Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Thirteenth Board Meeting
Geneva, 27 - 28 April 2006

GF/B13/8

Annex 9

FUNDING OPTIONS PAPER:
BOARD REQUIRED PROCUREMENT OF SECOND-LINE DRUGS FOR MULTI-DRUG RESISTANCE TUBERCULOSIS THROUGH THE GREEN LIGHT COMMITTEE

Outline: This paper reviews the demand Global Fund-funded grants make on the Green Light Committee (GLC) as a result of the Third Board decision on procurement of second-line Tuberculosis drugs. Based on GLC service costs, this paper also offers a menu of options for PC consideration of the financial contribution the Global Fund could or should make to support the GLC.

Summary of Decision Points: N/A (to be discussed with Board relations)

Part 1: Background

1. The Portfolio Committee (PC) has been informed of the GLC's funding gap for 2006 and beyond and is aware that insufficient funding of the GLC will impair delivery of MDR-TB treatment to patients in Global Fund-financed programs. This paper will review the demand Global Fund-funded grants make on the Green Light Committee (GLC) as a result of the Third Board decision on procurement of second-line Tuberculosis drugs, and provide a menu of options for PC consideration of the financial contribution the Global Fund could or should make to support the GLC.

Part 2: GLC's Role in MDR-TB Management

1. Approximately 300,000 to 600,000 new (MDR-TB) cases emerge each year as a result of the misuse of first line anti-tuberculosis drugs and transmission of drug-resistant TB strains. In the absence of quality and easily accessible treatment for MDR-TB, over 60 percent of people with MDR-TB will die within five years.

2. A myriad of difficulties exist for treatment of MDR-TB in resource-constrained settings. Second-line TB drugs cost 1,000 to 3,000 times more than first-line TB treatment (on average US$ 20,000 per full course). In addition, there are few effective drugs available for treatment of MDR-TB. These drugs can often be of poor quality, dispensed at a prohibitive fee to patients and administered with little or no systematic follow-up. This misuse of second-line TB drugs contributes to the rapid creation of drug resistance, and increases the risk of widespread transmission of incurable strains of TB.

3. Therefore, a global public health need exists for a coordinated, international effort to i) increase access to affordable, high quality second-line TB drugs; and ii) establish mechanisms to administer these drugs, develop laboratory support, and track MDR-TB treatment to ensure adherence to treatment. These coordinated efforts will decrease MDR-TB transmission, slow the evolution of drug resistance and ultimately decrease MDR-TB related morbidity and mortality.

4. Directly Observed Therapy Short Course (DOTS-Plus) was launched in 1999 to pilot a strategy to combat the challenges of managing MDR-TB treatment in resource-limited settings. The Green Light Committee (GLC) was subsequently formed in 2000 as a sub-group of the Stop TB Partnership's Working Group on DOTS-Plus on MDR-TB. It was established as a multi-institutional partnership to promote access to and rational use of low-cost second-line TB drugs, and to develop a strategy for managing MDR-TB in resource-constrained national and regional programs. The GLC is the only existing mechanism to ensure responsible use of second-line drugs. A thorough explanation of the function of the GLC is provided in *A Business Plan for the GLC 2006 - 2008* (Annex 2, Section III.)

5. Over the past 5 years, DOTS-Plus and the GLC have increased the feasibility and cost-effectiveness of MDR-TB treatment in national programs contributing to the establishment of international guidelines for management of MDR-TB. The GLC has specifically enabled increased access to second-line TB drugs at significantly decreased prices (on average, a 90 percent discount) through pooled procurement and negotiating with second-line drug manufacturers, while enforcing adherence to MDR-TB management guidelines that emphasize rational drug administration, observed therapy, and tracking of treatment outcomes and drug resistance patterns.

Part 3: Expansion of MDR-TB Treatment and Impact on GLC Resource Needs

1. The development of WHO guidelines for MDR-TB management in national and regional programs is expected to contribute to rapid global expansion of MDR-TB programs. The 2006 *Global Plan to Stop TB*, estimates that up to 100,000 new MDR-TB patients will be on program-managed second-line TB therapy by 2008. Almost 800,000 new patients are projected to be on therapy by 2015. Currently, less than 13,000 patients (2 percent of the global MDR-TB burden) receive MDR-TB treatment in GLC-approved projects.

2. This projected expansion of patients on MDR-TB treatment will more than triple the number of patients in GLC-approved projects by 2008. The GLC will require significant operational expansion to meet increased patient- and project-load demands in a timely and effective manner. A more thorough explanation of growth projections for the GLC for 2006-2008 can be found in *A Business Plan for the GLC 2006 - 2008* (Annex 2, Section IV.)

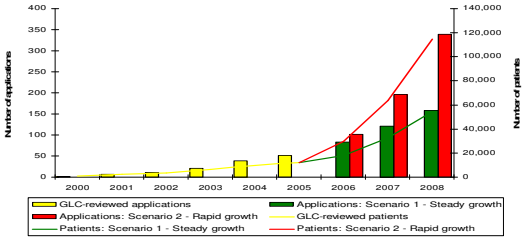


Figure 1: Actual and projected growth of MDR-TB patients.

3. The GLC currently receives funding from a consortium of donors, including the United States Agency for International Development (USAID), the United Kingdom's Department for International Development (DFID), Eli Lilly, the Bill and Melinda Gates Foundation and the WHO's regular budget. This consortium has pledged US$ 2.8 million for the GLC in 2006, US$ 1.24 million in 2007, and US$ 958,000 in 2008.

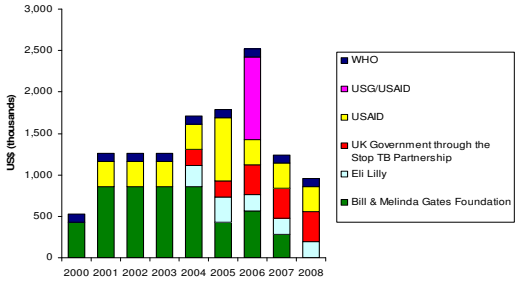


Figure 2. Actual and projected Funding for the GLC; 2000 to 2008 (thousands of USD).

4. In the context of an expanding patient load, the GLC expects to face critical resource shortfalls.

5. In order to transition to a new funding model, the GLC has developed a patient-based per-unit cost model for its services. For details, see Annex 2, Section VI and VII.

Part 4: Global Fund–Financed Program Use of GLC Services

1. The Global Fund Board addressed MDR-TB treatment at its Third Board Meeting (October 2002) in the context of developing Global Fund procurement and supply guidelines. The Board recognized the specific challenges of MDR-TB treatment, and the need for consistent international policies on procurement and use of second-line TB drugs. The Board recognized the GLC as the only viable mechanism available to ensure responsible use and cost-effective access to MDR-TB drugs. As such, the Global Fund Board decided,

> "To help contain resistance to second-line TB drugs and consistent with the policies of other international funding sources, all procurement of medications to treat Multi-Drug Resistant TB (MDR-TB) must be conducted through the Green Light Committee (GLC)." (Procurement Agenda Item 10: 3b)

2. It is important to note that procurement of second-line TB drugs through the GLC cannot be disaggregated from capacity assessment and monitoring services provided by the GLC. These services are essential safeguards against the development of drug resistance and promote the continued effectiveness of MDR-TB treatment. In other words, procurement activities cannot be provided without the other essential services that the GLC provides.

3. Therefore, Global Fund-financed programs with MDR-TB components receive the following services from the GLC:

i. assessment of baseline capacity for MDR-TB treatment and identification of technical assistance needs (including training of local health staff) prior to application to the GLC,
ii. GLC application review,
iii. monitoring of GLC approved projects (evaluating adherence to established guidelines for programmatic treatment of MDR-TB and monitoring of adherence to treatment regiments, treatment outcomes, and drug resistance patterns), and
iv. pooled procurement of quality-assured, low-cost second-line anti-TB drugs.

4. GLC resource needs have been limited over the last five years because only a small number of patients have been enrolled in MDR-TB treatment programs. The expansion of MDR-TB treatment programs over the next three years will push the GLC's funding needs beyond the financial support of existing donors.

5. The expansion of MDR-TB programs is directly related to an increase in available funding from the Global Fund for TB. Global Fund programs with MDR-TB components currently account for 82 percent of the total patients in approved GLC projects, and are projected to account for 76 percent of the total patient population in approved GLC

projects over the next three years. The GLC affords Global Fund programs a 90 percent reduction in costs for quality-assured, second-line TB drugs. This means savings totaling $17,500 USD per patient for a full course of treatment, enabling the treatment of eight instead of one patient with the same funds.

Part 5: Funding Options

A. Suggested General Funding Principles

1. Global Fund-financed programs require GLC services. Therefore, the Global Fund should be concerned with sustaining GLC operations.

2. Any funding from the Global Fund should supplement and not replace existing funding from the GLC's donor consortium.

3. Any funding from the Global Fund should apply a predictable funding mechanism, so that the GLC continues to provide essential services.

4. The amount of funding received from the Global Fund should be calculated using the GLC's patient-based unit cost model. The total costs of Global Fund-financed patients in GLC projects should constitute the upper-limit for Global Fund funding given to the GLC. This amount may cover but not exceed the GLC's funding gap for any given year.

5. WHO staffing procedures require an operating budget at the beginning of each year and as such, funding should be available accordingly.

B. Suggested Source of Funds

1. Three main options are available for Global Fund support to the GLC: direct funding from the Global Fund, funding from Board-approved (grant) funds of Global Fund programs that use GLC services, and a hybrid funding model. Each of these funding options is based on the premise that the Global Fund has a vested interest in ensuring that the GLC operates as a sustainable institution that provides a global public good, of which Global Fund-financed programs are a primary beneficiary.

2. **Option 1: Direct Funding from Global Fund Budget.** This option would involve seeking approval from the Board to provide annual contributions to the GLC in a lump sum, based on the estimated number of patients on MDR-TB programs funded by the Global Fund (based on the unit cost per patient). This amount would be in addition to the total amount approved by the Board for grants at each Round.

3. The amounts would vary from year to year based on the GLC funding gap and the actual reported number of patients placed on treatment. For example, in 2006, the Board would need to approve US$ 1.476 million and in 2007, approximately US$ 5.413 million (see Table 1).

4. As a financing institution, however, Global Fund-financed programs should use grant funds to pay for services delivered at a country level. Thus, while GLC services are board-mandated, such a precedent may be one that the PC may wish to consider with due care.

5. **Option 2: Funding from Board-approved Grant Funds.** Another option would be to "bill" each grant for GLC services provided. In other words, the Global Fund would require Principal Recipients (PRs) to pay for the services provided by the GLC for each patient on a MDR-TB treatment from Board-approved grant funds. This cost would be built into PRs' budgets.

6. The main difficulty associated with this option would be imposing a requirement on PRs in the middle of the calendar year after budgets and workplans have been completed. It would force PRs to identify savings from their 2006 budgets for this additional expense. Communications would, of course, highlight that this requirement is based on the Third Board decision though this approach may lead to discontent. It is important to note that the scope of the expenses is small (on average, US$ 52,000 or 0.3 percent of each program's total lifetime budget).

7. As a result, exercising this option would be more prudent starting in Round 6 and beyond where PRs would be informed up front to budget for this expense. In addition, application of this option would require up-front direct payment to WHO – details are provided on the payment structure section below.

8. **Option 3: Hybrid Option:** Given the critical funding shortfalls of the GLC, a third option is available for PC consideration. It involves applying option 1 in 2006 and option 2 in 2007 and beyond.

9. The PC would propose that the Board authorize, on an exceptional basis, funds required to cover the GLC funding gap associated with the services provided for Global Fund-financed programs for 2006 (US$ 1.476 million). At the same time, the Board would direct the Secretariat to operationalize a system whereby all Global Fund-financed programs with a MDR-TB treatment component should pay the GLC for the services provided to each program starting in 2007.

10. This option would ensure sustainability for the GLC starting in 2006 and allow a smooth transition to a different funding model whereby, starting in 2007, PRs would be given ample time to prepare for this requirement.

C. Payment Structure

1. The estimates described in Table 1 illustrate that the GLC's funding needs and gaps are based on the estimated number of patients on MDR-TB treatments at the beginning of each year. It is important to highlight that these funding needs will be adjusted as the GLC reports on actual numbers of patients on treatment at the end of each year.

2. Operationalizing the proposed options outlined above is likely to work most efficiently if a "direct payment" model is applied. This implies that based on estimates provided by the PR at the end of each calendar year, the Global Fund will make a direct payment, deducted form the PR's grant funds, to the GLC. Essentially, Principal Recipients would make a disbursement request specific to the GLC service costs, and the Secretariat would then transfer the appropriate funds directly to the GLC. The Global Fund could establish a deadline at the beginning of each year for relevant programs to submit their direct payment requests.

3. A precedent has been established in applying this model, notably in direct payment methods used in the context of purchasing Long-Lasting Insecticidal Nets for malaria control to speed up procurement processes.

Table 1: Estimated Costs and Funding Associated with GLC services: 2006 – 2008

GF program associated costs for GLC services and estimated funding for 2006 – 2008 (Steady Growth Scenario)	2006	2007	2008
Unit Cost Per Patient (USD)	$227	$221	$149
Projected Number of GF Patients in Approved GLC Projects (USD)	14,477	23,489	38,271
Upper Limit of GF Funding to the GLC (USD)	$3,286,279	$5,191,069	$5,702,379
GLC Funding Gap (USD)*	$1,476,000	$5,413,000	$6,453,958
Total GF Funding to GLC (USD)*	$1,476,000	$5,191,069	$5,702,379

* Figures for GLC Funding Gap and Total GF Funding to the GLC for 2007 and 2008 do not account for rolled over funds or funds from additional donors

Part 6: Conclusions

1. The GLC mechanism provides a necessary global public good and is an essential service used by Global Fund-financed programs with MDR-TB components. The funding options outlined above provide a menu of options for preserving this global public good without which global TB control will be jeopardized.

****

Annex 1

Determination Proportional Cost Based on Global Fund Patient Burden

The Global Fund could determine annual funding to the GLC based on unit costs per patient and the GLC funding gap.

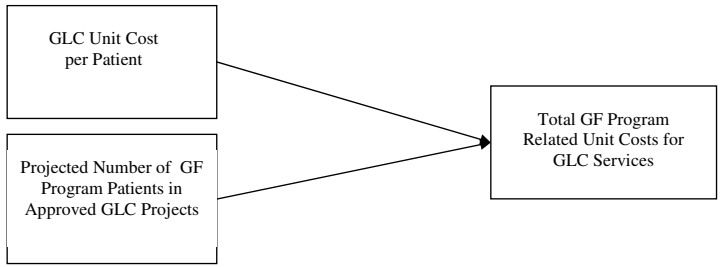
a) Determine the total cost of GLC services to Global Fund programs, based on unit costs per patient for each year. This cost would be the upper-limit for Global Fund funds given to the GLC for that year.

b) Assess the GLC funding gap. Funding would not exceed the GLC's funding gap. For example, if the GLC has a funding gap of $1 million USD, and the total unit cost for Global Fund program's use of GLC services is $2 million USD, the GLC would receive $1 million USD from Global Fund programs.

c) Each Global Fund program using GLC services would pay a proportion of the total cost of GLC services for Global Fund programs. This proportion would be determined by the number of MDR-TB patients in GLC approved projects for each program.

Step 1: Determine Total Unit Cost for MDR-TB patients from Global Fund programs in Approved GLC projects for 2006.

A. Concept Diagram

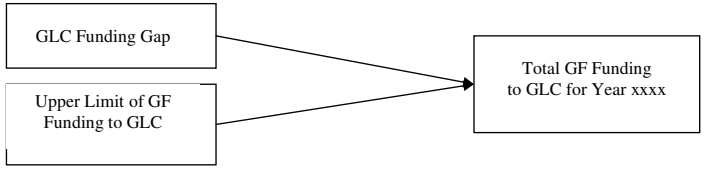


B. Example Calculation

Projected Number of GF Program Patients in Approved GLC Projects for 2006	14,477
GLC Unit Costs (per patient)	$227 USD
Total Costs	$ 3.3 million USD

Step 2: Determine Total Global Fund Funding to the GLC

A. Concept Diagram

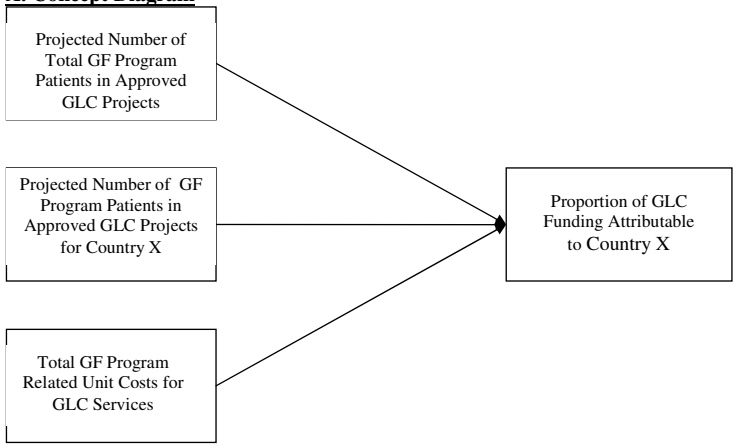


B. Example Calculation

Upper Limit of GF Funding to the GLC	$3.3 million USD
GLC Funding Gap	$1.5 million USD
Total GF Funding to GLC	$1.5 million USD

Step 3: Determine Proportion of GLC Funding Attributable to Each Relevant Global Fund Program

A. Concept Diagram



B. Example Calculation : Global Fund Program in Peru

Projected Number of Patients from Peru Program in Approved GLC Projects for 2006	4,800		
Projected Number of Total GF Patients in Approved GLC Projects	14, 477	*Equals*	33 Percent of Total GF Patients in Approved GLC Projects Attriutable to Peru Program

Percentage of Total GF Patients in Approved GLC Projects Attriutable to Peru Program)	33 Percent
Total GF Funding to GLC for 2006 (USD)	$1.5 million
Total Cost for GLC Services Attributable Peru for 2006 (USD)	$500,000

Annex 2

A Business Plan for the Green Light Committee 2006–2008

15 February 2006

Table of Contents

Annexes

This document was developed by Paul Nunn, Ernesto Jaramillo and Eva Nathanson, Stop TB Department, WHO, on behalf of the Stop TB Working Group on DOTS-Plus for MDR-TB, and Mursaleena Islam, from the US Agency for International Development-funded Partners for Health Reform*plus* (PHR*plus*) project.

We acknowledge with thanks the support provided by the US Agency for International Development and the Bill & Melinda Gates Foundation in the development of this business plan.

Executive Summary

The Green Light Committee (GLC) of the Stop TB Partnership is a unique mechanism which ensures the quality of programmes to treat multi-drug resistant tuberculosis (MDR-TB) in low-income countries and by so doing prevents the spread of resistance to the only drugs we have left. This protection against potentially incurable TB is a public good available to all. The GLC is the only mechanism to provide concessional priced second-line anti-TB drugs and thus maximises the use of resources, saving, on average, US$17,000 per patient treated, compared to commercial prices.

In its pilot phase, 2000-2005, the GLC has treated (or is treating) 12,805 MDR-TB patients and established that treatment of MDR-TB is efficacious, feasible and cost-effective in low-income settings. The demand for MDR-TB programmes in such settings is rising substantially as surveys reveal its extent and magnitude, especially in the former Soviet Union. Fortunately, increasing amounts of external financial assistance to countries are becoming available, especially from the Global Fund Against AIDS, Tuberculosis and Malaria (GFATM), who have determined that all applications for such programmes must be approved by the GLC.

This document lays out the expansion plan, with projected operating costs, for the GLC to meet this demand through expansion of its capacity to approve proposals, provision of the necessary technical support to countries, including the drug procurement process and the monitoring of progress. It presents two scenarios: the Steady Growth Scenario envisages that 42,000 patients in resource poor countries will be treated between now (February 2006) and the end of 2008 at a cost of US$ 18 million, while the ambitious but realistic Rapid Growth Scenario, based on the Stop TB Partnership's Global Plan to Stop TB, 2006-2015,[1] foresees treatment of 102,000 patients if US$ 30 million are made available. Pledges from the current funding agencies amount to US$ 4.7 million for the period 2006-2008. This leaves gaps of US$ 13 million and US$ 25 million for the Steady and Rapid Growth scenarios, respectively.

The financial needs of the GLC should be viewed hand in hand with the imperative of quickly expanding the human resources (from Stop TB Partners) to at least double each year over the next two years. This staffing is required to process the increased number of applications, provide pre-approval technical support and post-approval monitoring and evaluation, as well as expansion of the drug procurement function, based in the World Health Organization. It is important to note that the GLC mechanism does not encompass all the needs for expansion of MDR-TB control, and resources supplied to the GLC need to be matched with parallel efforts to support especially human resources for MDR-TB management and laboratory strengthening in low-income settings. Finally, the bulk of the

[1] The Stop TB Partnership launched its Second Global Plan to Stop TB, 2006-2015, on January 27, 2006 in Davos, Switzerland. The Plan shows how the Millennium Development Goals for TB can be reached if sufficient resources are made available. It includes provision for the treatment of 800,000 cases of MDR-TB, so that, by 2015, 56% of all cases of MDR-TB are receiving treatment.

costs for addressing the urgent need for prequalification of manufacturers of second-line anti-TB drugs is being addressed separately by WHO's Prequalification Programme, and these costs are thus excluded from this plan.

I. The rationale for the Green Light Committee

MDR-TB[2] is a significant threat to TB control. An estimated 300,000 to 600,000 MDR-TB cases emerge every year as a result of misuse of anti-TB drugs and transmission of drug resistant strains.[3] China, India and the countries of the former Soviet Union account for 79% of the burden. The highest MDR-TB prevalence rates have been observed in countries of the former Soviet Union and provinces of China but all other regions have at least one country with an MDR-TB prevalence above 3% in TB cases never previously treated (figure 1).

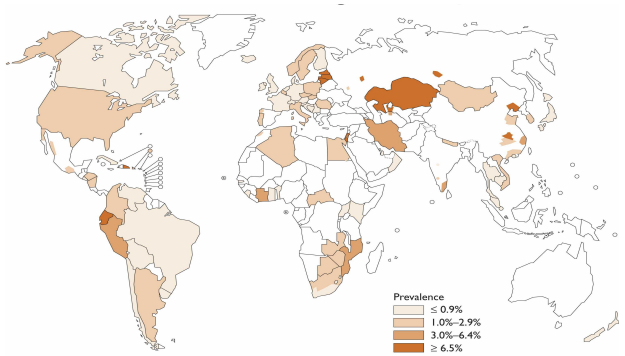


Figure 1. MDR-TB prevalence among new cases, 1994-2002.

Without the availability of good quality treatment for MDR-TB over 60% of these cases will die within five years. One of the major barriers to MDR-TB treatment is the high cost of second-line TB drugs which are at least 100 times more expensive than first-line drugs on the basis of GLC prices and 1000-3000 times more expensive in terms of market prices.[4] As a result, patients and affected communities in most parts of the world struggle to get access to these drugs. When available, drugs are often of poor quality, usually dispensed by private practitioners with treatment practices that fail to meet acceptable standards and for a fee exhausting the patient's resources, and with no systematic follow-up. This misuse of second-line drugs has already led to the creation and circulation of incurable TB strains. Based on the worldwide sales of a manufacturer

[2] Resistance to at least the two most powerful first line anti-TB drugs, rifampicin and isoniazid.
[3] Zignol M. *et al*. Global incidence of multidrug-resistant tuberculosis. [Submitted for publication].
[4] On average, a full course of first-line TB drugs cost US$ 18 (through the Global Drug Facility), while a full course of second-line drugs cost US$ 20,000 in market prices and US$ 3,000 through the GLC.

of second-line TB drugs it is estimated that at least US$ 170 million is spent annually on second-line drugs outside of quality treatment programmes.

II. The Green Light Committee

The GLC was formed in 2000 as a sub-group of the Stop TB Partnership's Working Group on DOTS-Plus MDR-TB. It was established as a multi-institutional partnership to promote access to life-saving second-line drugs at reduced prices for the treatment of MDR-TB and under rigorous monitoring to prevent the creation of resistance to second-line drugs, the last line of defence against TB.

The first five years of the GLC were crucial for developing a replicable model for feasible and cost-effective MDR-TB control in resource-limited countries. The pilot phase ended in 2005, when compelling evidence on feasibility, effectiveness and cost-effectiveness of MDR-TB management under programmatic conditions was obtained from the projects approved and monitored by the GLC. By the end of 2005, 33 projects in 31 countries[5] had been granted access to quality-assured second-line drugs at reduced cost to almost 13,000 MDR-TB patients (figure 2 and annex 1). Drawing upon the experiences in these projects, WHO has developed international guidelines for the programmatic management of drug resistant tuberculosis.[6] Major reductions in the prices of second-line drugs were achieved through negotiations with pharmaceutical companies and pooled procurement of drugs.

GLC's benefits for global TB control are shown in table 1.

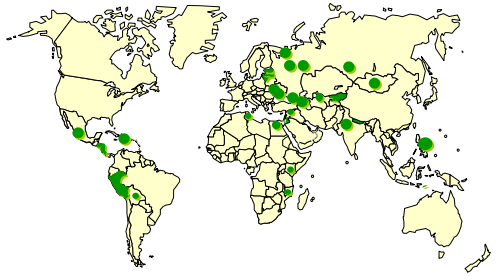


Figure 2. GLC-approved MDR-TB management programmes as of February 2006.

[5] Azerbaijan, Bolivia, Costa Rica, Dominican Republic, El Salvador, Egypt, Estonia, Georgia, Haiti, Honduras, India, Jordan, Kenya, Kyrgyzstan, Latvia, Lebanon, Lithuania, Malawi, Mexico, Moldova, Mongolia, Nepal, Nicaragua, Peru, the Philippines, Romania, Russian Federation, Syrian Arab Republic, Timor-Leste, Tunisia and Uzbekistan.

[6] World Health Organization. *Guidelines for the programmatic management of drug-resistant tuberculosis*. Geneva, Switzerland: World Health Organization; 2006 (WHO/HTM/TB/2006.361)

Currently less than 2% of the estimated incidence of MDR-TB patients get appropriate treatment endorsed by the GLC. While the last five years have been crucial for developing the foundation for practical approaches to manage MDR-TB in resource-limited countries, during 2006-2008, the GLC must scale-up MDR-TB treatment programmes to meet the global demand from countries wanting to ensure access to MDR-TB treatment.

Table 1. Impact of the GLC on the global fight against TB

	With GLC	Without GLC
✧ Global TB Control	GLC-approved MDR-TB control programmes substantially strengthen overall TB control[7]	Improvements in TB control occur slowly
✧ MDR-TB Control	• Resource-constrained countries able to purchase quality-assured second-line drugs as a result of major cost reductions • Prevention of the development of incurable forms of TB • Improved credibility of National TB Control Programmes (NTPs) • Improved cure rates and decreased death rates as witnessed in GLC-approved projects	• Most resource-constrained countries not able to treat MDR-TB adequately leaving patients with little hope of recovery, further spread of MDR-TB, incurable forms of TB and significant costs for families to purchase available second-line drugs of unknown quality • Reduced credibility of NTPs
✧ Number of cases	Decreasing as witnessed in GLC-approved countries[8]	Increasing and worsening of drug resistant patterns
✧ Capacity to diagnose and treat MDR-TB	Created or strengthened as access to MDR-TB treatment promotes training, laboratory and capacity development	Remains limited
✧ Rational use of quality-assured second-line drugs	Ensured through the GLC technical review panel and monitoring and evaluation system	Not ensured leading to the creation and circulation of incurable TB strains[9]
✧ Costs for quality-assured drugs[10]	Approximately US$ 3,000	Approximately US$ 20,000
✧ Cost of treatment regimen	Stable or decreasing as market for second-line drugs increases and amplification of drug resistance is prevented	Increased as countries cannot benefit from scale economies from pooled procurement and as drug resistance profiles deteriorate[11]
✧ Patient costs	Reduced	Expected continuous increase
✧ Drug safety, quality and efficacy	Ensured and increase in number of manufacturers producing quality-assured second-line drugs	Unknown and no mobilization of second-line drug manufacturers to apply to WHO prequalification project
✧ Evaluation of programmes	Ensured and more data contributing to further refinement of global MDR-TB control policies	Evaluation of individual patients, national programmes and global progress in MDR-TB control very difficult, if not impossible.

[7] Kim J.Y. et al. Multidrug-resistant tuberculosis to DOTS expansion and beyond: making the most of a paradigm shift. Tuberculosis, 2003, 83:59-65.
[8] Estonia and Latvia have seen a reduction in MDR-TB cases during the last five years.
[9] A recent study from the former Soviet Union revealed 31% of MDR-TB strains also resistant to three or more classes of second-line drugs signifying virtually incurable TB.
[10] Average price of drug regimen using GLC prices (US$ 3,000) and market prices (US$ 20,000).
[11] The former Soviet Union countries have the most severe drug resistance pattern. The GLC estimates that the drug costs alone to treat these patients are US$ 4000 compared to US$ 2500 in Asia and South America and US$ 1500 in Africa. With amplification of drug resistance not only will the regimens become more expensive, and cause more side-effects to patients, but also incurable strains will develop.

The Stop TB Partnership's Global Plan to Stop TB, 2006-2015, estimates that over 100,000 MDR-TB patients will begin treatment over 2006-2008 (with almost 800,000 new cases over the next ten years).[12] Any projects providing such treatment in developing countries will need GLC approval for access to quality-assured and GLC negotiated concessional priced second-line drugs. In addition, any projects receiving funding from the GFATM will also have to seek GLC approval as required by GFATM (see box below). This expected growth cannot be met by the currently capacity-constrained GLC and steps will have to be taken in 2006 to significantly increase the capacity and resources of GLC by beginning of 2007 at the latest.

GLC services required by the Global Fund to Fight AIDS, TB and Malaria

"…to help contain resistance to second-line anti-TB drugs and consistent with the policies of other international funding sources, all procurement of medications to treat MDR-TB must be conducted through the Green Light Committee (GLC)"

Third Board Meeting, 10-11 October, 2002
The Global Fund to Fight AIDS, Tuberculosis and Malaria

III. What the Green Light Committee does

Pre-application

Countries that plan to benefit from the GLC mechanism to manage MDR-TB need to perform several steps before having access to medicines and start treating patients. First, a needs assessment is conducted to determine the capacity in place and the gaps that need to be filled. This needs assessment, which is often facilitated by the GLC (but does not have to be), is conducted by MDR-TB experts, knowledgeable in MDR-TB management and the GLC mechanism, who visit the potential site to determine the current capacity for all aspects of MDR-TB management. One of the most important outcomes of this assessment is a plan for technical assistance to enable the country to meet the minimum conditions of the technical review panel of the GLC. Several aspects of TB control can vary between countries, but the following are essential to ensure the proper management of cases and prevent the emergence of drug-resistance to second-line drugs:

- Reasonable quality basic TB control programme (DOTS) for drug susceptible TB
- Quality assured laboratories for diagnosis and monitoring of treatment response
- Delivery of treatment under directly observed treatment
- Quality assured second-line drugs

Technical review

[12] Stop TB Partnership and World Health Organization. *Global Plan to Stop TB 2006–2015*. Geneva, World Health Organization, 2006 (WHO/HTM/STB/2006.35). Available at: www.stoptb.org/globalplan

Once a minimum of capacity is in place, the country submits to the GLC an application that details the plan for MDR-TB management. An independent technical review panel[13] evaluates the proposal to determine if it is in compliance with WHO guidelines. The technical review panels meets six times per year in pre-announced two-month review cycles. Staff at the GLC Secretariat coordinate project applications and their technical review. In order to make the process more efficient and to ensure that good quality applications are submitted, staff at the GLC Secretariat work closely with country projects during the pre-application phase and also conduct an initial application screening before sending the application to the technical review panel. The applications most likely to succeed are those that build on a sound needs assessment, that have received technical assistance to develop capacity, and that have received support in preparing the application.

If the application does not meet the minimum conditions, the GLC responds in one of three ways: if the concerns are minor, the applicant simply answers a set of questions and agrees to specific recommendations. If the concerns are more serious, the GLC may propose a site visit to assess the problem and determine the necessary response. If the concerns are unlikely to be resolved by a site visit, the applicant is invited to seek technical assistance to fix the specific problems and to resubmit a revised application once the major problems are satisfactorily resolved. Failure in the first application usually delays by several months the implementation of the project.

Access to quality-assured and reduced priced second-line drugs

GLC's procurement unit supports each approved project to purchase and manage quality-assured second-line drugs through a procurement agent. The unit works closely with country projects to make sure drug needs are forecast correctly and orders are placed in time with the procurement agent to prevent stock-outs.[14] The procurement agent has a contract with WHO for the purchase, storage and supply of second-line TB drugs to GLC approved projects. This is a pooled procurement mechanism which allows a further reduction in final cost of drugs to projects. The procurement agent only supplies drugs from "eligible" manufacturers. GLC's procurement unit collaborates with the WHO prequalification project to produce this list of eligible TB manufacturers and drugs that meet WHO standards for Good Manufacturing Practices (GMP) and for safety, quality and efficacy of the product. In order to increase the numbers of manufacturers, the procurement unit also works to identify and mobilize drug manufacturers to apply to the WHO prequalification project. The procurement unit has recently merged with the GDF, which will allow a more comprehensive approach with the TB drugs manufacturers and will benefit from the pooling of technical knowledge on drug management for TB drugs.

[13] The member institutions of the review panel are currently: US Centers for Disease Control and Prevention, Harvard Medical School/Partners in Health, the International Union Against Tuberculosis and Lung Diseases, the Medical Research Council of South Africa, the NTPs of Estonia and Latvia and WHO. An expansion to include other institutions is being discussed.

[14] This is necessary because of the time lag for production, lack of buffer stock and short shelf life of some drugs.

Monitoring and evaluation of GLC-approved programmes at global level

Regular monitoring and evaluations of programmes are organized by the GLC to ensure project compliance with MDR-TB management guidelines and the rational use of drugs, including timely access to them. The GLC also contributes to the evidence base necessary for future policy development by collecting and sharing information on epidemiological, clinical, cost and programmatic data from GLC-approved projects.

Structurally, the GLC consists of the following operational units (figure 3):

- The GLC Secretariat
- The Procurement Unit
- The Technical Review Panel

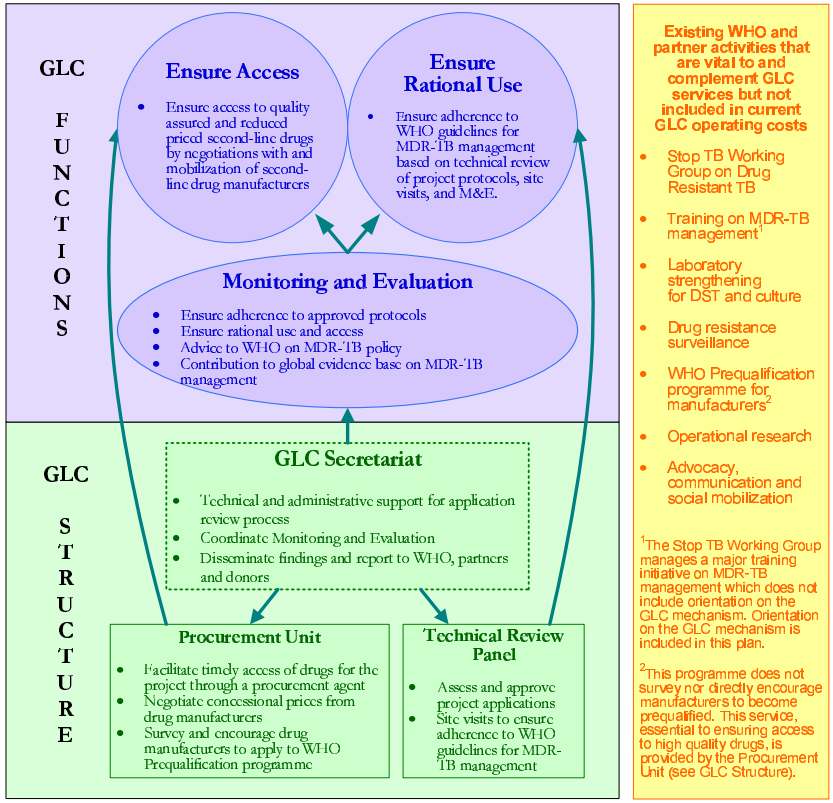


Figure 3. GLC Functions and Structural Units. The GLC functions in the above schematic are depicted by the blue circles, and GLC structural or administrative units are depicted by the green squares.

Provision of quality-assured MDR-TB treatment programmes is a global public good protecting all countries from further spread of MDR-TB and incurable TB strains. The GLC is the only mechanism in place capable of preserving this good. The GLC was created to expand access to second-line TB drugs while, at the same time, ensuring their rational use to prevent creation or amplification of drug resistance.

The GLC cannot function effectively unless other activities are running in parallel (yellow box in figure 3). These include the coordination and networking undertaken within the Stop TB Working Group on drug resistant TB; the work of WHO and partners in assisting countries in development of human resource capacity, strengthening of

laboratory capacity to carry out culture and drug susceptibility testing, drug resistance surveys, advocacy and social mobilization, and the production of a List of Approved Manufacturers of Second-line drugs by the WHO Prequalification Programme. Efficient functioning of the GLC depends upon the timely delivery of these related services.

IV. Growth projections for 2006-2008

In order to assess GLC's expansion and capacity needs, the number of projects expected to seek and receive GLC approval have to be first estimated. The number of applications received and the number of approved projects together determine the GLC's operating costs. The number of applications received drives the cost of application review including pre-application and pre-approval site visits. The number of approved projects drives the cost of drug procurement-related services and of monitoring and evaluation of these projects. For 2006-2008, the model assumes that 75% of all approved applications to the GLC are new projects and not expansions of existing projects.[15]

For the purposes of this business plan, two growth scenarios for increase in project applications to the GLC have been developed: 1) a steady growth scenario based on current and likely resource commitments to MDR-TB; and, 2) a rapid growth scenario based on treatment projections presented in the Global Plan to Stop TB, 2006-2015.

Scenario 1: Steady Growth Scenario

This scenario is estimated based on GLC staff's best understanding of current funding levels for MDR-TB treatment and country status for providing such treatment. It represents a steady growth in the number of MDR-TB cases brought under GLC-approved treatment. This scenario was developed by identifying the number of project applications and the corresponding number of patients expected from each country in each year. In this scenario, GLC aims to ensure quality assured, low cost treatment of 50,000 MDR-TB patients from 2006 to 2008 in at least 50 countries as the first phase of MDR-TB control scale-up (see Annex 2).

Scenario 2: Rapid Growth Scenario

Scenario 2 is based on the projected number of MDR-TB cases on treatment as presented in the Global Plan to Stop TB, 2006-2015. This is adjusted to exclude cases in high-income countries. Scenario 2 assumes that all these new cases will seek approval for treatment through the GLC. In this scenario, the GLC aims to ensure quality assured, low cost treatment of over 100,000 MDR-TB patients from 2006 to 2008 assuming resource commitments are as estimated in the Global Plan to Stop TB, 2006-2015. To calculate the number of applications the GLC will have to review under this scenario, we used an average number of patients per application based on GLC's experience. We used the average number of patients per application reviewed by the GLC between 2000 and 2005

[15] In future years, as more countries are familiar with MDR-TB management, a larger number of approved applications will be for expansions versus completely new projects.

for projects that included over 100 patients (GLC staff expects the size of projects to become larger in the future).

Figure 4 shows the number of applications (with the corresponding number of patients) projected for review by the GLC under each of the two scenarios over 2006-2008, as well as the numbers reviewed in the past by GLC over 2000-2005 (all shown cumulative by year). Both future scenarios start with an assumption for the number of applications to be submitted to GLC with a corresponding number of patients to be treated. It is then assumed (based on GLC's experience to date) that on average 80% of all applications received will be reviewed and approved within the first year, while 15 % will require further review (and communication with the projects) and will be approved in the second year after submission. The remaining 5% will not be approved on average.

Many countries are new to MDR-TB treatment and even more are new to the GLC and to the WHO guidelines for MDR-TB management. Thus, the expected growth over the next three years will be driven by new projects (many in new countries) as opposed to expansion of treatment in existing projects. This is a critically factored into the model for GLC expansion.

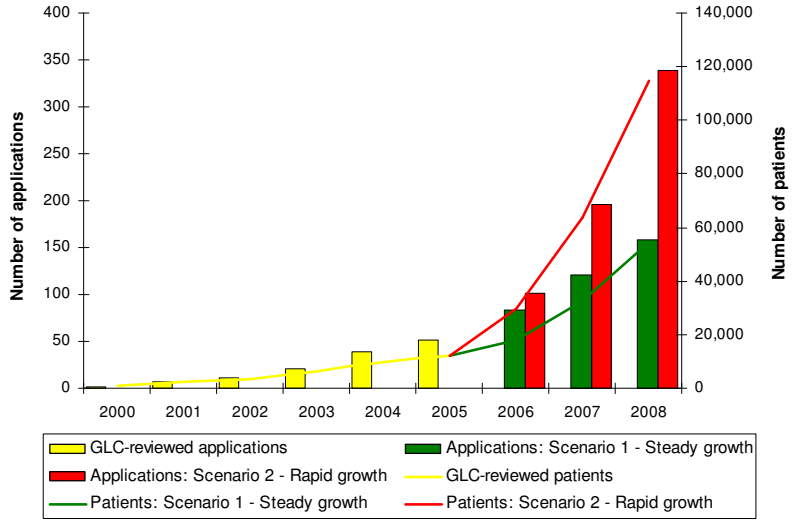


Figure 4: Growth projections for number MDR-TB patients and applications for GLC review (cumulative).

V. Business Model for GLC

Based on both growth scenarios above, there is a clear need for the GLC to expand its operations significantly in order to meet its objectives and to ensure timely and efficient response to country projects. The GLC will take the following approach in scaling-up to meeting the challenges of either growth scenario.

GLC secretariat

- Expansion of capacity to respond to increased number of applications and the increased demand for GLC services. This includes: regular communication with projects submitting applications and those with approved applications, coordinating the technical review panel, scheduling site visits, and coordinating monitoring and evaluation of approved projects.
- Expansion of pre-application phase activities and application screening – this is to increase the efficiency of the technical review process by ensuring higher quality applications are submitted for review.
- Coordinate GLC orientation workshops at international, regional, subregional level and in China, India and the Russian Federation, to improve the quality of GLC applications.

Technical review panel

- Streamline the application review process using newly developed WHO guidelines in order to increase productivity of the panel
- Expand the panel to seven members but require full application review by only two of the seven members
- In person meetings for each review cycle
- Support GLC members for their time in the technical review panel[16]

Monitoring and evaluation

- Hire country-level and regional staff for more efficient close-to-programme evaluation: ensuring quality scale-up of programmes using local expertise
- Annual evaluation of each active project by multidisciplinary teams in order to ensure rational use and adherence to WHO guidelines for MDR-TB management
- Half-yearly project monitoring: staff in WHO headquarters, region and country offices for analysis and dissemination of data reported by projects to GLC

Procurement unit

[16] The GLC technical review panel institutions have contributed with human resources with minimal compensation. These institutions cannot continue working with the GLC with the expected increase in the demand of its services without appropriate remuneration to their institutions.

- Expansion of capacity to meet increased demand for drug procurement and to ensure business-like liaison with the second-line drug procurement agency
- Increase the number of WHO pre-qualified manufacturers of second-line drugs in order to increase market competition (and thus lower prices) and to increase the availability of these drugs

VI. Modeling Resource Requirements

Based on the above model for expansion, a costing tool has been developed to estimate GLC staffing and resource needs under the two growth scenarios and to estimate its budget for 2006-2008.[17] A section of the tool outlines the assumptions used in detail. Annex 3 highlights the key assumptions.

The budget was estimated for three categories of expenses: 1) GLC staff; 2) Consultants; and, 3) Travel expenses. Travel expenses calculated in category (3) are related to activities listed below for categories (1) and (2) that will be carried out by GLC staff and consultants. Activities for GLC services for each category can be summarized as follows (see Annex 3 and "Assumptions" for more detail):

1) GLC staff - these represent all activities that will be conducted by staff (some in coordination in consultants listed in (2) below)

i) GLC Secretariat
- Management and reporting
- Application review and approval process including pre-application site visits (in coordination with Technical Review Panel)

ii) Procurement Unit
- Ensure access: efficient and timely supply of quality-assured drugs

iii) Monitoring and evaluation of country projects
- Annual evaluations
- Half-yearly monitoring (including analysis of data received from projects)

2) Consultants - these represent all activities to be conducted by consultants

i) Technical review panel
- GLC members for application review
- Consultants for pre-approval site visits

ii) Procurement unit
- Mobilize market for second-line drugs

iii) Monitoring and evaluation
- Annual evaluation teams to project sites

3) Travel expenses

i) Technical review panel
- Application review meetings
- Pre-application site visits
- Pre-approval site visits

ii) Procurement unit
- Meetings with procurement agent and approved manufacturers
- Meetings to mobilize new manufacturers

iii) Monitoring and evaluation
- Annual evaluation teams to project sites

[17] The GLC staffing and budgeting tool has been developed in collaboration with Partners for Health Reform*plus* (PHR*plus*) project. This tool is available upon request from WHO.

The GLC's staffing and resource needs are modeled to vary directly with the number of applications received by GLC and the number of approved projects. Table 2 presents the staffing needs for an expanded GLC under each growth scenario (this only includes staff needs and not consultants).

Table 2. GLC staff needs for two growth scenarios (cumulative). 2005 figures are actuals and 2006-2008 are estimates. For both scenarios, GLC staff will be stationed at WHO Regional Offices and in China, India and the Russian Federation.

	Number of fixed-term GLC staff	
Year	**Scenario 1**	**Scenario 2**
2005	5	5
2006	11	13
2007	21	29
2008	23	40

In calculating costs, WHO rates for staff, consultants and travel are used. Table 3 presents the total estimated costs for GLC and the associated number of patients treated in each growth scenario. Costs included are those for staff, consultants and travel.

Table 3. Total costs estimated in each growth scenario. 2005 figures are actuals and 2006-2008 are estimates.

	Number of cases in GLC-approved projects (cumulative from past years)		Total Costs (Annual US$)	
	Scenario 1	**Scenario 2**	**Scenario 1**	**Scenario 2**
2005	12,805	12,805		
2006	17,613	27,017	4,001,573	4,943,890
2007	30,075	56,834	6,654,149	10,056,469
2008	49,870	102,576	7,411,144	14,661,835
Total	**49,870**	**102,576**	**18,066,865**	**29,662,194**

The model does not currently have an inflation factor to adjust WHO rates upwards in 2007 and 2008 (it is based on current WHO rates).

As previously mentioned, for the GLC mechanism to be effective and efficient it is essential that complementary activities are performed by WHO and partners (figure 3, yellow box). This business plan focuses on the GLC mechanism and does not include estimated costs for these complementary activities.

Unit costs for GLC services

It may be useful to compare GLC's average cost of operation per patient to the cost of treatment per patient. Table 4 shows unit cost of US$ 227 per patient during GLC expansion and a low of US$ 143 after the expansion is complete. Compare this to an average cost of MDR-TB treatment (using GLC drug prices) of about U$ 3,000 versus treatment costs of over U$ 20,000 without GLC drug prices.

Table 4. GLC's unit cost of operation (average cost per patient in approved treatment)

	Unit Cost per Patient (US$/patient)	
	Scenario 1	**Scenario 2**
2006	227	183
2007	221	177
2008	149	143

VII. Resource commitments to date and gaps 2006-2008

The initial work of the GLC of developing a model for controlling MDR-TB in resource-limited countries was funded by the Bill & Melinda Gates Foundation, the United States Agency for International Development and WHO. Apart from providing two second-line drugs at concessional prices, Eli Lilly started to support the GLC monitoring and evaluation function in 2004. Also in 2004, the Stop TB Partnership began its support to mainly the technical review panel and the GLC secretariat through a donation from the Department for International Development, United Kingdom. From 2000 to 2005 the total budget for the GLC was US$ 16 million (an average of
US$ 1.3 million per year) (figures 5 and 6). From 2000 to 2005 the GLC funding increased more than three fold.

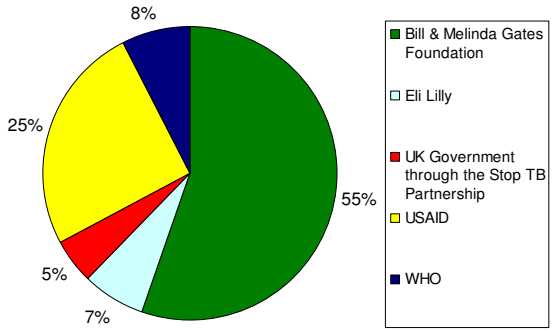


Figure 5. Total funding share of the Green Light Committee from 2000 to 2005. The average annual funds during these five years was 1.3 million US$ (15.6 million US$ for the five year period).

As a result of recent commitments from the US Agency for International Development and the Bill & Melinda Gates Foundation, the budget estimated for 2006 is US$ 2.5 million. For 2007 and 2008, however, with the current pledges the funding for the GLC is again at its 2001-2003 levels when MDR-TB control in resource-limited settings was still being piloted. The pledged amounts for 2006-2008 are US$ 4.7 million. This leaves gaps of US$ 13 million and US$ 25 million for the Steady and Rapid Growth scenarios, respectively (table 3 and figure 7).

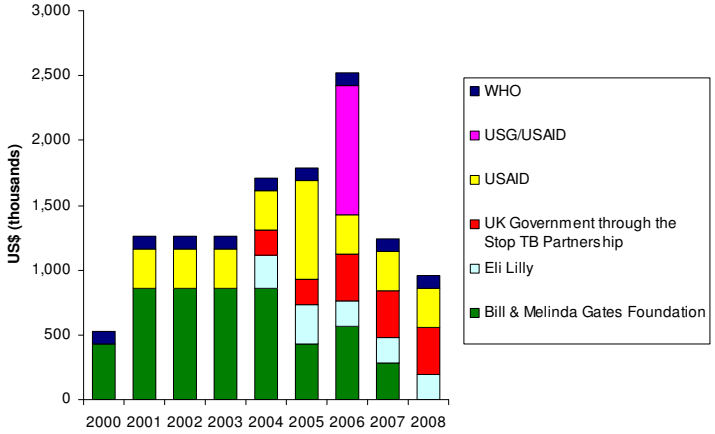


Figure 6. Funding sources for the GLC from 2000 to 2008 in thousands of US$. The funds from Eli Lilly for 2006 to 2008 are not secured. US$ 1,000,000 was made available in 2006 by the United States Global

AIDS Coordinator (USG) through USAID to support GLC costs associated with providing technical assistance and monitoring for GFATM grant recipients.

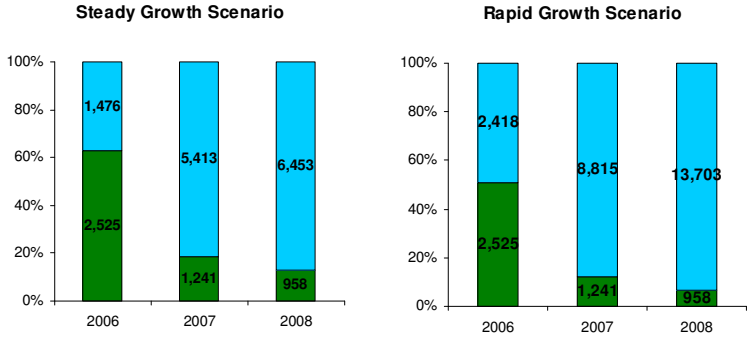


Figure 7. GLC pledged funding from 2006-2008 (in green) and funding gaps (in blue) based on the Steady and Rapid Growth Scenarios. The current pledges by year are US$ 2.5, 1.2 and 1 million. The budget gaps for the Steady Growth scenario for these years are US$ 1.5, 5.4 and 6.5 million. For the Rapid Growth scenario the gaps are US$ 2.4, 8.8 and 14 million.

VIII. Moving Forward

The Global Plan to Stop TB, 2006-2015, projects enrollment of 800,000 MDR-TB cases on treatment over the next ten years. A massive effort of donors, technical agencies and countries is required to achieve this goal. The GLC mechanism is the most powerful tool for scaling up MDR-TB management under the new Stop TB Strategy. Adequate funding for the GLC, will facilitate not only the implementation of the Global Plan to Stop TB, 2006-2015, but will also contribute to preserve the efficacy of second-line drugs as a global public good. Moreover, the GLC mechanism will play a fundamental role in promoting activities to tackle three major bottlenecks for scaling up MDR-TB management: supply of quality-assured second-line TB drugs and human resource capacity through direct support and, indirectly, TB and MDR-TB laboratory capacity.

The GLC provides a global public good protecting all people and countries from MDR-TB and incurable TB strains. Therefore, it is appropriate for the GLC to be funded by international funding mechanisms. In any event, resource-poor governments will be shouldering a large part of the cost for national MDR-TB treatment programmes. The GLC will therefore seek financial support at the international level. Furthermore, significant cost-savings are achievable through use of the GLC services: the GFATM for example is estimating already to have saved US$ 100 million by purchasing drugs through the GLC rather than on the open market. These savings are major compared to the annual GLC costs, even under the Rapid Growth Scenario.

This business plan provides the unit operating cost, per MDR-TB patient, of GLC services. Investors can thus determine how many patients will be supported by their investment.

The GLC could continue its work in 2006 at existing funding levels but these will support only a low-level of activity, falling far short of even the Steady Growth Scenario. Furthermore, the funding currently available in 2007 prevents any expansion of global MDR-TB control leaving only 2% of the world's MDR-TB cases under proper treatment.

Taxing projects in retrospect may be sufficient for ongoing expenditures but we need to have sufficient funding upfront to pay the GLC Secretariat staff based at WHO Headquarters. Should additional funds not be available for these staff members by December 2006, the sustainability of the GLC efforts will be jeopardized.

For the future success of global TB control, the GLC must be supported.

Annex 1. Countries with applications approved and under review by the Green Light Committee

Countries with GLC approved applications	Area	Year of approval	Cohort size	Technical partner[18,19]	External Funding[2]
Abkhazia		2004	156	MSF	MSF
Azerbaijan	Prison project	2005	100	ICRC	GFATM
Bolivia		2003	110		GFATM
Costa Rica		2003	24		
Dominican Republic		2005	125		GFATM
Egypt		2005	75		GFATM
El Salvador		2004	57		GFATM
Estonia	Countrywide	2001	400		
Georgia	Prison project	2004	50	ICRC	KfW
Haiti		2003	60	PIH	GFATM
Honduras		2004	50		GFATM
India	New Delhi	2005	100		
Jordan		2004	45		
Kenya		2004	40		GFATM
Kyrgyzstan		2004	50		GFATM
Latvia	Countrywide	2001	350		
Lebanon		2004	20		
Lithuania	Countrywide	2005	972	CDC	
Mexico		2003	125		
Moldova		2005	190		GFATM
Mongolia		2005	375		GFATM
Nepal		2004	350		DFID
Nicaragua		2004	21		GFATM
Peru		2000	3600	PIH	GFATM
Philippines		2000	950		GFATM
Romania		2004	400		GFATM
Russian Federation	Tomsk	2001	1530	PIH	GFATM
	Orel	2003	200	CDC	USAID/GFATM
	Arkhangelsk	2003	890	LHL	GFATM
	Ivanovo	2003	200		GFATM
Syrian Arab Republic		2004	161		
Timor-Leste		2005	18	Caritas and LHL	
Tunisia		2005	65		
Uzbekistan	Karakalpakstan	2004	946	MSF	MSF
Cohort size			**12,805**		

[18] WHO provides technical assistance to all countries.
[19] MSF, Médecins Sans Frontières, ICRC, International Committee of the Red Cross, GFATM, Global Fund to Fight AIDS, Tuberculosis and Malaria, KfW, Kreditanstalt Für Wiederaufbau, PIH, Partners in Health, CDC, US Centres for Disease Control and Prevention, LHL, Norwegian Association of Heart and Lung Patients, IFRC, International Federation of Red Cross and Red Crescent Societies, IUATLD, International Union Against Tuberculosis and Lung Disease, KNCV, KNCV Tuberculosis Foundation

Countries with applications under review	Area	Cohort size	Technical partner[1,2]	External Funding[2]
Benin		20	IUATLD	
Burkina Faso		10		
Ecuador		900	Canadian Lung Association	GFATM
Paraguay		50		GFATM
Russian Federation	Khakassia	40	IFRC/CDC	USAID/GFATM
	Buryatiya	110		GFATM
	Vladimir	150	CDC	USAID/GFATM

Annex 2. Projections for Scenario 1

	Projected number of MDR-TB patients to be treated under GLC support				Projected number of GLC applications to review			
	2006	2007	2008	Total	2006	2007	2008	Total
Armenia	100	150	170	420	1	1		2
Azerbaijan	100	250	350	700	1			1
Bangladesh	60	100	150	310	1			1
Belarus		50	100	150		1		1
Benin	20	10	10	40	1			1
Bolivia	50	50	50	150			1	1
Bosnia and Herzegovina	20	20	20	60	1			1
Bulgaria		50	100	150		1		1
Burkina Faso	10	20	20	50	1			1
China	500	1,500	3,000	5,000	2	3	3	8
Costa Rica	10	10	10	30	1			1
Djibouti	10	10	10	30	1			1
Dominican Republic	50	150	150	350		1		1
DRC Congo	100	300	300	700	1	1	1	3
Ecuador	100	300	500	900	1		1	2
Egypt	50	50	50	150			1	1
El Salvador	20	20	20	60			1	1
Estonia	100	100	100	300			1	1
Georgia	50	150	150	350	1			1
Haiti	40	40	40	120			1	1
Honduras	20	20	20	60				0
India	500	2,000	3,000	5,500	2	2	2	6
Indonesia			100	100		1	2	3
Jordan	45	45	45	135		1		1
Kazakhstan	50	200	800	1,050	1	1	2	4
Kenya	10	20	20	50			1	1
Kyrgyzstan	150	150	200	500		1		1
Latvia	200	200	200	600				0
Lebanon	10	10	10	30			1	1
Lithuania	100	200	300	600			1	1
Mexico	50	100	200	350	1	1	1	3
Moldova	50	100	100	250	1			1
Mongolia	75	150	150	375				0
Myanmar			150	150		1		1
Nepal	70	200	200	470		1		1
Nicaragua	10	10	10	30			1	1
Namibia	100	200	300	600	1			1
Paraguay	50	50	50	150	1			1
Peru	1,500	1,500	1,500	4,500		1		1
Philippines	250	500	1,500	2,250		1		1
Romania	100	200	350	650		1		1
Russian Federation	1,000	2,000	4,000	7,000	10	7	7	24
Serbia and Montenegro	20	20	20	60	1			1
South Africa		2,500	2,500	5,000		4	5	9

	Projected number of MDR-TB patients to be treated under GLC support				Projected number of GLC applications to review			
	2006	2007	2008	Total	2006	2007	2008	Total
Syrian Arab Republic	40	40	40	120			1	1
Tajikistan		25	50	75		1		1
Tanzania		20	50	70		1		1
Timor-Leste	10	10	20	40				0
Tunisia	10	20	20	50				0
Turkmenistan		30	30	60		1		1
Ukraine		200	300	500		2	2	4
Uzbekistan	200	300	300	800	1	1	1	3
Viet Nam		100	200	300		1		1
Total	6,010	14,450	22,035	42,495	32	38	37	107
GFATM related (countries in bold)	5,255	10,280	16,550	32,085	25	21	23	69
GFATM as percent of total	87%	71%	75%	76%	78%	55%	62%	64%

Note: A new MDR-TB case does not necessarily receive treatment the year the application is submitted for review, since new cohorts can be treated in subsequent years.

Annex 3. Green Light Committee services assumed in the Staffing and Budgeting Tool

Note: These assumptions are used to estimate total operating cost of the GLC. For further details on assumptions (such as, assumptions for site visits, evaluation missions, etc.) please see "Assumptions" page of the GLC Staffing and Budgeting Tool.

Abbreviations:
MO: Medical officer
TO: Technical officer

I) PERSONNEL NEEDS - GLC STAFF (ANNUAL FTE)	
GLC Secretariat	
Management and reporting	1 Manager (P6), 1 MO (P4), 0.25 budget officer and 1 administrative staff for overall management, advocacy, reporting to donors, liaisoning with partners and members, advice to WHO on policy re MDR-TB treatment. The MO will also coordinate with projects and with the procurement unit and M&E team to keep them apprised of project approvals.
Application review and approval process	1 MO (P4) with 1 TO (P2) for every 30 applications received in a year (assuming a workload of 5 applications per review cycle). This work includes: - Pre-application communication with country projects and pre-application project site visit - Application screening - Coordination of Technical Review Panel (TRP) to ensure timely and efficient review of applications - Coordination and communication with projects during and after application review As countries and projects are new to MDR-TB management and GLC guidelines, they will need pre-application support and site visit to ensure that they meet some minimum standards. This will save time and effort of the TRP later. It is assumed that GLC staff will do this.
Procurement services	
Ensure access: efficient and timely supply of quality-assured and reduced-priced drugs	1 TO (P4) and 1 secretary for the following activities: - Overall management of procurement services - Work closely with projects and procurement agent to: i) monitor order request and firm order placed by projects to procurement agent, ii) collect and analyze bi-annual reports on drug consumption and stock position by project - Coordination with manufacturers including developing accurate quarterly forecasts for some manufacturers - this is important given short shelf life of some drugs, the two year treatment course for MDR-TB, and limited production capacity for some manufacturers - Collaboration with the WHO Pre-qualification project to add new manufacturers and to develop list of eligible manufacturers - Reporting to GLC secretariat and GLC members 1 TO (P2) for every 30 approved projects for above activities

Monitoring and evaluation

Annual evaluations and half-yearly monitoring of country projects	1 MO (P4) and 1 administrative staff for overall management, coordination with country projects, coordination with regional staff and evaluation missions, and reporting to GLC Secretariat. The new business model for GLC calls for regional staff who will schedule and work with evaluations missions.
Data analysis	1 TO (P2) for data analysis for every 30 approved projects. This is assuming that country projects will send data to GLC on a half-yearly basis which will be compiled by this TO in a database and analyzed and reported.

II) PERSONNEL NEEDS - CONSULTANTS (FTE DAYS)
Costs for consultants are calculated based on WHO rate and the following needs.

Application review and approval process

GLC members of the Technical Review Panel for application review	A streamlined application review process will involve the following: - 2 TRP members to fully review an application and summarize comments - it is expected that not all TRP members will fully review each application - Remaining TRP members to review comments from full application review on and discuss each application but not necessarily fully review each application - All TRP members to meet once each review cycle to discuss each application and vote for approval or comments to be sent to the project - TRP members to review and approve letters sent to the country project from the GLC secretariat
Consultants for pre-approval site visits	Assume that 50 percent of all applications will require a site visit during the application review process to ensure adherence to their own protocols and WHO guidelines (this is not 100 percent since pre-application support and application screening is expected to minimize the need for this). Assume that this activity will be carried out by consultants and not by GLC staff: - 2 consultant team in country for 4 days with 2 days each for pre-trip preparation and post-trip reporting. (Note that a separate pre-application site visit

Procurement services

Mobilize market for second-line drugs	Assume one consultant for 30 days in India in 2006, China in 2007 and a third country in 2008 to work with GLC staff (and WHO Pre-qualification project) for the following activities: - Market research and survey to identify potential manufacturers for second-line drugs - Facilitate meeting with identified manufacturers to encourage them to meet WHO standards and enter the market - Identify short-list of potential manufacturers to increase competition and availability of quality-assured drugs

Monitoring and evaluation

Evaluation teams	Assume that all individual projects (not site expansions) will require one evaluation mission a year. These will be carried out by consultants: - 3 consultant multi-disciplinary team in project site for 5 days with 2 days for pre-trip preparation and 3 days for post-trip reporting.

III) TRAVEL NEEDS (NUMBER OF PERSON-TRIPS)
Costs related to travel are based on the number of trips required (as noted below).

Application review and approval process

Technical review meetings	Assume all TRP members will travel for in-person meetings once in each review cycle (6 review cycles a year)
Pre-application site visits	Assume one person-trip (by GLC staff) for each project preparing to submit an application to the GLC.
Pre-approval site visits	Assume two person-trips (by consultants) for 50 percent of the projects seeking approval.

Procurement services

Ensure access: efficient and timely supply of quality-assured and reduced-priced drugs	Assume for travel needs that GLC staff has to meet with procurement agent and manufacturers: - 1 staff meeting with procurement agent every three months (two procurement agents until 2007) - 8 person-trips per year - 1 staff meeting with two manufacturers every three months - 8 person-trips per year
Mobilize market for second-line drugs	Assume for travel needs that GLC staff and WHO Pre-qualification staff have to travel to the countries noted above: - 4 persons traveling to two meetings per year (8 person-trips)

Monitoring and evaluation

Evaluation missions	Assume 3 person-trips a year for each approved project