement may provide incentives for further development of industry over the medium term. Strategies will be identified to gradually transfer procurement responsibility back to participating nations prior to the GDF's closure.

    Sustainability generally signifies the ability to maintain resources (human, capital, financial, physical, environmental, etc.), activities and results for a given objective over the long term. In the international development arena, it is often understood to mean that countries receiving external assistance should not become or remain dependent on external resource flows. Moreover, recipients should begin to assume the financial burden long before external assistance ends.

    Sustainability depends on the premise that a local sense of ownership and commitment must exist to ensure the maintenance of an activity. Various mechanisms have been utilized to encourage donor-recipient partnerships and shared ownership in projects. These include cost-sharing mechanisms, capacity building, phase-out plans, and revenue generating mechanisms as well as participation and dialogue of all stakeholders in project planning and evaluation.

23. **Strengthening** of national procurement and supply capacity should continue to be aided by other donors and governments themselves, in the context of Essential Drug Programmes (EDPs), with the long-term view of integrating responsibility for TB drugs once incidence and prevalence have been reduced to a fraction of present levels. The GDF could help facilitate that support and offer lessons learned in drug supply management.

24. **The GDF** will ensure independent appraisal and monitoring of treatment standards, drug supply management, and verifiable outcome indicators of patients treated and cured. The results of this monitoring will inform decisions on maintenance or renewal of GDF support.

Governance and management

25. **GDF governance and management principles**—The GDF management team and contractors will follow the directives of stakeholders. The governance structure will build on existing mechanisms in keeping with its overarching principles. The Facility would strive for the best features of private business operations as well as build on the strengths of public and community interventions. It would be responsive to clients, have an effective, executive office, and forge and

implement operating partnerships with others based on capacity and needs. A lean management team would rely maximally on contractors to ensure effective financial, procurement, legal, and monitoring functions.

26. **GDF governance and management options**—A planning meeting for the GDF was held in November 2000 as part of the Cairo Meeting on DOTS Expansion. At this meeting a core technical group (CTG) for the GDF was created. As one of its terms of reference this group was asked to create an options paper on governance—a report outlining the various governance options for the GDF with their relative strengths and weaknesses.

In the report, the CTG recommends that the GDF have an independent Board with clear authority and responsibility for GDF management, resources and mission. The GDF management should be completely dedicated to GDF functions, and be led by a senior, experienced professional who will report to the GDF Board. The GDF should be housed within an STB partner organization, and its activities should be funded through a dedicated trust fund. Subject to satisfactory negotiation of a support agreement, the CTG recommended that this be the Stop TB Secretariat/WHO for an initial trial period of, perhaps, two years. The GDF Board will need to sign a clear and specific agreement with any GDF host organization. This agreement should specify arrangements the host will make so that the GDF can fulfill its functions and do so rapidly, flexibly and efficiently, etc. The GDF Board should formally evaluate, at specified intervals, whether the GDF's performance is enhanced or impeded by the host organization. The Board has the responsibility to move the GDF and its assets to a new host, if necessary to achieve the GDF objectives.

The report was presented to the Stop TB Coordinating Board in February 2001 and the governance and management recommendations were endorsed at this time. The full report is presented in Annex E.

Operations

27. **Application process**—Written application for in-kind grant assistance for countries or nongovernmental organizations* would include the following elements:

- A brief report on current TB control programme and service organizations, financing, technical assistance, progress in DOTS establishment/extension, and performance as defined and measured by international standards and indicators. These would include: government support and commitment, proven diagnostic capacities, treatment capacities, arrangements for treatment observation, as well as management systems for case recording, reporting and monitoring.
- A monitorable strategic action plan (including detailed first year work plan) for scale-up of the existing programme to meet DOTS targets over the course of the next five years via extension of DOTS and health infrastructure strengthening (as required). This would also include a financial plan, incorporating national and international contributions, and accompanying letters confirming technical and financial partners' commitment to work with the government for DOTS Expansion. It should also include plans for fast tracking of drug registration and waiver of registration fees on GDF drug donations, and for exempting GDF drug donations from all tariffs, duties and taxes.
- The strategic plan should include detailed procedures for importation and registration of GDF donated drugs. GDF drugs are to be registered and should, in most cases, comply with legal and regulatory requirements administered by the local National Regulatory Authority (NRA). The GDF will work with its suppliers to develop and supply a common dossier of product information that would include, for example, the WHO Certificate for Pharmaceutical Products Moving in

* *Specific criteria for consideration of applications from nongovernmental organizations active in TB control will be established based on advice from countries and other stakeholders.*

International Commerce, and other information commonly required for drug registration. This dossier on GDF drugs will be acceptable to Regulatory Authorities in many recipient countries. Where the dossier does not satisfy all local regulatory requirements, applicants must demonstrate that they have arranged through their National Regulatory Authorities for expeditious exemption for GDF donations from the unmet requirements. The GDF will work thereafter with the NRA to amend its dossier to include national requirements. In that work, pursuant to its interest in harmonization of drug registration requirements, the GDF will encourage the development of common and recognized regional standards.

- The plan should likewise provide evidence that mutually satisfactory arrangements have been negotiated between the Ministry of Health and the appropriate tax and/or customs authorities to fulfil the government's responsibility for customs duties and fees. These arrangements should also provide for expedited clearance through customs for GDF drugs at the port of entry and immediate forwarding.
- A letter from government confirming its commitment to DOTS expansion and to the defined strategic plan.

28. **In general,** written agreement to the following will be required from the participating government:
    - Regular and independent assessments of TB programme performance, including TB drug management, by an independent technical agency, with a completed assessment provided to the GDF.
    - Any required revision of treatment guidelines to be consistent with standardized and WHO-recommended drug regimens.
    - All drugs supplied by the GDF will be used only:
        1. For treatment of TB patients,
        2. Free of costs to patients,
        3. In programmes following national guidelines for DOTS implementation.
    - All TB drugs procured by the government independently of the GDF, and used in conjunction with GDF supplied drugs, must be of acceptable quality, as demonstrated by either:
      a) Certification of compliance with Good Manufacturing Practice (GMP), issued by a competent regulatory authority,
      b) Certification of quality following testing by an independent quality control laboratory.
    - Due diligence of government in the onward distribution of GDF-financed drugs to the treatment points, and in strengthening weak links in the national drug management, quality assurance and distribution systems, if necessary with international technical assistance.
    - The government will take full responsibility for any import duties and taxes levied on drugs supplied by the GDF.
    - Government will keep open any current budget line dedicated to TB drugs so that drugs can be procured to manage the few patients who require variation of the standardized regimens, emergency needs could be purchased should a short-fall occur for any reason, and ensure that budget can be swiftly allocated when the recipient begins to assume additional responsibility for drug procurement financing.

29. **The process** of application review and selection of recipients will be determined based on stakeholder selection of the governance and management model. The review process will be transparent and based on the expert opinion of TB, procurement, and health development experts.

30. **Drawing** on existing expertise and capacity for appraisal and monitoring, such as exists within and outside the Stop TB partnership (for example, partners involved in country and global expansion plans), the GDF would arrange for application review and programme appraisal visits (unless a recent tuberculosis programme review(s) exists that follows international standards of WHO or the IUATLD). This would be achieved either via the technical reviewers' funded mandates or under contract with the Facility.

31. **Prioritization**—If resources are limited the GDF would have to prioritize based on clearly defined criteria that must be determined by stakeholders. These might relate to both income level, urgency of epidemiological situation or drug supply situation, and demonstrated performance to date with DOTS implementation. Other criteria may also be identified.

32. **Grant agreements**—GDF in-kind grants would be provided based on carefully negotiated grant agreements between the GDF and participating governments and NGOs. The grant agreement would specify the objectives, standards, dimensions, reporting and monitoring arrangements, and other salient operating details of the TB control programme to which the GDF commits its support. The grant agreement would outline provision of the agreed drug supply in annual tranches, subject to the programme adhering to the agreed performance standards and meeting the agreed scale-up objectives. The provision of drugs would normally be authorized by the GDF on the basis of annual performance reports to be submitted by the participating pro-gramme and forecasted need. As needed, these performance reports would be supplemented by field reviews arranged by the GDF and carried out by its partners or consultants. Grant agreements will likewise govern GDF procurement assistance, even when financing is supplied by the recipient country.

33. **Annual review and grant renewal**—In order to qualify for continued support, countries will need to demonstrate progress towards DOTS targets. This process will include independent monitoring of programme performance as well as compliance with terms of the grant agreement. Countries that do not adhere to the agreed plan would be provided with the GDF support for one probationary year based on a remedial action plan to be agreed with the GDF. GDF will call upon its Stop TB partners to assist the programme in taking the agreed remedial action. If the government failed to implement the remedial action plan, GDF assistance would be suspended.

Procurement

34. **Procurement agency**—Drugs to be supplied as grants-in-kind would be purchased by GDF through international competitive bidding among pharmaceutical manufacturers who meet pre-qualification standards on experience, quality, and capacity. Procurement would be contracted, on a competitive basis, to one or more public or private professional procurement agencies with periodic re-competition. The agent(s) would undertake all tender management and contracting, monitoring of contractors, and communications with recipients. It is expected that the procurement agent(s) would receive a set administrative fee.

