GREEN LIGHT COMMITTEE
THE STOP TB PARTNERSHIP WORKING GROUP

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APPLICATION INSTRUCTIONS

Subgroup of the stop tb partnership working group on multidrug-resistant tuberculosis

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http://www.who.int/entity/tb/challenges/mdr/greenlightcommittee/en/index.html

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Introduction

Management of drug-resistant tuberculosis (DR-TB) under programmatic conditions is a complex intervention in public health, not yet fully established in many countries. The treatment that does not meet international standards, however, risks amplifying and spreading multidrug-resistant tuberculosis (MDR-TB) and extensively drug resistant tuberculosis (XDR-TB) further. The global response to MDR-TB and XDR-TB, embedded in the Global Plan to Stop TB 2006-2015[1], has the target of achieving universal access to diagnosis and treatment of MDR-TB by 2015. The WHO *Guidelines For The Programmatic Management Of Drug Resistant* Tuberculosis (herein after referred to as the WHO Guidelines)[2] provide recommendations for appropriate management of DR-TB to control it, avoid generation of further drug resistance and taking into consideration community based / ambulatory and patient centered care. The Green Light Committee (GLC) was created by WHO and its partners in January 2000 with the objective to help programmes/projects[3] develop and implement strategies for the management of DR-TB,

The GLC a subgroup of the Stop TB Partnership's Working Group on MDR-TB and serves both WHO and the Stop TB Partnership (STP) as an advisory body. The GLC has the following functions:

- Evaluates applications for access to second-line anti-TB drugs (SLD) in relation to current WHO guidelines, available evidence, and collective experience;
- Advises WHO and the STP as to the outcome of each application;
- Monitors the progress and performance of GLC-approved programmes/projects;
- Promotes the development of programme/project capacity to manage DR-TB;
- Promotes capacity development for expert technical assistance and consultation on DR-TB;
- Promotes and participates in the analysis of data from GLC-approved programs and in the dissemination of new data-driven information on treatment of DR-TB.

Today GLC forms part of the Green Light Committee Initiative ("GLC Initiative"), which is a mechanism that:

- Establishes compliance of country MDR-TB programmes/projects with the WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis and other international standards set in the field of TB care and control;
- Enables access to affordable, high-quality, second-line anti-TB drugs for the treatment of MDR-TB;
- Provides monitoring and technical assistance to countries in scaling up their MDR-TB programmes/projects;

[1] http://www.stoptb.org/globalplan/

[2] WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis, emergency update 2008 (WHO/HTM/TB/2008.402 http://www.who.int/tb/publications/2008/programmatic_guidelines_for_mdrtb/en/index.html.)

[3] The GLC encourages countries to scale up their MDR-TB response by changing initial projects with small patient cohorts into nation-wide MDR-TB programmes.

- Advises WHO on policy-related matters to effectively prevent and control MDR-TB based on the best available scientific evidence;
- Fosters research to strengthen the evidence base for the programmatic management of DR-TB.

The GLC consists of nine member institutions[4] that are drawn from the Stop TB Partnership Working Group on MDR-TB and chosen based on a competitive selection process which is regulated by the GLC Operating Procedures. The member institutions have a demonstrated leadership in public health and are active in TB care and control internationally. Each member institution is represented by two experts in programmatic, scientific, clinical, or microbiological aspects of TB who serve WHO in an advisory capacity. The GLC freely consults outside experts as needed. All members are required to adhere to rules of conflict of interest and confidentiality and, thus, cannot participate in the decision-making on applications from programmes/projects, in relation to which they have or had a direct or perceived conflict of interest. Each institution is allowed one vote, and all decisions are taken on the basis of consensus.

The services offered by the GLC include the following:

- Pre-application assistance with DR-TB programme/project development and needs assessment;
- Expert technical review of applications;
- Evaluation of proposed programmes/projects;
- Regular monitoring of approved programmes/projects;
- Peer support and knowledge sharing with other GLC-approved programmes/projects;
- Promotion of training and technical assistance;
- Contribution to the evidence base for the programmatic management of DR-TB.

