THE GREEN LIGHT COMMITTEE (GLC) INITIATIVE

FREQUENTLY ASKED QUESTIONS
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1. What is the Green Light Committee Initiative?

Component two of the Stop TB Strategy calls for the control and prevention of multidrug-resistant tuberculosis (MDR-TB) through: (i) increased access to quality-assured second-line anti-TB drugs; and (ii) prevention of development of resistance to anti-TB drugs.


Established in 2000, the GLC Initiative is the mechanism that enables access to affordable, high-quality, second-line anti-TB drugs for the treatment of MDR-TB. Its objectives are:

- ensuring effective treatment of patients with MDR-TB in accordance with guidelines published by the World Health Organization (WHO) on the programmatic management of MDR-TB;
- increasing access to technical assistance to facilitate rapid scale-up of MDR-TB management;
- increasing access to high-quality, low-cost, second-line anti-TB drugs for the treatment of MDR-TB among well-performing programmes;
- preventing the development of resistance to second-line anti-TB drugs by ensuring rational drug use;
- advising WHO on policy-related matters to effectively prevent and control MDR-TB based on the best available scientific evidence.

The GLC Initiative therefore contributes to reducing transmission of TB, preventing further drug resistance and ultimately reducing the global burden of TB. The Initiative is coordinated by the GLC Secretariat, which is hosted and administered by WHO. The Global Drug Facility (GDF), an arm of the Stop TB Partnership, which is also hosted and administered by WHO, carries out drug procurement for GLC-approved programmes. Technical assistance to MDR-TB programmes is coordinated and delivered by WHO and its technical partners. Please see Diagram 1.
2. What assistance does the Green Light Committee Initiative offer to countries in treating MDR-TB patients?

The Green Light Committee Initiative offers assistance to countries with MDR-TB patients by providing:

- expertise in the programmatic management of MDR-TB based on best available evidence and collective experience;
- high-quality, second-line anti-TB drugs to treat MDR-TB patients at reduced prices;
- technical assistance on management of MDR-TB through a wide network of technical partners;
- peer support and knowledge sharing in communication with other GLC-approved programmes;
- independent external monitoring and evaluation of GLC-approved programmes to help develop appropriate treatment regimens;
- funding for MDR-TB programmes and concessionally-priced second-line anti-TB drugs from the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) and UNITAID.

**Note.** The GLC Initiative is NOT a funding mechanism; rather, it ensures that programmes are technically sound so that the Global Fund and UNITAID can continue to disburse funds. Feedback from GLC-approved programmes provides
important clinical and programmatic experience needed to develop global standards for the prevention and control of drug-resistant TB.

3. What is the Green Light Committee?

The GLC is a component of the GLC Initiative that serves as a technical advisory body to the Stop TB Partnership and WHO. Its primary tasks are:

- **reviewing** applications from countries that wish to benefit from quality-assured, second-line anti-TB drugs at reduced prices;
- **promoting** technical assistance to countries throughout the application and implementation processes;
- **monitoring** and **evaluating** GLC-approved programmes to assess their progress and continued adherence to WHO guidelines;
- **informing** WHO of GLC findings, deliberations and recommendations, and assisting WHO with developing policy to control MDR-TB.

The GLC is comprised of representatives from institutions with specific programmatic, clinical, advocacy, scientific and managerial expertise. Its membership rests with institutions, not individuals. WHO is a permanent member of the Committee. All other institutions are normally drawn from the Stop TB Partnership Working Group on MDR-TB. Each institution designates two representatives, a principal and an alternate. Institutions are eligible for Committee membership for a maximum of two years. The GLC Secretariat widely disseminates an open call for membership whenever a vacancy occurs or is anticipated.

The current members of the Green Light Committee are:

- Partners In Health (PIH) - *Current Chair*
- U.S. Centers for Disease Control (CDC)
- Hospital General de "Francisco J. Muniz"
- International Union Against Tuberculosis and Lung Disease (IUATLD)
- KNCV Tuberculosis Foundation
- Médecins sans Frontières (MSF)
- State Agency for TB & Lung Disease, Latvia
- World Care Council (WCC)
- World Health Organization (WHO) - *standing member*
4. How do programmes apply to the Green Light Committee?

For instructions on how to apply to the Green Light Committee please refer to the GLC Website http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/.

5. What is the application process? How does the Green Light Committee review applications?

Applications are reviewed by and decided upon by members of the GLC; a final decision requires consensus among Committee members. Each member is allowed one vote, and the Committee freely consults external experts as needed. All Committee members are required to observe rules of conflict of interest and confidentiality and are therefore not permitted to vote on applications from applicants with whom they have or have had a direct relation.

The process usually starts with a pre-application phase, which may include a needs assessment to determine local capacity and gaps that need to be filled. The GLC itself does not assist countries with preparation of applications. Countries in need of technical assistance should contact WHO or technical partners of the Stop TB Partnership. A needs assessment is conducted by experts who are knowledgeable in MDR-TB management and the GLC Initiative. These experts, who may or may not be members of the Committee, visit the applicant’s site to determine the current capacity for all aspects of MDR-TB management. An important outcome of the needs assessment is a technical assistance plan that will help the applicant meet the minimum conditions to move to the next phase – the application process – that is conducted by the Committee. Please see Diagram 2.

![Diagram 2: The GLC Application Process](image)

After the minimum requirements are in place and well before you plan to start treating patients, you should:
• prepare and submit an application to the GLC Secretariat according to the procedures outlined in the WHO guidebook *Instructions for applying to the Green Light Committee for access to second-line anti-tuberculosis drugs*;
• work closely with the GLC Secretariat to address comments, questions or problems that were identified by the Committee during review of the application;
• facilitate a site visit, if requested by the Committee, to assess problems and determine necessary responses;
• seek technical assistance to solve specific, major problems if the concerns are unlikely to be resolved by a site visit, and within three months, re-submit a revised application after these problems are satisfactorily resolved.

Application review cycles cover a period of two months, beginning on 20 January each year. The outcome of the review process is communicated to the applicant by the GLC Secretariat before the end of the review cycle. Applications for expansion of GLC-approved programmes are reviewed as soon as they are received.

**Note.** This process should take into account the option of fast track application and drug requests for very small cohorts, including a single patient. To ensure that there is sufficient time to complete all necessary steps in the process (for example, application review, site visit preparations, drug procurement after the application is approved), it is recommended that applicants submit applications to the GLC Secretariat at least one year before the start of treatment for the first patient in the programme. For fewer than 50 patients, the GLC uses a fast-track application review process.

6. **How does the Committee approve programmes? What are the key success factors for a well-functioning programme?**

Before submitting an application to the GLC, programmes must adhere to the following minimum requirements:

• secure political and administrative support for the planned activities;
• access to a functional and quality-assured laboratory that has culture diagnostic facilities, that can provide drug-susceptibility testing (DST) and that is quality assured by a supranational TB reference laboratory;
• access to functioning health-care facilities;
• capacity to ensure patients’ adherence to the treatment regimen under patient-centred
directly observed therapy (DOT), without exception;
• access to a functioning information and data management system.

Experience shows that with the above five elements in place, programmes are much more
likely to succeed and become approved by the GLC.

7. **What second-line anti-TB drugs are available for programmes approved by the
Committee, and how are drug prices determined?**

Major price reductions in second-line anti-TB drugs are achieved for GLC-approved
programmes through negotiations with pharmaceutical companies and pooled procurement of
drugs. The International Dispensary Association (IDA), based in the Netherlands, is the drug
procurement agent for GLC-approved programmes on behalf of the GDF and the GLC. The
IDA, which was selected through a tender process, continuously negotiates the best possible
prices for second-line anti-TB drugs.

The second-line anti-TB drugs that are available for GLC-approved programmes at negotiated
prices are:

- kanamycin, powder for injection – 1 gram vial
- capreomycin, powder for injection – 1 gram vial
- cycloserin, 250 mg capsule
- ethionamide, 250 mg tablet
- prothionamide, 250 mg tablet
- levofloxacin, 250 and 500 mg tablet
- ofloxacin, 200 mg tablet
- PASER, 4 gram granule sachet.

The IDA adds a 7% procurement agent fee to the drug prices to cover its operational costs.
This fee is included in the prices quoted on the GDF web site and in IDA quotations to
GLC-approved programmes. IDA quotations are valid for 30 days only, because the
availability of second-line anti-TB drugs at concessional or negotiated prices varies and prices
are therefore subject to change.
For other second-line anti-TB drugs that are recommended in WHO MDR-TB treatment guidelines and are not listed above, GDF and IDA can supply quality-assured drugs at best available prices. Further details about second-line anti-TB drugs (for example, dosage, pack size, prices) can be found on the GDF web site.¹

Note. Following an agreement between WHO and the drug manufacturer Eli Lilly, limited quantities of capreomycin and cycloserine are offered at concessional prices to GLC-approved programmes. The prices of these two drugs are therefore more likely to vary given the availability of these two drugs at the time of procuring an approved request.

8. How do programmes approved by the Committee procure second-line anti-TB drugs?

Following approval of a programme by the GLC, the GLC Secretariat informs the GDF, which manages the procurement of second-line anti-TB drugs for GLC-approved programmes. The programme is required to calculate the quantity of required drugs according to the approved regimens for the cohort number approved by the GLC. Based on this calculation, the GDF sends a letter to the IDA authorizing the procurement of drugs for the programme. Then, the GDF establishes and facilitates contact between the programme and the IDA. The GLC-approved programme works directly with IDA, copying GDF, to:

- obtain and confirm quotations;
- conclude the sales contract;
- define delivery schedules and payment modalities;
- detail and produce all the necessary documents required for the importation of the drugs into the country where the programme is located.

For subsequent drug orders of the authorized quantity, the GLC-approved programme must contact the IDA directly, copying GDF, to request quotations until the balance of the GLC-authorized quantity is extinguished for the approved cohort of patients. For programmes that benefit from UNITAID support, the GDF Secretariat will guide the programmes based on their country-specific situation.

¹ http://www.stoptb.org/gdf/drugsupply/drugs_available.asp
To obtain drugs above the authorized quantity, the GLC-approved programme must submit a request to the GLC for an expansion of the cohort. If the request is approved, GDF will be notified and the drug procurement process will continue as described above.

9. **What are the lead times for ordering second-line anti-TB drugs?**

Following receipt of payment for the approved quotation by the IDA, there is a lead time of approximately 4–6 months for the drugs to be delivered to the programme at the port. It is recommended that programmes factor in additional lead time that is required for requesting and reviewing quotations, disbursing the necessary funds for the drug order and for other steps in the importation process such as customs clearances. To ensure smooth and uninterrupted delivery of the drugs, it is important that programmes plan and forecast the procurement of drugs in a timely manner.

Most manufacturers of second-line anti-TB drugs produce these drugs on demand; stocks are currently not kept, although plans for a strategic rotating stockpile are under way. Even when this stockpile is in place, programmes should forecast, plan properly and communicate with the IDA to ensure that a continuous supply of drugs is available to meet the programme’s needs.

**Note.** Lead times are expected to be reduced before the end of 2007 following the creation of the stockpile of second-line anti-TB drugs in the IDA warehouse. Forecasting and planning of second-line drug orders, however, remain important tasks of the GLC-approved programme’s project manager to guarantee uninterrupted supply of drugs, especially for large programmes.

10. **How is the quality of second-line anti-TB drugs assured?**

Second-line anti-TB drugs supplied to GLC-approved programmes should comply with national regulatory standards, WHO Prequalification Programme standards for good manufacturing practices (GMP) set by WHO/Quality Assurances & Safety: Medicines (QSM) and the Global Fund’s quality assurance policies (for programs with Global Fund grants). The drugs currently supplied through the GLC Initiative are: (i) prequalified by WHO; (ii) approved for marketing by a stringent regulatory authority (defined as a national drug regulatory authority participating in the International Conference on Harmonization of
Technical Requirements for Registration of Pharmaceuticals for Human Use or the Pharmaceutical Inspection Co-operation Scheme); or (iii) manufactured at a site that is compliant with WHO or stringent regulatory authority GMP standards.

The Global Drug Facility (GDF) and the International Dispensary Association (IDA) are responsible for the quality assurance and quality control of second line anti-TB drugs supplied to GLC-approved programmes. In the future, an external agent will be contracted to perform quality control on second line anti-TB drug batches supplied by IDA.

The GDF, in its efforts to expand its product range, aims to provide and tender for products that are either WHO prequalified and/or registered for marketing by a stringent regulatory authority.

11. What is the WHO Prequalification Programme?

The WHO Prequalification Programme facilitates access to quality-assured medicines through the assessment of products and inspection of manufacturing facilities. Further information about the Programme and invitations for Expression of Interest required to submit TB products for evaluation is available from the WHO Prequalification Programme web site.²

12. What should programmes do if second-line anti-TB drugs are not registered in the country?

Countries may require that second-line drugs are registered before they can be imported. Some second-line anti-TB drugs have already been registered with drug regulatory authorities in many countries. GLC-approved programmes based in countries requiring registration should inform the GLC procurement agent – the IDA – at the earliest possible stage. It is important to begin the registration process as soon as possible because it can take up to two years in some countries. After it has been notified by the programmes, the IDA can facilitate transfer of the required information and documentation from manufacturers to the registration authority in the country of destination. If the time required to properly register the drugs will delay deliveries to the programme, countries should seek a temporary waiver of drug registration to allow drugs to arrive in time for patients to be treated, while continuing to

² http://mednet3.who.int/prequal/
properly register the drugs products with authorities. Waivers of drug registration should never be considered a long-term solution for programmes.

National project managers of GLC-approved programmes are responsible for arranging the necessary requirements, including the registration status, for importation of second-line anti-TB drugs for continuous supply to the GLC-approved programme. WHO and the IDA can help facilitate the registration process.

13. How can programmes not approved by the Committee purchase second-line anti-TB drugs?

Programmes not wishing to benefit from the services of the GLC Initiative, including its concessional prices, can purchase second-line anti-TB drugs at market prices direct from suppliers. Access to second-line drugs is not restricted or controlled by any institution, but access to quality-assured, affordable, second-line anti-TB drugs through the GDF is provided only to programmes approved by the GLC.

14. How does the Green Light Committee monitor programmes?

Programmes approved by the GLC are monitored annually via site visits to ensure continued adherence to their original protocols and WHO guidelines. Monitoring and evaluation activities are managed by the GLC Secretariat and WHO regional offices and are carried out by GLC-endorsed consultants. The team leader of each monitoring mission is responsible for submitting a written report to the GLC Secretariat within two weeks following the site visit. In addition, the project manager for each GLC-approved programme is required to submit an annual report to the GLC Secretariat within one month of the anniversary of the programme’s approval.

Gaps or deficiencies identified in either the annual programme report or the monitoring report should be rectified by the programme seeking technical assistance. If, after reassessment, the programme is still found to be in violation of the approved protocol, the GLC has the option of withdrawing approval for further procurement of second-line anti-TB drugs through the GLC Initiative.
15. Whom should programmes contact for assistance?

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<tr>
<th>For information about assistance with setting up the programme:</th>
<th>For information about GLC monitoring and evaluation missions:</th>
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<tr>
<td>• WHO country or regional office (<a href="http://www.who.int">www.who.int</a>)</td>
<td>• GLC Secretariat (<a href="mailto:glc_secretariat@who.int">glc_secretariat@who.int</a>)</td>
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<tr>
<th>For information about technical assistance (at any time):</th>
<th>For questions about the GDF and its procurement agent (the IDA):</th>
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<tr>
<td>• WHO country or regional office (<a href="http://www.who.int">www.who.int</a>)</td>
<td>• GDF (<a href="mailto:gdf@who.int">gdf@who.int</a>)</td>
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<tr>
<td>• WHO TB Team (<a href="mailto:tbteam@who.int">tbteam@who.int</a>)</td>
<td>• IDA (<a href="mailto:service@idafoundation.org">service@idafoundation.org</a>)</td>
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<tr>
<td>• GLC Secretariat (<a href="mailto:glc_secretariat@who.int">glc_secretariat@who.int</a>)</td>
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16. How do the Global Drug Facility, the Green Light Committee, the Global Fund and UNITAID collaborate?

Recognizing the need to address the growing problem of MDR-TB, the GDF, the Global Fund, the GLC and UNITAID are working together to increase access to, and affordability of, high-quality, second-line anti-TB drugs.

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<tr>
<th>Service providers</th>
<th>Green Light Committee Initiative</th>
<th>Global Drug Facility</th>
<th>Global Fund to Fight AIDS, Tuberculosis and Malaria</th>
<th>UNITAID</th>
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<tr>
<td>Green Light</td>
<td>The GLC Initiative aims to increase access to preferentially priced, quality assured, second-line anti-TB drugs for the treatment of drug resistant TB in resource-limited settings. Its activities are coordinated by a GLC Secretariat hosted by WHO. The objectives of the Initiative are: (i) increasing access to high-quality, second-line anti-TB drugs among well-performing TB control programmes; (ii) ensuring proper use of second-line anti-TB drugs to prevent the development of acquired resistance to second-line anti-TB drugs; (iii) serving as a technical advisory body to WHO and its Member States for development of policies and procedures for the control and management of drug-resistant TB.</td>
<td>The GDF is an initiative of the Stop TB Partnership that responds to four key drug-related impediments to achieving the global targets for TB control: (i) lack of resources to purchase anti-TB drugs; (ii) inadequate in-country procurement mechanisms to purchase high-quality anti-TB drugs; (iii) lack of standardization of anti-TB drugs used internationally; and (iv) inadequate management and monitoring of anti-TB drugs. Drug procurement for GLC-approved programmes is managed and coordinated by the GDF.</td>
<td>The Global Fund attracts, manages and disburses additional resources through a public–private partnership that makes a sustainable and significant contribution to the reduction in the number of infections, illnesses and deaths; thereby mitigating the impact caused by HIV/AIDS, tuberculosis and malaria in countries in need and contributing to poverty reduction as part of the Millennium Development Goals. To help limit resistance to second-line anti-TB drugs, the Global Fund requires that all procurement of these drugs under Global Fund grants is conducted through the GLC Initiative.</td>
<td>UNITAID is an international drug purchasing facility that was established to provide long-term, sustainable and predictable funding to increase access and reduce prices of high-quality drugs and diagnostics for the treatment of HIV/AIDS, malaria and tuberculosis. It works through the collaborative efforts of donors and collaborating partners and is not a separate legal entity. UNITAID is hosted and administered by WHO and provides funding for grants of second-line anti-TB drugs to GLC-approved programmes.</td>
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The Green Light Committee Initiative: frequently asked questions

### How we work together

The GLC reviews, evaluates and monitors technical aspects of beneficiary country MDR-TB management programmes, which operate with funding from governments, bilateral and multilateral organizations, Global Fund grants and through other independent mechanisms, such as UNITAID. The GDF coordinates all procurement and delivery functions for all GLC-approved programmes, allowing negotiation of better prices for second-line anti-TB drugs by pooling the procurement needs and resources of many programmes. The Global Fund and GLC monitor the performance of the MDR-TB management programmes, including programme results and targets relevant to MDR-TB scale up.

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<th>17. How does the Green Light Committee Initiative support Principal Recipients of Global Fund grants with an MDR-TB component?</th>
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<tr>
<td>Principal Recipients of Global Fund grants with an MDR-TB component have access to:</td>
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<td>• high-level expertise on the management of MDR-TB programmes based on best available evidence and collective experience;</td>
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<td>• high-quality drugs to treat MDR-TB at considerably lower than market prices;</td>
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<td>• technical assistance through a wide network of technical partners;</td>
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<td>• peer support and knowledge sharing in communication with other GLC-approved programmes;</td>
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<td>• independent external monitoring and evaluation of programmes.</td>
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<th>18. How should Principal Recipients of a Global Fund grant that includes an MDR-TB component proceed?</th>
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<td>At its third Board Meeting, the Global Fund recognized that the GLC Initiative provides a package of services for treatment of MDR-TB that cannot be disaggregated, and determined that Principal Recipients of Global Fund grants must procure their second-line anti-TB drugs through the GLC Initiative. Global Fund Principal Recipients with an MDR-TB component are responsible for:</td>
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<td>• submitting an application to the GLC at least one year before the start of treatment for the first patient in the programme;</td>
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<tr>
<td>• preparing and maintaining a detailed forecast and plan for second-line anti-TB drug needs throughout programme implementation;</td>
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• paying the cost-sharing element of US$50,000 per grant per calendar year for the packages of services provided by the GLC.

**Note:** Global Fund grant recipients should not expect to cover all the technical assistance needs from the payment of the cost-sharing element of US$50,000. Experience shows that countries' needs in managing an MDR-TB programme are extensive and highly demanding, therefore it is recommended that national programme managers include the complete request for technical assistance in the Global Fund proposals or approach other donors and partners for more funding.

**19. How are services provided by the Green Light Committee Initiative funded?**

The Stop TB Partnership and WHO raise funds to sustain the work of the GLC, in accordance with WHO established policies and principles, from national and government-supported agencies, regional and international organizations, nongovernmental organizations, universities, research institutions and other sources.

In addition, following the 13th Board Meeting of the Global Fund, a cost-sharing mechanism was introduced into all Global Fund grants with an MDR-TB component. This cost-sharing mechanism is a flat-fee payment of US$50,000 to the GLC Secretariat per Global Fund grant, per year of implementation of an MDR-TB component. Funding from this mechanism helps support the efforts of the GLC Initiative in countries receiving Global Fund grants.

Funds are used for convening GLC meetings, supporting the work of the GLC Secretariat, participating in the GLC by member institutions, carrying out needs assessment of programmes, monitoring and evaluating GLC-approved programmes, and in some cases, paying for second-line anti-TB drugs for GLC-approved programmes (through support from UNITAID).

The WHO Stop TB Department monitors new funding initiatives to explore possibilities of funding the MDR-TB management scale up in countries with limited resources.
20. How should UNITAID-funded recipients with an MDR-TB component proceed?

Countries that have been approved for UNITAID support should have received a letter from the Stop TB Partnership informing them of the UNITAID initiative. Based on the country and programme-specific situation, the letter outlines the steps required in order to receive drugs. GLC and GDF standard terms and conditions apply for the procurement of UNITAID-funded drugs. If the scale-up is implemented within the Global Fund grant framework, the Global Fund Portfolio Manager should be contacted for more information.

21. How has the Green Light Committee performed?

The number of countries applying to the GLC has increased steeply over the years. Since March 2000, the GLC has received and reviewed applications from 48 countries to manage and treat MDR-TB. In 2006 alone, the GLC reviewed and approved applications for a total of 12,604 patients, a six-fold increase over the number of patients approved in 2005. From September 2007, national TB control programmes worldwide were enabled to provide high-quality drugs and cost-effective treatment to almost 30,000 patients. Further information about the performance and activities of the GLC is contained in the 'Annual Report 2006 for the Green Light Committee of the Stop TB Working Group on Multidrug-Resistant Tuberculosis'.

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3 Available at www.stoptb.org/gdf/glc/