35. **Standardization of treatment regimens**—In order to control cost and enhance administrative efficiency and the quality of patient care, the GDF will reduce to the minimum possible the range of products to be purchased. Accordingly it will only supply WHO-recommended regimens. The GDF will supply not only individual or fixed-dose combination drugs but also aim to supply the full treatment packages needed for patients, through the use of blister packaging and "patient-wise boxes". This will help ensure that no patient is initiated on treatment without a full stock of drugs for the full course of therapy, and assist in pharmaceutical management and proper dosing. In addition, these steps should improve the ease of patient care for providers and confidence of the patient in the quality of care provided. Initially, the GDF would be expected to procure double-fixed dose combinations, and consider procurement of four-drug combinations as more data becomes available on the generalized application of this relatively new formulation.

36. **Technical specifications**—Technical specifications would be based on the best available current experience from WHO, UNICEF, the World Bank, and other agencies. Significant advances have been made in the past five years in refining technical specifications for tuberculosis drugs. Such specifications include clear terms regarding raw product, product formulation, presentation, packaging and labeling. Given that all first-line tuberculosis drugs are off-patent, generic-based

specifications will be utilized. The further harmonization of treatment regimens as well as ongoing technical assistance via Stop TB partners will also improve the accuracy of drug need forecasting, which is essential for effective operation of the GDF.

37. **Pre-qualification**—Pre-qualification of suppliers will be essential to the viability, efficiency and effectiveness of the GDF. Pre-qualification is especially important for the procurement of fixed dose combinations of TB drugs, given the variable bio-availability of these products. The process of pre-qualification will be contracted out under the direction of the GDF. Economies of scale, and the likely regularity of a supply schedule given direct financing from the GDF, should enable a routine, transparent, and professional system of pre-qualification. Independent current Good Manufacturing Practices (GMP) inspections would be done as part of the pre-qualification process as well as during the procurement process.

38. **Tendering and requisitioning**—The GDF would offer economies of scale via prequalification, and through bulk purchasing on a regional or global basis. The quantities to be procured would have to be established on the basis of GDF and recipients' forecasts of likely drawdowns under the active grant agreements. International competitive bidding for rate-based and multi-year-contracts with suppliers would be utilized. However, the GDF will also engage in regional bidding, where circumstances allow it, and where it would further the GDF goal of improving national and regional drug procurement and supply capacity There are few suppliers today that produce all required TB drugs and provide necessary packaging. Hence, it is likely that GDF will contract with multiple manufacturers, necessitating significant coordination to ensure timely supply and quality control at each stage of the process. The contracts will assign liability in the event of quality deficiencies, delivery delays or other problems. Manufacturers will be responsible for maintaining an inventory and supplying upon authorization. Responsibility for provision of emergency drug stocks will also be assigned. Procurement documents would allow financial penalties as well as removal of suppliers from the pre-qualified list ("white list") in the event of supply failure or quality control problems on two or more batches of drugs supplied. The GDF will establish efficient electronic systems for requisitioning and monitoring of supply shipments, and general communications with suppliers and recipients.

39. **Registration**—GDF donated drugs should, under normal circumstances, be registered in the recipient country, but should not be delayed in the registration process. As noted above (Paragraph 27), a description of procedures to expedite registration through the National Registration Authority (NRA) are to be included in the grant application. The application should acknowledge that GDF donated drugs are to be exempt from registration charges and fees.

40. **Transport,** insurance, pre-shipment inspection and delivery. The procurement agent(s) will be responsible for arranging separate contracts for pre-shipment inspection, freight forwarding, and insurance. The grantee generally will be responsible for customs clearance and delivery to central government or agency medical stores or supply depots. The responsibility of the GDF and its procurement will end at the port of entry and be assumed by the recipient country. GDF procurement agent(s) will not be responsible for in-country drug delivery to TB treatment service locations or in-country supply monitoring.

41. **Passage of customs**—As noted above, the GDF will require recipient governments to waive import duties and tariffs and to provide expedited passage through customs.

Monitoring and technical assistance

42. **The GDF** will rely on the expertise of the World Health Organization and its Stop TB partners for technical recommendations, quality evaluation, and programme review and monitoring.

43. **Facilitating** improvement of in-country distribution—The GDF will call upon its Stop TB partners to appraise and monitor in-country distribution of GDF donated drugs and their application in DOTS programmes. The GDF will maintain a small contingency fund to resolve unforseen contingencies that threaten the survival of GDF drugs. *See Paragraph 50.*

Financial requirements

44. **Drugs**—The average estimated cost of GDF drug procurement will be US$ 47 million annually over the next five years. *Detailed financial projections can be found in Annex A.*

45. **Operating costs**—The GDF's budget will have to also provide for operating, administrative and contracting costs. Preliminary estimates for these costs are US$ 6 million.

46. **Total GDF resource** needs in the first five years would then be US$ 235 million (using average prices). The range is roughly US$150–US$ 300 million, depending on the price of drugs, and the operational costs. For example, in order to reach the 2007 targets, drug prices (including loss, spoilage and freight) could be as low as US$ 115 million per year or as high as US$ 272 million. *See Annex A for a cost breakdown and estimates.*

Summary risk analysis

Establishment of the GDF is a complex and bold international initiative. Important risks to the attainment of its goals and objectives need to be clearly identified and managed.

47. **Funding risks**—In most high-burden countries, establishing sustainable TB control systems will be a 15–20-year undertaking. Success requires a sustained international financial commitment to the supply of grant-financed drugs. With current preferences of both private and public donors for three to five year pledges, this means that a 15–20-year commitment will have to be financed in segments. This funding insecurity holds the risk of funding shortages that call for the up-front establishment of transparent prioritization criteria and cost-sharing arrangements that are considered earlier in this prospectus. The defined agreements by recipient governments to their continued programme ownership and their contingent funding responsibilities must be enforced.

48. **A funding risk** will also result from the proclivity of donors to "tie" or "earmark" their funds to pursue geo-political, development, human rights, or ideological objectives in addition to the overall objectives of the GDF and TB control in general. Such "conditioned" funding should be discouraged because it would create serious problems for the GDF's pooled procurement and for the efficient overall management of the Facility.

49. **Procurement risks**—Bulk procurement based on pooled demand forecasting is fundamental for efficient and effective operation of the GDF. It is, however, likely that this approach to the procurement of drugs will be opposed by some governments who would otherwise be eager to avail themselves of financing for their own procurement of drugs. This opposition will reflect many different concerns, such as by-passing national procurement processes and agencies, inability to apply national procurement preferences, and displacement of expensive sole-sourcing that may be lucrative for local economies or individuals. As a result, acceptance of the pooled procurement model proposed by the GDF will be challenged by many governments and could result in protracted bargaining and divisive deal-making, unless GDF's donors and stakeholders establish and uphold pooled procurement up-front as a basic operating principle as defined in this document.

50. **Supply and distribution risks**—Under GDF contracts, drugs will generally only be delivered to a limited number of points in the recipient country, and recipient governments will be responsible for drug distribution thereafter. Negotiations between GDF and the applicants will provide the best occasion to anticipate possible distribution risks, to arrange assistance and to make contingency plans for dealing with unanticipated circumstances. There are known weaknesses in many national drug distribution systems, and these should be accounted for in the grant negotiations and planning by the GDF and the applicant government, and assistance should be sought beforehand from Stop TB partner organizations to assure effective distribution of donated drugs. In exceptional cases, however, unanticipated circumstances may disrupt distribution and threaten the usefulness donated drugs after arrival. In these instances, the GDF will first appeal to an appropriate Stop TB partner to help alleviate the situation. If no such help is available, GDF management may find it necessary to contract with a third party for technical assistance or supplementary distribution. GDF will establish a small contingency fund to finance such extraordinary measures. But use of this fund is anticipated only when necessary to safeguard the value of donated drugs.

51. **Programme risks**—The proposal to establish a GDF reflects the expectation that an internationally financed free supply of quality TB drugs will be able to catalyze increased government commitment to TB control and more decisive actions by governments in support of their national TB control programmes. Realism, however, requires allowance for the fact that in many cases the incentives provided by free drugs will not be sufficient to induce the required government response on programme standards and coverage, and therefore will have to be further reinforced by international programme reviews, high-level policy dialogue, as well as targeted technical and capacity-building assistance. There will also be cases in which fundamental deficiencies in the national policy framework and governance will preclude the operation of a viable national TB control programme, and may mean that the GDF supports selected NGOs operating independently. These programme risks will have to be managed by the GDF, adhering firmly and professionally to the principle that its support can only be extended to national and NGO programmes that set and meet monitorable IUATLD/WHO programme performance standards; and by cooperative agreements with qualified STB partners which commit these partners to provide international assistance to governments that show the will, but as yet lack the capacity to design and operate a viable national TB programme.

52. **Governance risks**—Containment of programme risks and management of the other operating risks points to three distinct governance risks:

- The first of these risks is clearly beyond GDF's control, and reflects the fact that for GDF to be effective, it depends upon a minimum quality of governance in the recipient country.
- The second reflects the fact that GDF is dependent on effective coordination and management of STB partners in assisting high TB burden countries via resource mobilization, programme reviews, technical support, operational research, and national capacity-building. GDF donors and other stakeholders can actively contribute to ensuring establishment of an effective and transparent governance structure.
- Finally, concerns with the successful management of programme and procurement risks provides the strongest argument for the establishment of GDF under a governance and structure that ensures that the GDF will be run by an independent, professional management that can say "no" to the pressures that constituencies and diverse interest groups bring to bear on procurement and deployment of GDF drugs.

Time-line

53. **The Facility** will establish its operations in a phased manner, responding to grant requests, developing operating practices and partnerships, and building its experience in operations. Credibility and reputation of the Facility will be established during this process. Expansion will rely on fund availability and experience as well as country interest and capacity. In an optimal scenario, five-year financing of US$ 250 million would be assured by the end of the GDF's first year. With a lower level of initial investment, countries and/or patients may have to be prioritized based on the criteria mentioned above.

54. **This Prospectus** is intended to be widely shared for views and comments, particularly from developing countries with high TB burdens. This consultation—with country representatives, WHO TB staff and Stop TB Partners—began at the Cairo Working Group on DOTS Expansion in November 2000 and continued at the meeting of the Stop TB Coordinating Board in Bellagio, Italy in February 2001, which was hosted by the Rockefeller Foundation. The Stop TB Initiative Secretariat will continue to provide interim management of the GDF, with assistance from its partners, until the independent management of the GDF is established.

55. **The GDF** will depend significantly on assistance from Stop TB partners. But uncertainties on the timing and scope of GDF operations present difficulties for Stop TB organizations in budgets and operational plans for the next several years. GDF management will work to ensure that Stop TB partners are as fully informed as possible of GDF plans and support needs, and will request that partner organizations make plans to support the reporting, monitoring and technical advice for the GDF.

56. **The GDF** will begin a pilot programme in the first quarter of 2001, and will begin at that time to recruit support for its permanent funding. Applications for pilot programme grants will be reviewed in the second quarter of 2001, and, ideally, drug supply drugs would begin in the fourth quarter of 2001.

Benefits

57. **The GDF** will facilitate the rapid expansion of DOTS in many countries and contribute to worldwide efforts to reach WHO's global targets for TB control by 2005.

58. **Approximately** 10 million patients will be served during the first five years of operation and 45 million would benefit over a ten-year period.

59. **The Facility** will also serve as a possible model for improved management of other diseases.

60. **Strengthened** TB treatment services can increase the credibility and functioning of the primary care system, drawing more patients into health care facilities so that they also benefit from immunization, other preventive or curative services, and other public health initiatives.

61. **One of the advantages** of TB control programmes is the robust system for monitoring treatment outcomes. Maintaining the system, which has been developed and implemented over many years through the expertise of IUATLD/KNCV/WHO and national governments, will be a firm requirement of all grant recipients. Reporting to this system will allow an accounting of the exact numbers of patients treated, patients cured, and programme effectiveness. It also provides reliable estimates of the number of lives saved. The information will be reported at least annually to the Board of Directors as well as the global public.

62. **By reaching** and maintaining effective tuberculosis control, including achievement of global targets, the following benefits would be accrued by 2020:

    - 25 million TB deaths averted;
    - 50 million TB cases prevented;
    - Emergence of drug resistance prevented;
    - TB prevalence reduced by more than 75%;
    - TB incidence reduced by 50%.

63. **In addition,** even if the GDF were to cease operating after 10–15 years, it would have contributed to sustained improvements in global TB control capacity including:

    - Large numbers of trained staff;
    - Increased national and local budgets for TB control;
    - Improved diagnostic capacity and practices;
    - Improved treatment practices;
    - Sustainable monitoring systems, which track the outcome of every patient treated, and which are a condition of GDF support;
    - Established practices for ongoing supervision and monitoring;
    - Rationalized procurement mechanisms, so that drug purchasing would be more cost-effective;
    - Models for prequalification and improved quality of TB drugs worldwide; and
    - A successful model of global commitment and cooperation to confront a global epidemic.

Annex A

Financial projections related to DOTS expansion

Financial requirements of the GDF

The cost of the GDF will be directly related to three key elements: the price of drugs, the number of cases treated and the operational costs of the GDF.

- ***Price of drugs***

The cost of drugs would be US$ 160 million with additional costs for loss, spoilage and freight charges being US$ 44 million, or a total drug costs of US$ 204 million for the five-year period beginning in 2001. Drug costs were determined based on prices from procurements realized in a wide number of countries for the years 1999 and 2000: cost of drugs for SS+ cases were US$ 15 with SS– regimen costs US$ 11 and the costs of re-treatment cases at US$ 25. Depending on the GDF's success in negotiating these average prices, the drug costs could be as low as US$ 90 million (with additional costs for loss, spoilage, freight of and US$ 25 million) or as high as US$ 213 million, plus additional costs of US$ 59 million if prices are in the high range.

- ***Cases treated***

The cases treated with drugs from GDF comprise new SS+ DOTS cases, SS– cases treated and SS+ retreatment cases. Table A presents the number of SS+ cases treated each year to reach the 2007 targets: 5 891 000 by the end of year 5. The number of SS– and retreatment cases using drugs from GDF are shown and account for an additional 5 730 000 cases treated.

If a more modest approach in cases treated by GDF drugs is taken, the total SS+ cases treated in five years time is 3 682 000 *(see Table B)*. The medium prices would require US$ 98.9 for drugs to treat the 7.2 million SS+, SS– and retreatment cases over five years.

- ***Operating cost***

In addition to the costs determined by the drug costs and number of cases treated there will be operational costs for the GDF. These will be costs for GDF staff, operation of the board, and contracting costs. It has been assumed that there will be six professional staff and six support staff for the GDF. The costs of operations for these staff and contracting function will be nearly US$ 33 million for 2001–2005. A more modest plan of four professional staff and five support staff would reduce these costs to US$ 27.5 million.

- ***Total Resources***

With an investment of US$ 235 million over five years, the GDF will be able to be treating 50% of DOTS cases by the end of year 2005. This assumes a start up of US$ 30 million pledged GDF contributions for year 1. The GDF would raise sufficient funds to cover its costs each year and would not accumulate a large cash balance. What cash is on hand would be invested to net a small level of interest income.

Table A: Scenario 1—Treating 600 000 SS+ DOTS cases in year 1 and reaching targets by 2007

	2001	2002	2003	2004	2005	total cases 2001-2005
Total new SS+ DOTS cases treated with GDF support	600 000	840 000	1 134 000	1 474 000	1 843 000	5 891 000
Total new SS- cases treated with GDF support	578 000	783 000	996 000	1 315 000	1 470 000	5 142 000
Total retreatment cases treated with GDF support	60 000	84 000	113 000	147 000	184 000	588 000
Total cases treated with GDF support	1 238 000	1 707 000	2 243 000	2 936 000	3 497 000	11 621 000
Drug costs, medium drug price *(in US$ millions)*	16.9	23.3	30.8	40.3	48.4	159.6
Drug costs, low drug price *(in US$ millions)*	9.4	13.0	17.2	22.5	27.1	89.3
Drug costs, high drug price *(in US$ millions)*	22.5	31.1	41.1	53.8	64.5	213.0

Notes: Cases rounded to nearest 1 000 and drug costs rounded to US$ 100 000
Drug costs exclude additional costs of loss, spoilage, insurance and freight

Table B: Scenario 2—More modest in treating 375 000 SS+ DOTS cases in year 1

	2001	2002	2003	2004	2005	total cases 2001-2005
Total new SS+ DOTS cases treated with GDF support	375 000	525 000	709 000	921 000	1 152 000	3 682 000
Total new SS- cases treated with GDF support	257 000	482 000	664 000	809 000	919 000	3 130 000
Total retreatment cases treated with GDF support	37 000	52 000	71 000	92 000	115 000	368 000
Total cases treated with GDF support	669 000	1 059 000	1 444 000	1 822 000	2 186 000	7 180 000
Drug costs, medium drug price *(in US$ millions)*	9.4	14.5	19.7	25.0	30.3	98.9
Drug costs, low drug price *(in US$ millions)*	5.3	8.1	11.0	14.0	16.9	55.3
Drug costs, high drug price *(in US$ millions)*	12.5	19.4	26.3	33.4	40.3	131.9

Notes: Cases rounded to nearest 1 000 and drug costs rounded to US$ 100 000
Drug costs exclude additional costs of loss, spoilage, insurance and freight

Annex B

Risk analysis

This analysis informed the development of the prospectus. The goal of the GDF is to:

- Ensure uninterrupted access to quality TB drugs for DOTS implementation;
- Catalyze rapid DOTS expansion to achieve global TB cure and coverage targets;
- To stimulate political and popular support in countries throughout the world for public funding of TB drug supplies; and
- Lay the foundation for sustainable global TB control and eventual elimination.

This analysis examines the most important risks to the attainment of this goal under six headings:

I. Funding risks

II. Procurement risks

III. Supply and distribution risks

IV. Programme risks

V. Relationship risks

VI. Governance risks

Steps to contain and manage these risks are also discussed.

I. Funding risks

The epidemiology of TB and the experience with TB control programmes in industrialized countries suggests that the attainment of TB control i.e. the attainment of a declining rate of infection, requires the operation of a high quality control programme for at least 15 years. In cases where TB control needs to be established in the face of a dual epidemic of TB and HIV/AIDS, it is projected that the effort may have to be extended for 20-plus years. Thus pursuit of the GDF objective requires in most countries a long-term commitment to the international funding of TB drugs in order to achieve sustainable results. With the current preference of both public and private donors for three to five year pledges with, at the most, tenuous commitment to renewals, this results in a funding mismatch that must be given explicit attention in the design and operation of the GDF.

Most importantly, the funding mismatch calls for cost-sharing agreements with recipient countries that serve to remind the government of its overall ownership of the national TB control programme, and of its contingent funding responsibilities in case of shortfalls in GDF-funded drug supplies.

The funding risks also require up-front establishment of rationing criteria that would be applied in the case of funding shortfalls. Experience with the deployment of limited pools of concessional or grant funding suggests that these rationing criteria need to be simple and transparent so as to obviate divisive "judgement calls" by GDF Board or Management.

Another form of "funding risks" would arise if donors were to "tie" or "earmark" their contributions by specifying that their funds can only be used in selected priority countries, or in support of countries meeting certain criteria in the conduct of their national affairs. Such restrictions would create serious problems for pooled procurement of TB drugs and for efficient overall management and use of GDF funding. GDF requires pooled funding for efficient operation, "conditioned" contributions that require segregation of funds and/or separate donor approval before they can be used, should be rejected from the outset.

II. Procurement risks

Pooled procurement will be an important tool for the GDF in its efficient and cost effective supply of quality TB drugs. It is likely, however, that the GDF's pooled procurement will be opposed by many applicant governments eager to avail themselves of GDF grants. These governments will be concerned that GDF pooled procurement will threaten the survival of local drug suppliers that are regionally competitive producers of TB drugs, or that GDF supply will threaten uncompetitive or sole source licensees.

However, the GDF is not solely concerned with supplying TB drugs at the lowest possible price. A clear GDF goal is to develop political and popular support for TB control and to nurture and strengthen national TB control programmes. Hence to destroy competitive local manufactures of quality TB drugs would be to undermine a fundamental goal of the GDF.

As a result, the GDF expects to procure drugs through regional, as well as international, procurement mechanisms, often pooled but not exclusively. The GDF will in no instance compromise on its mission of supplying drugs of assured, consistent quality, and of standardizing its supply, over time, as much as possible. However, the GDF will be cognisant of the impact its purchases will have on local manufacturers that supply quality drugs at regionally competitive prices. Wherever possible, the GDF will attempt to encourage and support these suppliers in procuring drugs for regional grants, and will expect these suppliers to work with the GDF to meet its standards and requirements.

But the GDF will not make similar accommodations for non-competitive suppliers, for suppliers of inferior or inconsistent quality, or who operate under exclusive contracts. The GDF's obligations to National TB programmes, to TB patients and to its donors preclude any such compromises on the quality of its drugs, or on the achievement of the GDF's broader mission.

III. Supply and distribution risks

Under GDF contracts, drugs will generally only be delivered to a limited number of points in the recipient country, and recipient governments will be responsible for drug distribution thereafter. Negotiations between GDF and the applicants will provide the best occasion to anticipate possible distribution risks, to arrange assistance and to make contingency plans for dealing with unanticipated circumstances. There are known weaknesses in many national drug distribution systems, and these should be accounted for in the grant negotiations and planning by the GDF and the applicant government, and assistance should be sought beforehand from Stop TB partner organizations to assure effective distribution of donated drugs. In exceptional circumstances, however, unanticipated circumstances may disrupt distribution and threaten the usefulness donated drugs after arrival. In these instances, the GDF will first appeal to an appropriate Stop TB partner to help alleviate the situation. If no such help is available, GDF management may find it necessary to contract with a third party for technical assistance or supplementary distribution. GDF will establish a small contingency fund to finance such extraordinary measures. But use of this fund is anticipated only when necessary to safeguard the value of donated drugs.

IV. Relationship risks

TB drug suppliers may view GDF's pursuit of pooled procurement as a threatening attempt to establish a monopoly in the procurement of TB drugs. An early commitment by GDF to the use of multiple procurement agents could allay these apprehensions.

Development agencies may see the GDF as crowding out their drug financing. In such cases it will be essential for GDF to work with these parties to ensure that their displaced funds are used to improve overall programme performance and accelerate programme scale-up. Overall, a sharply focussed GDF that, as a matter of policy, leaves capacity-building tasks to partners and co-financiers will minimize these relationship problems.

Finally, agencies which undertake significant amounts of drug procurement may see the GDF as a threat; transparent selection of one or more of these public or private procurement agencies to support GDF's pooled procurement will minimize this relationship risk.

V. Governance risks

Effective and efficient management of the GDF will require a governance and structure that promotes and ensures independence, agility, transparency, and the courage and competence to employ innovative participatory approaches and partnerships.

For the GDF to attain its objectives, the governance and structures that are considered as viable options most likely will have to be "customized" options in order to meet these requirements. Existing bureaucratic structures, when drafted into trust fund administration, have generally performed poorly when measured by the above-stated requirements. It is thus important to shape governance that meets the specific needs of the GDF, rather than to press existing structures into sub-optimal service.

Another risk is that, due to administrative complexity and inadequate marketing of the GDF, there may be limited interest expressed and applications submitted to the Facility.

Conclusion

The proposal to establish a GDF reflects the firm expectation that an internationally financed, free supply of TB drugs will be able to catalyze urgently needed improvements in national TB control efforts, despite the well-known obstacles which deficiencies in policy frameworks and governance are presenting in many countries to the widening and deepening of priority public health programmes. In order to validate this expectation, the risks identified in this analysis will have to be contained and managed with skill and determination, and the governance of GDF will have to be structured and staffed to meet this challenge.

The risks reviewed above are real but manageable. They must therefore not be allowed to detract from the fact that the most serious risk to the attainment of improved global TB control is that the GDF will not be established, the global TB epidemic will continue to grow, drug resistance will continue to spread, and the international community will have missed a critical opportunity to Stop TB before it is too late.

Annex C

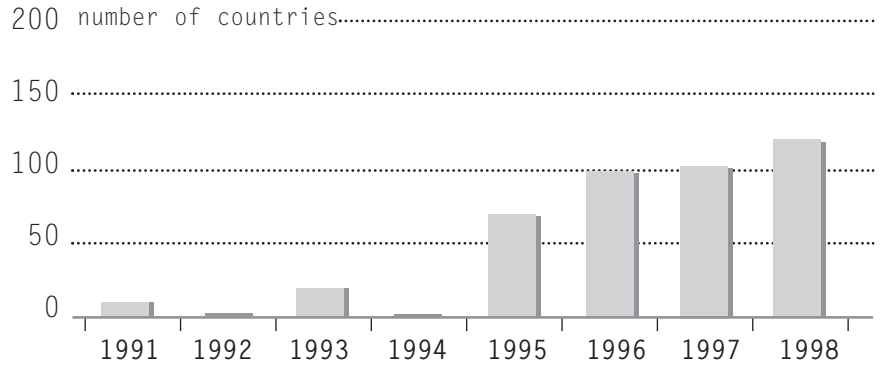
Status of DOTS expansion and projected impact of meeting global targets

I. Current DOTS progress[1]

DOTS is the internationally recommended strategy for TB control and ensures high cure rates in people with TB[2]. The number of countries adopting the DOTS strategy increased from 10 in 1991 to 119 in 1998 and included the 22 high-burden countries (Fig. 2). In 1998, 43% of the global population had access to DOTS, double the fraction reported in 1995. The total number of cases notified to WHO for 1998 was 45% of the estimated global total and the total number of smear positive cases was 40% of the estimated total. The number of new smear positive TB cases detected by DOTS was 21% of estimated global incidence.

Overall, DOTS programmes have demonstrated that they can achieve high treatment success rates. The average treatment success rate in 1998 was 78% globally and 82% in the high-burden countries, a little below the 85 % target. This compares with 45% in programmes not implementing DOTS[3].

Figure 2: Total number of countries that have adopted DOTS, 1991-1998[4]



II. DOTS forecast

WHO has developed an age-structured mathematical model to forecast the epidemiological consequences of reaching global targets for DOTS in years 2000, 2010 and 2020[5]. The model uses data on the natural history of TB and from the history of successful TB control in industrialized countries. The inferences from the model are that if WHO targets are reached by 2010, this would prevent 23% or 48 million cases of TB by 2020. By corollary, without greater effort to control tuberculosis, the annual incidence of the disease will increase by 41% between 1998 and 2020 (from 7.4 million to 10.6 million cases per year).

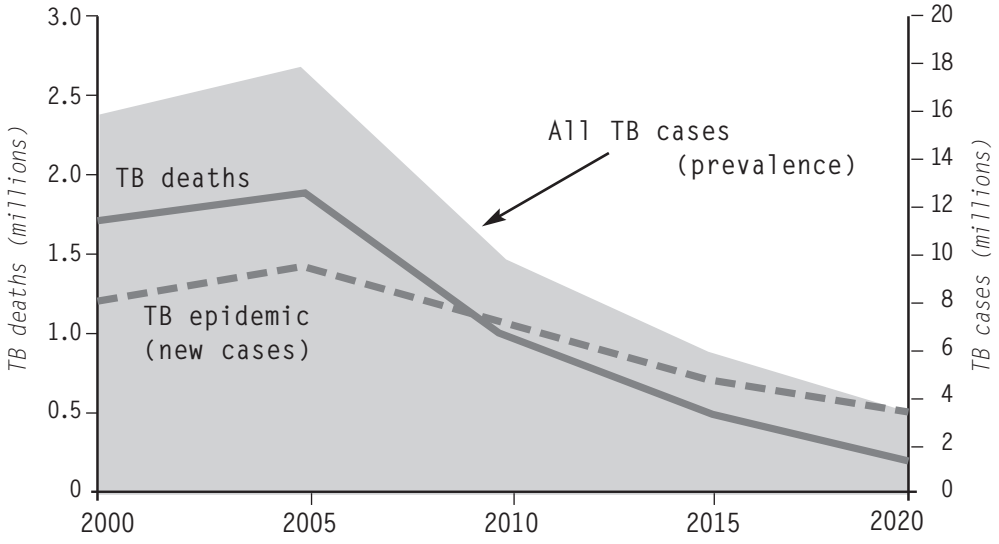
Based on current treatment rates for DOTS expansion, the global targets for TB control will be achieved only in 2012[6] The GDF, however, will facilitate the expansion of DOTS in many countries and will enable countries to reach the global targets earlier, by 2005. Approximately 45 million TB patients

would benefit from the GDF over a ten-year period. By reaching and maintaining effective tuberculosis control by 2005, the following benefits would be accrued by 2020[7]:

- 25 million TB deaths averted,
- 50 million TB cases prevented,
- emergence of drug resistance prevented,
- TB prevalence reduced by more than 75%,
- the TB incidence reduced by 50%.

The model below uses these figures to show graphically the potential impact of the GDF on TB deaths and cases if the global targets are achieved by 2005[8].

Figure 3: The impact of DOTS expansion on TB epidemiology after targets are met in 2005



III. DOTS progress in the high-burden countries

TB control in the high-burden countries improved between 1997 and 1998, as indicated by higher DOTS coverage, better case detection, and a higher treatment success rates[9]. This is explained primarily by improvements in case detection and cure rates in Bangladesh, China, India, Philippines and South Africa. Based on 1998 data, high-burden countries can be ranked in terms of DOTS implementation as follows:

Group 1: (treatment success: 70 %, case detection: 50%)—Cambodia, Peru, United Republic of Tanzania, Viet Nam.

Group 2: (treatment success: 70 %, case detection: 10–49%)—Bangladesh, China, Ethiopia, Myanmar, Nigeria, Philippines, South Africa.

Group 3: (treatment success: 70 %, case detection: < 10 %)—India.

Group 4: (treatment success: < 70 %)—Afghanistan, DR Congo, Indonesia, Kenya, Pakistan, Russian Federation, Thailand, Uganda.

Group 5: (non DOTS or incomplete data)—Brazil, Zimbabwe.

The top performing high-burden countries in 1998 come from all corners of the globe: Cambodia, Peru, United Republic of Tanzania, and Viet Nam[10]. Little progress. however, was made in Indonesia,

Pakistan, Russian Federation, and Uganda among others. Reasons for this lack of progress are varied, but can be summarized under seven headings: financial constraints, human resource constraints, inadequate drug supply, insufficient political commitment, lack of coordination, weak health services infrastructure, and HIV. *A summary of these key constraints by country is provided in Table C.*

IV. Key constraints to DOTS

- ***Financial constraints***

It is often observed that TB control receives an insufficient proportion of already under-funded health budgets. This is despite the fact that TB control is an extremely cost-effective way to use public funds. There is often a lack of finance to expand or sustain the DOTS strategy, which leaves countries dependent to a large extent on bilateral or multilateral assistance. Misallocation or inefficient financing for TB control is also common and, where DOTS programmes are not in place, financial resources are often used on costly and ineffective control strategies[11]. In addition, user fees for TB treatment and low health worker salaries act as financial disincentives to the DOTS strategy.

- ***Human resources constraints***

Human resource constraints restricting expansion of the DOTS strategy are many and include absolute lack of staff, quality and capacity of staff, inadequate compensation mechanisms, poor conditions of service, low morale, corruption, inadequate training, and ineffective management styles (such as highly bureaucratic systems). As TB has been long neglected in many countries, such constraints are embedded and are related in part to financing and in part to the stigma attached to TB. Young public health professionals often find a career in public sector TB control unattractive due to irregular and nominal salaries, and administrative inefficiencies.

- ***Inadequate drug supply***

The process of securely funding, ordering, obtaining appropriate prices, distributing and storing quality TB drugs is a major constraint to DOTS in TB endemic countries. Overall shortages of TB drugs are often due to insufficient funds, lack of buffer stocks, and difficulties in transportation.

- ***Insufficient political commitment***

One overriding constraint to DOTS expansion is weak political will due to the fact that political leaders, policy-makers, and citizens are unaware of the risks of the global TB epidemic as well as the strategies for effective control. Insufficient political commitment is evident in inadequate public attention to TB as a development issue and inadequate resource commitments.

- ***Lack of coordination***

The complexity of health service delivery and decentralization means that lack of coordination can be a key constraint to DOTS expansion in many countries. In some countries the issue is coordination between donors or between NTPs, district and provincial TB units. In other countries, coordination between public and private health care providers is weak, with a multitude of treatment practices and transfer of patients between the two systems leading to discontinuity of treatment.

- ***Weak health services infrastructure***

Health sector reforms in many countries have led to decentralization and the transfer of state facility services to municipal governments, often without adequate training or follow-up on TB programme organization. In other countries, poor infrastructure including the laboratory network, peripheral health care services, transport and communication facilities are major constraints to DOTS expansion.

- ***HIV***

In many countries, a dual epidemic of TB and HIV has emerged over the past two decades. The TB/HIV co-epidemic puts additional burdens on the capacity of health facilities to provide diagnostic facilities, access to drugs and treatment, and integration of TB and HIV services.

Table C: Summary of key constraints to DOTS in the high-burden countries[12]

Country	Financing	Human resources	Drug supply	Political commitment	Coordination	Health services infrastructure	HIV
Afghanistan	•	•	•	•		•	
Bangladesh		•	•	•	•		
Brazil				•	•		
Cambodia	•	•	•			•	•
China	•		•	•	•		
DR Congo	•		•			•	•
Ethiopia		•	•		•	•	•
India	•	•	•	•	•		
Indonesia		•		•	•		
Kenya	•		•				•
Myanmar	•		•		•		
Nigeria	•	•	•	•	•	•	•
Pakistan	•	•	•	•	•		
Peru							
Philippines			•		•		
Russian Fed.	•	•	•	•			
South Africa		•			•		•
UR of Tanzania	•	•		•			•
Thailand				•	•		
Uganda					•		•
Viet Nam		•	•		•		
Zimbabwe					•		•

1. This summary is based on data available as of 24 January 2000. It therefore reports on cases notified during 1998 and treatment outcomes for patients registered in 1997. Ref. World Health Organization. *Global Tuberculosis Control.* Geneva, Switzerland: WHO Report 2000, WHO/CDS/TB/2000.275.
2. Raviglione M, et al. Assessment of worldwide tuberculosis control. *Lancet,* 1997; 350:624–629.
3. The Stop TB Initiative. *Tuberculosis and Sustainable Development.* Stop TB Initiative 2000 Report, Geneva, Switzerland; WHO/CDS/STB/2000.4.
4. Table is adapted from World Health Organization. *Global Tuberculosis Control.* WHO Report 2000, Geneva, Switzerland, WHO/CDS/TB/2000.275.
5. Details of this model are available on the Lancet's website at http://www.thelancet.com – Figures are taken from Dye C, et al. Prospects for worldwide tuberculosis control under the WHO DOTS strategy. *Lancet,* 1998; 352:1886–91.
6. Refer to figure 15, p. 30, World Health Organization. *Global Tuberculosis Control.* WHO Report 2000, Geneva, Switzerland, WHO/CDS/TB/2000.275.
7. These figures for 2005 are drawn from the data for 2000 and 2010 as outlined in Dye C, et al. Prospects for worldwide tuberculosis control under the WHO DOTS strategy. *Lancet,* 1998; 352:1890.
8. Figure 2 is adapted from Dye C, et al. Prospects for worldwide tuberculosis control under the WHO DOTS strategy. *Lancet,* 1998; 352: Figure 5, 1890.
9. World Health Organization. *Global Tuberculosis Control.* Geneva, Switzerland, WHO Report 2000, WHO/CDS/TB/2000.275
10. Top performers are measured by a treatment success rate of 70% and a DOTS detection rate of 50%.
11. Hospitalization, repeated BCG vaccinations, over reliance on X-rays for diagnosis and follow-up.
12. Table uses data from World Health Organization. Status of tuberculosis in the 22 high-burden countries and global constraints to TB control, WHO/TB/98.242 and World Health Organization. *Global Tuberculosis Control.* WHO Report 2000, WHO/CDS/TB/2000.275 and The Stop TB Initiative. Country Profiles, WHO/CDS/STB/2000.

Annex D

WHO survey on TB drug supply experiences in WHO Member States, 1999-2000

RESULTS—as of 15 February 2001

- ***Background***

There is a global consensus that poor supply of TB drugs is an impediment to the control of the TB epidemic, here are a few signs that this consensus exists:

– A regular system for supply of TB drugs is among the five principal elements of the WHO-recommended Directly-observed Treatment, Short course (DOTS), strategy for effective TB control.

– The WHO-organized ad hoc Committee on the TB epidemic which met in 1997 identified ongoing drug supply problems as a top obstacles to effective launch and/or expansion of DOTS programmes and to meeting global TB control targets.

– The Stop Tuberculosis Initiative, a global partnership which was launched at the end of 1998, has included overcoming obstacles to drug supply among its major objectives.

– The World Health Assembly 2000 endorsed the "Amsterdam Declaration" made by 20 high TB burden countries in March 2000, and this Declaration called urgently for new approaches to TB drug supply.

– Two recent initiatives have helped set the stage for new responses to drug access problems in TB control: the recent launch of the Global Alliance for TB Drug Development (GATB) and the efforts underway by Stop TB partners to develop a Global TB Drug Facility in order to ensure uninterrupted access to TB drugs and catalyze global TB control by financing TB drug procurement.

- ***Objective***

To help inform those aiming to respond to the TB drug supply challenge, the WHO Communicable Diseases Programme pursued a survey of its Member States to learn about their experiences in TB drug supply in recent years and identify common and specific concerns.

- ***Methods***

This survey was based on a WHO survey conducted in 1992, although substantially revised. A full final report will include comparisons to the earlier survey, to which 74 countries responded. A written questionnaire was drafted in mid-2000, based on the 1992 instrument. The draft was tested, by requesting on-site completion of the questionnaire by national TB control programme (NTP) managers participating in the IUALTD year 2000 Africa regional meeting in Conakry, Guinea. Twelve pilot responses were received. Revisions were made and in August 2000 the final questionnaire was distributed by the Communicable Disease Programme via the WHO Regional Offices to NTP managers or responsible officers for TB control in Member States.* Spanish and Russian translations were also provided. Replies to the survey could be made directly on a URL (internet) link, via fax, electronic mail, or pouch. WHO was responsible for analyzing and reporting on results, and ensuring utilization of the findings by Member States and other partners in the Stop TB Initiative.

The questionnaire included open and closed questions covering the following major themes: drug need forecasting, drug regimens and packaging, financing (amounts and sources), procurement methods,

** The Western Pacific Region forwarded the survey only to the four "high TB burden" nations in that region.*

distribution, local production and quality control. No detailed information was requested on the use of second-line (reserve) TB drugs, as the WHO Communicable Diseases Programme was separately collecting relevant information from selected countries, to inform the development of the WHO Green Light Committee for the procurement of second-line drugs.

- *Responses to date*

Seventy-three full or partial responses have been received, including 17 of the 22 "high-burden" nations. Several responses from high-income western European nations have been excluded and may be examined separately.
Note: *countries are starred (*) if they are among the 22 high-burden countries that collectively carry an estimated 80% of the global TB burden.*

Africa Region (AFR)

28 states or territories out of 47, including 7 high-burden out of 8 in the Region:

Algeria, Benin, Burkina Faso, Cameroon, Cape Verde, Central African Republic, Chad, *DR Congo, Côte d'Ivoire, Eritrea, *Ethiopia, Gambia, Ghana, *Kenya, Lesotho, Madagascar, Mali, Mauritania, Mozambique, Namibia, *Nigeria, Senegal, Seychelles, *South Africa, S. Tome/ Principe, *Tanzania, Togo, *Uganda.

Americas Region (AMR)

16 states out of 44 states/territories, including 2 high-burden countries out of 2 in the Region: Bolivia, *Brazil, Colombia, Cuba, El Salvador, Grenada, Guatemala, Haiti, Honduras, Mexico, Panama, Paraguay, *Peru, Suriname, Uruguay, Venezuela.
Note: *USA and Canada were not surveyed.*

Eastern Mediterranean Region (EMR)

12 states or territories received out of 23; 1 out of 2 high-burden in region:

*Afghanistan (NGO response), Djibouti, Egypt, Jordan, Lebanon, Morocco, Oman, Qatar, Saudia Arabia, Somalia, Syria, West Bank/Gaza. A partial response has just been received from Pakistan and will be included in the final report.

European Region (EUR)

11 responses received out of 22 low and middle-income countries in Europe: Albania, Bosnia & Herzegovina, Bulgaria, Estonia, Hungary, Kazakhstan, Latvia, Poland, Romania, Turkey, Ukraine.

South-Asia Region (SEAR)

3 of 10 nations received; including 3 of 4 high-burden nations: *Bangladesh,*India, Thailand

Western Pacific Region (WPR)

4 of 45 received (only high-burden countries surveyed); includes 4 of 4 high-burden nations: *Cambodia, *China, *Philippines, *Viet Nam.

Interim summary results

ESTIMATING NEED: 71% of respondents reported that the National Tuberculosis Control Programme (NTP) was responsible for estimating drug needs in cooperation with local authorities and health services. The proportion was the same among the high-burden countries; 61% of countries reported using a standardized formula for calculating need and 77% reported including buffer stocks in their estimates. The results suggest that NTPs with collaboration of central medical stores and essential drug programmes should be in a good position to define needs should they collaborate with the global TB drug facility. Respondents suggested that challenges remain in accurately estimating the rate of expansion of DOTS and any underlying trends in the epidemic.

FIXED-DOSE COMBINATIONS: Double fixed-dose combinations are already in wide used, even in low-income countries. Those that reported use of at least one type of fixed-dose combination: 85% in the Africa Region (AFR); 56% in the Americas (AMR); 67% in the Eastern Mediterranean (EMR); 54% in the European Region (EUR); 3 out of 3 respondents in South-East Asia (SEAR), an in 1 of 4 responding countries in the Western Pacific (WPR). Frequency distributions of the treatment regimens and fixed-dose combinations used based on responses from the survey will be available separately.

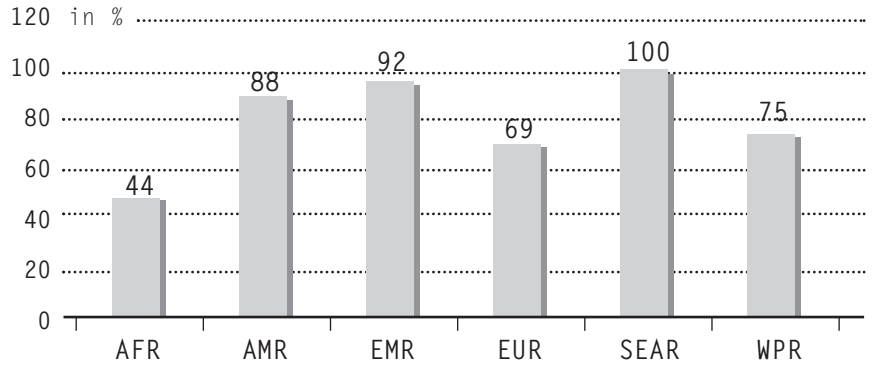
BLISTER PACKS: Only 28% of countries reported using blister packs, but those that are using them include two countries responsible for over one-third of the global TB burden—India and China. Given the risks of monotherapy and selection for drug-resistant strains in the absence of use of fixed-dose combinations or blister packs, the data will be reviewed again to determine what proportion of countries are not reporting use of either blister packs or fixed-dose combinations.

BUDGET PREPARATION: There was no clear pattern regarding responsibility for preparation of budgets for TB drug procurement. Overall, only 52% said national TB programmes were directly involved, 21% included central medical stores, and 21% provincial authorities. The responses may relate to the diverse administrative structures of national health systems, the presence of donors or other collaborators. It does suggest that agreements for budget support for TB drugs will need to involve more than NTPs in the planning and negotiation process.

FINANCING SECURITY: There is a mixed and disturbing picture with regard to security of financing. Only 73% of respondents reported that financing had been sufficient for their 1999 and 2000 needs (with the survey conducted near the end of 2000): 46% of respondents in European Region; 2 of 4-high-burden countries in the Western Pacific region; 70% of respondents in the African Region; 88% in the Americas; 92% of respondents in the Eastern Mediterranean, and the three high-burden nations in the South-East Asia that responded.

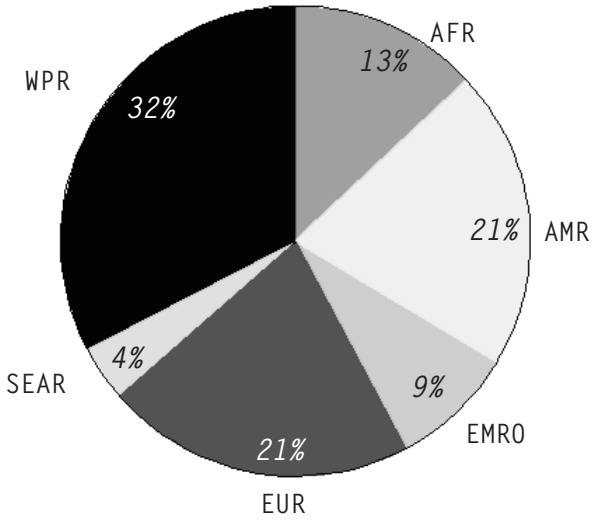
FOR 2001, only 69% of respondents had secured full financing for needs and the insecurity appeared greatest for low- and middle-income nations in Africa and Europe (*see* Fig. 4).

Figure 4: Respondents reporting that financing is secured for 2001 TB drug needs



TOTAL VOLUME OF SPENDING: Not all respondents provided information on total available financing and sources, and some (such as China) could only report on spending for areas under DOTS. For those that did respond, the total reported was US$ 78 million for 2000 (industry sources estimate that the total public tender market worldwide is over US$ 150 million). US$ 77 million was reported for 1999 and only US$ 54 million detailed so far for 2001. In 2000, US$ 58 million (74%) came from government sources and US$ 20 million for donors. The breakdown of reported spending by region is shown below. Specific information on prices received per drug are being analyzed for those countries providing data.

Figure 5: Proportion of US$ 78 million in reported TB drug spending by region



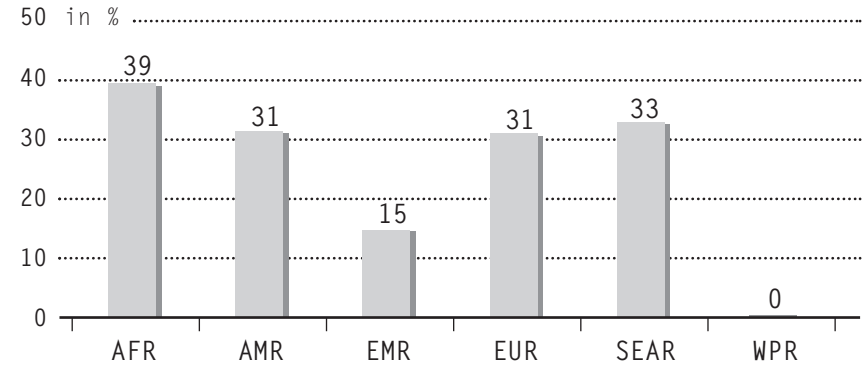
PROCUREMENT: International tenders for TB drugs are still somewhat limited in use; 33% of respondents stated that they used open tenders for some or all of their required drugs (ranging from 13% in AMR to 100% for the respondents from WPR); 22% noted using restricted international tenders; 35% noted using open and 13% reported restricted national tenders; 30% used direct and/or negotiated procurement with single suppliers; 10% noted using mixed procurement measures. The survey did not request information on why procurement methods were chosen, and this requires further exploration.

TB DRUG QUALTY CONTROL: Quality control still is not accessible for an important proportion of countries. Overall, 61% of countries reported having access to national mechanisms for TB drug quality control: 56% in AFR, 58% in the EMR, 62% in EUR, 63% in AMR, 75% in WPR, and all three respondents in SEAR. However, these responses probably overstate the utility of these resources, as the survey did not ask specific questions to assess the capacity or standards of quality control laboratories. Given discussions with programme managers and other partners, it may be reasonable to conclude that a majority of national quality control labs face problems of technical capacity and quality assurance.

DRUG STOCK-OUTS: National level stock-outs of drugs occur and could be related to a variety of factors (not clearly articulated in survey, for most countries). Those that stated existence of a national level stock-out in 1999 are shown in Figure 6.

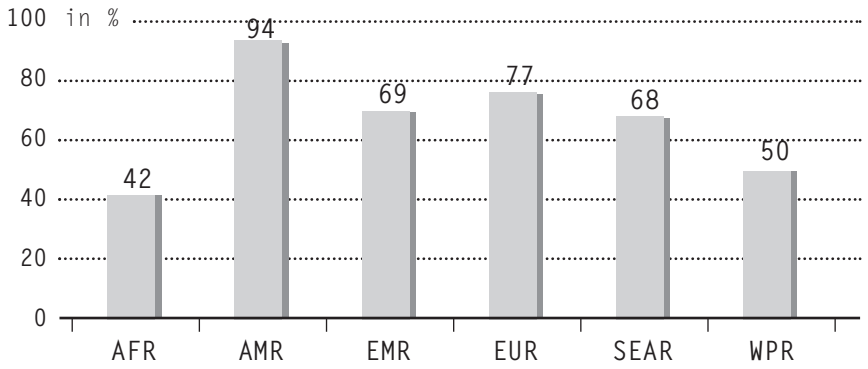
Note: *not all stock-outs carry equal risk—some stock-outs were noted to have been of short duration or of one drugs, others reported shortages of multiple drugs.*

Figure 6: Repondents reporting a national-level TB drug stock-out during 1999



PROVIDING DRUGS FREE-OF-CHARGE TO PATIENTS: Only 65% of respondents stated that TB drugs are provided free of charge. The range of free coverage is shown below by region (Fig. 7). The answers did not clearly differentiate between those that are charged as a result of national policies to charge, or more likely due to local decision making (particularly in an environment of cost-sharing). These results should be further explored.

Figure 7: Proportion of countries where TB drugs are free-of-charge to patients



CONTROL OF PURCHASING/USE: 28% of countries responded that public hospitals have authority to purchase anti-TB drugs (separately from national programmes). However, this figure was 41% in the high-burden countries. This may be of concern if there are problems with standardization of protocols and rational use and monitoring of drug use. A somewhat surprising 31% of the respondents reported that private sales of drugs are restricted—47% of the high-burden country respondents suggested that purchase was restricted.

LOCAL DRUG PRODUCTION: Less than 20 countries reported that TB drugs were produced locally, and provided information on these producers. Information can be provided separately on this.

Limitations

- Obtaining responses from all WHO Member States is a substantial challenge, even with follow-up communication from WHO Regional Offices or in-country personnel. Therefore there are still limits to the completeness and generalizability of these results.
- NTP managers (the principal respondents) are unlikely to be fully knowledgeable of the whole TB drug supply cycle in their countries, given integration and decentralization of tasks in many settings or continued dependence on donors/partners.
- Some respondents can speak only for areas of his/her country that is covered by their (DOTS) programme. Information may be lacking on the drug supply situation for the remainder of areas, and is likely less secure and more problematic.
- To facilitate replies from already over-burdened NTP managers, many questions were quite general. As a likely result, responses were sometimes inadequate and difficult to interpret. It will be difficult, and in some cases impossible, to verify the accuracy of responses provided or whether respondents correctly interpreted all questions.
- Given limited time and available information, a majority of programme managers did not provide data on specific drugs purchased (e.g., cost per unit, supplier, etc.). The data provided is being consolidated and will be available by end of February 2001.

Proposed next steps

- Answers are still expected from several other countries, including Russia and Indonesia.
- Individual tender price information will be analyzed as well as the responses to "open-ended" questions.
- A full report will be prepared, reviewed by WHO regional offices and selected Stop TB partners, and published.

Note:

Diana Weil, CDS/WHO on secondment to the World Bank, is responsible staff for this project. Lauren Mueenuddin, consultant, created the online database. EBV/CDS/WHO distributed the questionnaire to the WHO Regional Offices. WHO Regional TB Advisers and country medical officers forwarded these on to NTP managers and are contributing to the follow-up with the target recipients. Mario Raviglione, Dan Bleed, and Fabio Luelmo, in EBV/WHO, and Richard Laing, Boston University Medical School, Department of Public Health, offered valuable comments on the draft questionnaire. The World Bank provided administrative support for this work and the Rockefeller Foundation provided financing to assist with the database development.

Annex E

Options for governance and management

Executive summary

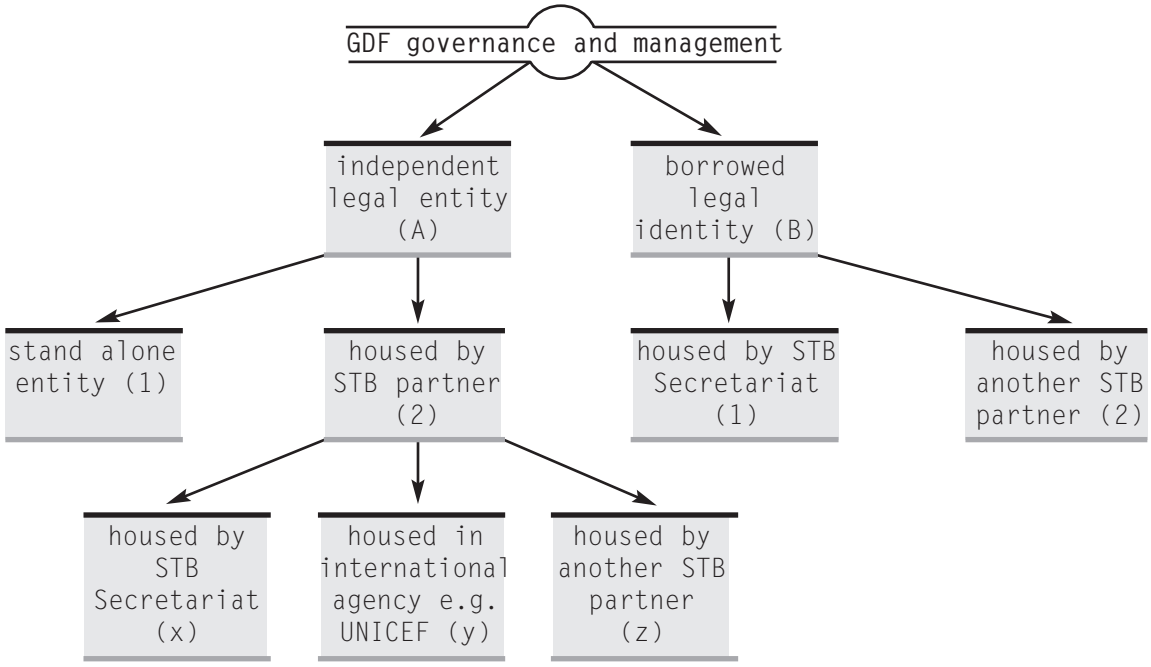
This paper presents three options for governance and management of the GDF and the Core Technical Group's (CTG) recommendation for one of these options. It summarizes reasons for the recommendation and presents strengths and weaknesses of all three options. The CTG received valuable analysis and research in background papers from several consultants in considering these options.

The CTG recommends that the GDF have an independent Board with clear authority and responsibility for GDF management, resources and mission. The GDF management should be completely dedicated to GDF functions, and be led by a senior, experienced professional who will report to the GDF Board. The GDF should be housed within an STB partner organization, and its activities should be funded through a dedicated trust fund. Subject to satisfactory negotiation of a support agreement, we recommend that this be the Stop TB Secretariat/WHO for an initial trial period of, perhaps, two years. The GDF Board will need to sign a clear and specific agreement with any GDF host organization. This agreement should specify arrangements the host will make so that the GDF can fulfill its functions and do so rapidly, flexibly and efficiently, etc. The GDF Board should formally evaluate, at specified intervals, whether the GDF's performance is enhanced or impeded by the host organization. The Board has the responsibility to move the GDF and its assets to a new host, if necessary to achieve the GDF objectives.

The CTG carefully considered the three options for governance and management described below. This recommendation for the initial two-year period is shown below as Option 3. The GDF may ultimately need to be structured as an independent legal entity (Options 1 and 2), and the GDF Board should establish a separate legal entity for the GDF if and when one is needed. But creating such an entity immediately for the GDF is impractical and unnecessary. Although it will contract out its procurement, quality control and most monitoring functions to independent agencies, the GDF will have extensive operating relationships and responsibilities in assisting DOTS Expansion (*see the Critical Functions Chart*). There are no clear models to follow for integrating an independent legal entity with such operational responsibilities in a separate host organization. These practical considerations are reflected in our recommendation of Option 3 for a trial period. But accomplishing the mission of the GDF may ultimately require a move to Option 1 or 2.

Analysis of Governance and Management Options

A planning meeting for the GDF, was held in November 2000, as part of the Cairo Meeting on DOTS Expansion. At this meeting a core technical group (CTG) for the GDF was created. As one of its terms of reference this group was asked to create an options paper on governance—a report outlining the various governance options for the GDF with their relative strengths and weaknesses. Seven weekly teleconferences were held since the Cairo Meeting. The "governance sub-group" in particular used the services of external consultants, who were generously supported by the Rockefeller Foundation and the Stop TB Partnership Secretariat, to produce background papers on governance for the CTG. The CTG then convened a face to face meeting of members in Washington DC, January 2001. At this meeting, the consultants'work was presented and governance/management options for the GDF discussed. Following the DC Meeting, two teleconferences were held to finalize governance options. Based on all of this work, the following decision tree is presented.



The CTG narrowed its choices to one of the following three options—giving the GDF:

1. An "independent legal identity" housed within the STB Secretariat
2. An "independent legal identity" housed in another STB Organization
3. A "borrowed legal identity," housed within the STB Secretariat

The background papers on "Governance and Management" suggested persuasively that the issue of the GDF's *legal identity* be considered separately from the issue of where the GDF is *housed*.

Legal identity—Roy Widdus—*consultant to the CTG*—provided several papers making it clear that if the GDF uses a borrowed legal identity, its board, ultimately, is only advisory. If the GDF operates as envisioned, and the host organization performs as promised, the GDF Board would never need its ultimate legal authority and responsibility for GDF resources. Yet it may want this final authority as a means of insuring that the GDF achieves its objectives and ensuring that a host organization consistently performs as promised over the life of the facility.

GDF location—The CTG felt strongly that GDF would benefit by being located within an institution whose mandate and capabilities enhanced the achievement of GDF objectives. In order to achieve its multiple objectives to ensure access to TB drugs for DOTS expansion, the GDF will need easy communication routes to the proposed clients, the countries, and to technical partners required to ensure timely appraisal and monitoring and evaluation. Such an arrangement would needs be governed host by an agreement detailing how the host would modify internal procedures as necessary to accommodate the GDF's functional needs, and to give the GDF its desired characteristics. If the host organization failed to fulfill the promises of that agreement the GDF Board would seek resolution. It would or would not have final authority to make a change, if necessary, depending on whether or not the GDF had a separate legal identity.

Stand-alone entity—The CTG did not consider this a strong option for the GDF, due to lost synergies, costs as well as the lack of bilateral commitment for this type of entity. The group took into account general UN concerns about the establishment of yet more new entities to serve public health needs. Member states of the UN have asked that health needs be served through existing mechanisms, rather than by creating new channels. The group also considered the concern voiced by some bilateral donors in the face of the multiplicity of special initiatives and their search for funds. To better address this issue, there is an ongoing discussion among certain bilaterals on the possibility of creating an overarching governance structure, with several pockets for procurement purposes for TB, HIV and malaria. The group also recognized the costs and difficulties involved to establish and operate a stand-alone entity.

Three options

1. A legally independent GDF housed within the Stop TB Secretariat/WHO

Advantages: WHO provides infrastructure throughout the developing world and has well-established links to health authorities and TB Control Programmes. WHO also offers credibility through its TB control standard-setting role, and its drug quality and regulatory expertise. In addition, the Stop TB Secretariat provides important advocacy, coordination and resource mobilization functions and facilitates communication with a range of international and non-governmental partners required to work with countries to rapidly expand DOTS and help ensure the related improvements needed to deliver the drugs to patients. For these important reasons the GDF's proximity—collegial and physical—to Stop TB/WHO would enhance its effectiveness.

Disadvantages: There is concern that a GDF housed in WHO would be constrained by existing operating procedures and governance in WHO. Despite the evident goodwill and intentions of WHO management to create new procedures to accommodate GDF—such as a dedicated GDF Trust Fund and management—there is experience to indicate that that administrative departments are reluctant to create such procedures and/or to sustain them over time. An agreement with WHO specifying GDF support and procedures would have to be carefully negotiated, adequately supported by senior WHO executives, and then closely monitored. Creating a new legal entity for the GDF may take time and would likely create challenges for WHO in relating to such an entity within its walls.

2. A legally independent GDF housed in another STB Partner organization

If WHO were not able, or no longer willing, to adequately support the GDF as required, alternate Stop TB partners such as the IUATLD and KNCV would offer parallel advantages because of their mission and capacities in TB control and their experience in TB drug procurement and supply management. Both would have to study the implications that housing the GDF would have for their organizations, and both would have to develop plans to increase capacity to manage the GDF. Hence neither organization would be immediately ready to assume this function. Although neither has formally considered the question at a Board level, both appear willing to consider it.

Advantages: Mission synergies. The Union and KNCV have working relationships with some National TB Programmes, Stop TB partners and with some bilateral donors. They also have extensive experience in drug procurement. The Union appears willing (subject to Board approval) to house a GDF that was governed by a legally independent board.

Disadvantages: The Union and KNCV would have to scale up to handle the GDF functions, particularly with regard to communication and financial agreements with large numbers of countries. KNCV is a national entity, rather than an international one, and that may be an issue for bilateral donors. The Union is an international entity. If either of these organizations housed the GDF, their own comparative advantage in procurement functions would be decreased, as they would not be able to serve as a GDF procurement agent.

3. "Embedded" GDF, with no separate legal identity, housed in STB Secretariat/WHO

Advantages: As above with Option 1.

Disadvantages: As above with Option 1. Further, the GDF would have no separate legal identity apart from WHO. The GDF Board would be, in the final analysis, only advisory. It would have limited authority to move the GDF to another host organization in the event that WHO organization and procedures were unable to accommodate the needs and required characteristics of the GDF. The Board's power, under such difficult circumstances, would only be derived from the support of stakeholders and donors, whose ongoing support will be necessary to sustain the GDF.

Recommended next steps for the GDF

- ✔ The STB Coordinating Board should consider the CTG's options and recommendations for GDF governance and management and provide its own recommendation on the issues presented above. Once endorsed by the STB Coordinating Committee, these plans would be incorporated into the GDF prospectus.

- ✔ The STB Coordinating Board should appoint a small committee to define the support and procedures that the GDF needs from its host organization in order to accomplish its objectives in the prescribed manner. This committee will begin discussions and negotiations with WHO on the terms of agreement for hosting the GDF.

- ✔ The Stop TB Secretariat, in close coordination with STB partner organizations, will proceed to launch the GDF pilot programme. The CTG expects this programme to provide important lessons for how the permanent GDF is to be organized, managed and structured. In this pilot programme, as in the permanent GDF, the Secretariat will call upon STB partner organizations to carry out many of the pilot GDF functions. A chart of Critical GDF Functions is attached, showing how responsibilities will be allocated.

- ✔ Simultaneous with the development of the GDF pilot programme, the Stop TB Partnership and its stakeholders should proceed expeditiously to establish the permanent GDF—drawing lessons from the pilot programme, negotiating the terms of a permanent agreement with the GDF host, and raising resources. It is expected that Stop TB Partners will jointly plan with the Stop TB Secretariat for resource development and resolution of other operational matters necessary to launch the permanent GDF. Financial stakeholders will make final decisions regarding the governance and technical review structures for the GDF.

- ✔ The GDF needs a significant infusion of resources. The donations received to date will not suffice to launch the GDF, so immediate efforts to mobilize support are critical. The CTG requests that the STB Coordinating Board address this GDF need, along with other TB funding priorities, and provides guidance and a coordinated plan for raising support.

- ✔ There remain a number of important GDF technical issues that need to be addressed in the near future. These include the menu of approved drugs to be procured, planning for possible regional contracting, etc. The CTG recommends that the interim Technical Review Committee for the pilot GDF be requested to pursue these critical questions within the next two months.

The following background papers are available separately and can be obtained from the Stop TB Secretariat:

1. Linkages of GDF to organizations such as the World Bank, as well as the Stop TB and the Massive Effort.

2. Institutional Arrangements for Governance and Management of the Global TB Drug Facility—A discussion paper.

3. Possible Trust Fund arrangements for the Global TB Drug Fund.

Table D: Global TB Drug Facility—Critical functions and governance

	Critical Functions			
GDF Function	GDF Management	Technical Review Committee	Third Party	GDF Board
1. GDF policy and standards				●
2. Application processes	●			
3. Grant review and recommendations		●		
4. Final award decisions				●
5. Grant agreements				
Apply standards		●		
Negotiate contracts	●			
Execute agreements	●			
Monitor performance	●		●	
6. Procurement				
Interpret and apply standards	●			
Contract with agent	●			
Contract with suppliers			●	
Execute agreements	●			
Monitor performance	●		●	
7. Standardization/Regulatory	●			
8. Monitoring—Overall	●	●		●
9. Management accountability	●			●