The Global Drug Facility (GDF) is presently the procurement arm of the GLC Initiative, with the Secretariat housed at WHO, which, together with its procurement agent(s) coordinates and implements drug order processes. Currently, all GLC approved programmes/projects are required to use the GDF procurement mechanism. GDF can begin providing services after a programme/project has received approval from the GLC in the so called operation phase. For detailed instructions on procurement, please refer to the Procurement Manual for MDR-TB Projects under the Green Light Committee Mechanism[5].

To benefit from the services of the GLC and, more broadly, of the GLC Initiative, programmes/projects must: (1) build on the foundation of a solid DOTS-based TB care and control programme/project; (2) design their programme/project within the principles put forth in the most recent WHO *Guidelines*; and (3) write their application in the format prescribed in these *Green Light Committee Application Instructions* (herein after referred to as the *Instructions*). Programmes/projects receiving approval can benefit from the pooled procurement of WHO prequalified quality assured SLD at preferential prices. Moreover, the application process leads to enhanced communication between programme/project sites, WHO, other public health agencies and the GLC Initiative. It also facilitates technical assistance to the programmes/projects. Feedback from programmes/projects provides important clinical and programmatic experience needed to develop global standards for the prevention and control of DR-TB.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) at its Third Board Meeting[6] recognized that the GLC provides a package of services for MDR-TB care and control that cannot be disaggregated. It further determined that Principal Recipients of Global Fund grants would be required to procure SLD through the GLC Initiative, including the pooled procurement mechanism (Third Board Decision).

[4] The current GLC member institutions are Partners In Health (PIH), KNCV Tuberculosis Foundation, International Union Against Tuberculosis & Lung Disease (IUATLD), Infectious Diseases Hospital F. J. Muñiz (HFJM),, U.S. Centers for Disease Control and Prevention (CDC), State Agency for TB & Lung Disease, Latvia , Médecins sans Frontières (MSF), World Health Organization (WHO), Indus Hosptial.

[5] http://whqlibdoc.who.int/hq/2008/WHO_HTM_STB_2008.51.pdf

[6] GF/B4/2 (January 2003).

The Global Fund at its Thirteenth Board Meeting[7] determined that Country Coordination Mechanisms (CCMs) applying for funding of MDR-TB care and control activities in a Proposal under Round 6 and subsequent rounds of funding, or in a Request for Continued Funding, must include in their Proposals or Requests for Continued Funding provision to share the cost of the GLC Initiative and reaffirmed the Third Board Decision. The Global Fund, in consultation with the GLC, has defined the cost-sharing element for GLC services as a flat rate per grant per year that will not exceed $50,000 per grant per calendar year (ending 31 December) (the "Cost-Sharing Element"). Countries using the GLC mechanism and basing themselves on the Global Fund funding must include this flat-rate payment in their Global Fund grant application budgets.

These Instructions were designed and written to be used in conjunction with the following source material, available at no cost from WHO in paper or the world wide web:

World Health Organization. Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis, emergency update 2008 (WHO/HTM/TB/2008.402)
http://www.who.int/tb/publications/2008/programmatic_guidelines_for_mdrtb/en/index.html

World Health Organization. Treatment of TB Guidelines - 4th Edition (WHO/HTM/TB/2009.420);
http://www.who.int/tb/publications/2009/who_htm_tb_2009_420_beforeprint.pdf

World Health Organization. Procurement Manual for MDR-TB projects under he Green Light Committee mechanism, September 2008, (WHO/HTM/STB/2008.51);
http://whqlibdoc.who.int/hq/2008/WHO_HTM_STB_2008.51.pdf

WHO policy on TB infection control in health-care facilities, congregate settings and households;
http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf