

**INSTRUCTIONS FOR APPLYING TO THE
GREEN LIGHT COMMITTEE FOR
ACCESS TO SECOND-LINE
ANTI-TUBERCULOSIS DRUGS**



2006

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***Green Light Committee of the
Working Group on MDR-TB
STOP TB PARTNERSHIP***

US Centers for Disease Control and Prevention, Partners in Health (Harvard Medical School), International Union against Tuberculosis and Lung Diseases, National Tuberculosis Programmes of Estonia and Latvia, Medical Research Council of South Africa, and World Health Organization

Contributors:

Kai Blöndal, Jose A. Caminero, Peter Cegielski, Marcos A. Espinal, Ernesto Jaramillo, Fabienne Jouberton, Salmaan Keshavjee, Jim Y. Kim, Kitty Lambregts-van Weezenbeek, Vaira Leimane, Joia Mukherjee, Fuad Mirzayev, Eva Nathanson, Charles Nolan, Mario C. Raviglione, Michael L. Rich, Arnaud Trebucq, Karin Weyer.

<http://www.who.int/tb/dots/dotsplus/en/>
E-mail: dotsplus@who.int

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SUMMARY

Controlling multi-drug resistant tuberculosis (MDR-TB) is one of the six components of the WHO Stop TB strategy¹. Although prevention must be the highest priority for TB control programmes, many countries have patients with drug-resistant TB who must be treated too. Such countries should take specific measures to gradually incorporate appropriate strategies for treatment of this form of tuberculosis into their programmes and prevent propagation of drug-resistant TB.

Misuse of second-line anti-TB drugs results in further resistance to these same second-line drugs, creating incurable forms of tuberculosis². It is imperative that second-line anti-TB drugs are used wisely. The WHO *Guidelines For The Programmatic Management Of Drug Resistant Tuberculosis* (herein after referred to as the *Guidelines*)³ provide recommendations for appropriate management of drug-resistant TB so as not to generate further drug resistance. To help programmes develop and implement strategies for the management of drug-resistant TB, the Green Light Committee for Access to Second-line Anti-tuberculosis Drugs (GLC) was created by WHO and its partners in January 2000.

The GLC consists of six to seven experts in programmatic, scientific, clinical, and microbiological aspects of TB that serve WHO in an advisory capacity. The Committee is responsible for reviewing applications, evaluating proposed projects, assisting applicants, monitoring approved projects, and contributing to the evidence base for the programmatic management of drug-resistant TB. Each individual and his/her alternate represent a leading public health institution active in TB control internationally. Each institution is allowed one vote, and the GLC freely consults outside experts as needed. All members are required to adhere to rules of conflict of interest and confidentiality and, thus, are recused for voting on applications from projects with which they have or had a direct relation.

More broadly, the GLC initiative provides several services: a) access to high-quality second-line drugs at reduced prices (up to 95%) for the treatment of drug-resistant TB; b) review of applications from countries seeking to purchase these drugs to ensure a sound project according to WHO guidelines; c) on-site evaluation of proposed projects for drug-resistant TB control; d) monitoring and evaluation of approved projects; e) promoting training and technical assistance; f) fostering and coordinating programmatically relevant research to improve control of drug-resistant tuberculosis.

To participate in this initiative, projects must (1) build on the foundation of a solid DOTS-based TB control programme, (2) design their project within the principles put forth in the most recent WHO *Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis*, and (3) write their application in the format prescribed in these *Instructions For Applying to the Green Light Committee for Access to Second-Line Anti-Tuberculosis Drugs* (herein after referred to as the *Instructions*). Projects receiving the “green light” benefit from the pooled procurement of second-line anti-TB drugs at preferential prices. Moreover, the application process leads to enhanced communication between project sites, WHO, other public health agencies and the GLC. It also facilitates technical assistance to the projects. Feedback from projects provides important clinical and programmatic experience needed to develop global standards for the prevention and control of drug-resistant tuberculosis.

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*, WHO/HTM/TB/2006.361 http://whqlibdoc.who.int/publications/2006/9241546956_eng.pdf

World Health Organization. *Treatment of Tuberculosis: guidelines for national programmes*, Third edition, with revised chapter 4. Geneva, WHO, 2003. WHO/CDS/TB/2003.313.

World Health Organization And International Dispensary Association. *Procurement Manual for The Dots-Plus Projects Approved By The Green Light Committee*. Geneva: WHO, 2004. WHO/HTM/TB/2003.328 Rev.1. http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2003.328_Rev.1.pdf

¹ http://www.who.int/tb/features_archive/stop_tb_strategy/en/index.html

² CDC Morbidity and Mortality Weekly Report. Emergence of *Mycobacterium tuberculosis* with Extensive Resistance to Second-Line Drugs --- Worldwide, 2000--2004 (March 24, 2006 / 55(11);301-305)

³ http://www.stoptb.org/resource_center/assets/documents/tb_guidelines.pdf

OVERVIEW OF APPLICATION PROCESS

Projects wishing to participate in this initiative should submit their application to the GLC Secretariat. The application enables GLC to understand the existing TB control programme and the proposed project for drug-resistant TB.

The GLC treats all information received during the application process as confidential. Decisions are taken by consensus during the GLC meeting and the GLC secretariat, hosted by the WHO, will communicate GLC's initial assessment to the project director within six weeks of the meeting date. In cases when the GLC needs additional information, a letter with questions and comments is sent to the project director. These questions must be answered within three months; otherwise, the GLC will suspend consideration of the application. In many cases, after reviewing an application, the GLC may decide that a site visit is necessary before it can make an informed decision.

After one or more rounds of correspondence and a site visit (when needed), the GLC may reach one of the following decisions:

1. The GLC advises WHO to endorse the project to procure second-line anti-TB drugs through its procurement agent at reduced prices,
2. The application needs modifications to incorporate the recommendations in the *Guidelines* before the GLC will advise WHO to endorse the project.

Approved projects must report to the GLC secretariat annually using the annual reporting forms in the Guidelines. In addition, approved projects are visited yearly to review implementation of the proposal and provide technical assistance (if needed) on behalf of the GLC. To help develop sound policy on drug-resistant TB (DR-TB) the WHO will request data from the project. It is understood the applicant agrees that WHO will be entitled to use these data for the purpose of developing global policy recommendations for the management of DR-TB. WHO will otherwise treat such data and information as confidential and proprietary to the applicant. Any review, analysis, and/or publication of the aforesaid data by WHO will be undertaken only in consultation and agreement with the applicant.

PHASES OF THE APPLICATION PROCESS

The application process has four phases. Each phase has several steps:

1. Pre-application Phase

Prior to applying to the GLC, the potential applicant should:

- a. Ensure that an adequate TB control programme is in place and functioning well;
- b. Secure government commitment and adequate funding;
- c. Develop a coordinated project management plan;
- d. Assure adequate laboratory services are in place;
- e. Devise an appropriate treatment and monitoring strategy;
- f. Develop an adequate information (data) management system;
- g. Confirm that the drugs requested are registered in the country of the project;
- h. Develop a plan for dealing with the local customs procedures for importing the drugs.

Project managers may contact the GLC Secretariat, the WHO country and/or Regional offices, a Stop TB Partnership technical partner working in the country, or any of the GLC members to request assistance including a pre-application assessment. The main objectives of a pre-application assessment mission would be to evaluate the proposed project site, its preparedness to start a project, and advise the project personnel on how to best prepare an application to the GLC.

2. *Application Phase*

Once the foundation of the programme is in place, the applicants should:

- a. Send to the GLC secretariat a letter of intent outlining the situation, extent of the problem, number of patients estimated, and the planned timeline for submitting a full application;
- b. Prepare and submit an application to GLC according to the *Instructions* (this document);
- c. Respond to GLC comments, questions, or instructions within three months (if a timely response is not possible, the applicant may resubmit a new application at the applicant's convenience);
- d. Facilitate a site visit, if requested by GLC.

3. *Approval Phase*

Once the application is approved:

- a. A Letter of Approval is sent to the project by the GLC secretariat;
- b. An Agreement is reached between the project and the WHO on specific terms and conditions regulating GLC procurement mechanism;
- c. The Project sends to the GLC Procurement Unit an updated drug request specifying the exact quantities of each drug to be purchased;
- d. The GLC sends authorization to the drug procurement agent based on the number of patients approved and the amounts indicated in the updated drug request.

4. *Operation Phase*

After a project is approved by the GLC, endorsed by WHO, and all preparations are made:

- a. The project sends a delivery order for second-line anti-TB drugs to the procurement agent and a copy to GLC secretariat;
- b. The procurement agent procures the drugs and delivers them to the site designated by the project;
- c. Members of the Working Group may provide technical assistance to the project as needed;
- d. The project begins enrollment, treatment, and monitoring of patients;
- e. The project sends periodic reports to WHO;
- f. The GLC or its consultants conduct periodic monitoring and evaluation visits.

These *Instructions* describe primarily the application process itself. The pre-application phase is detailed in the *Guidelines*. The *Guidelines* contain principles by which GLC will judge the application. Projects based on the *Guidelines* will have the highest likelihood of GLC approval and programmatic success. Details of the Approval and Operation phases will be discussed with applicants individually if their application is successful.

Applicants should be aware that if their application is reviewed favorably, to receive final approval, the project director will have to agree to specific terms with WHO. These terms include, but are not limited to, periodic data reporting to WHO, on-site monitoring by the GLC or its consultants, rules for procuring the preferentially priced second-line anti-TB drugs, procedures for reporting and resolving problems identified by the GLC or by the project manager(s), and sharing innovative and successful methods between similar project sites.

Application Procedure for Project Expansion

GLC-approved projects may find it necessary to expand beyond the cohort approved initially. Such projects should submit a formal request to GLC according to the timeline for review cycle for new applications. The GLC secretariat will contact the project director to resolve any additional issues. It may be necessary for the GLC to conduct a site visit as well. Review of this request will be performed according to the method of review of a new project application. The request should include following items:

- ✦ Cover letter justifying the need for project expansion;
- ✦ Case finding and cohort data of all TB patients;
- ✦ Case finding and cohort data (or preliminary outcome data) of all MDR-TB patients;
- ✦ Documentation of funding for the additional patients;
- ✦ Description of any changes to the project made or planned since the submission of the original application;
- ✦ Updated drug resistance surveillance data or patients' Drug Susceptibility Testing (DST) patterns;
- ✦ Drug request and procurement order to cover the complete treatment of the additional patients.

Projects for small number of patients

Projects intending to treat a small number of patients (generally less than 50) can minimize the time required for the application process using the fast-track option specifically designed for these cases. Such projects are welcome to contact the GLC secretariat for further details and instructions for the simplified application. It is important to note that even if process of the application is simplified the requirements for the project to fulfill in order to be approved are not downgraded in any way, especially evidence of sound TB control based on all elements of DOTS.

INSTRUCTIONS FOR APPLICANTS

The application can be submitted in any of the WHO official languages (English, Russian, Chinese, Arabic, Spanish, and French), and should conform to the format and include the content described in these *Instructions*. Applications submitted in languages other than English will require additional time and incur costs for professional translation. A complete application has three major sections:

1. Cover letter (two pages maximum).
2. Main body of the application (30 pages maximum).
3. Annexes (no page limit).

The GLC makes a final decision on complete applications. If GLC determines the application is incomplete or incorrect in form or content, the application will be returned with an explanation of the specific deficiencies. Applicants may revise and resubmit applications at their own convenience. The revised application should include a new cover letter responding to each of the GLC's comments, point-by-point, indicating how each specific deficiency was remedied.

An electronic version of the application, including all supporting documents and annexes are necessary and will greatly facilitate the review process. Please note that WHO and Stop TB technical partners can provide technical assistance necessary for the applicant to meet the conditions set by the GLC.

Cover Letter

The cover letter should be typed or printed on the applicant organization's original letterhead. It should be addressed to the "Green Light Committee." A formal request to the GLC to review the potential project for treatment of drug-resistant TB cases should be part of the letter. The cover letter should be signed by the project director and contain the following items:

- ▶ Size of cohort to be treated
- ▶ Location of the project
- ▶ Anticipated start date and duration
- ▶ Time schedule for inclusion of patients
- ▶ List of all organizations involved
- ▶ Brief justification of the need for a project.

Body of the Application

The application should describe in specific terms how the basic TB programme and the proposed project have implemented or plan to implement the principles and recommendations in the *Guidelines*. The body of the application is divided into the following sections:

1. Background
2. Existing TB control programme
3. Information on drug resistant TB in the area and past use of second line drugs
4. Government commitment and partnerships
5. Organization, management, and coordination
6. Case finding, diagnosis and definitions
7. Laboratory aspects
8. Treatment and follow-up strategy
9. Side effects monitoring and management
10. Treatment delivery and adherence
11. Drug management
12. Information systems and data management

Each section should include the topics and issues as described in the *Guidelines*. Although all applications should include these sections, other sections may be added if it would explain the project more clearly. In every case, the applicants should strive for a clear and concise description of the TB control programme at the site and the proposed project to detect, treat, and manage drug-resistant TB. To facilitate the review process, the application and annexes must follow the format, coding and section titles in these *Instructions*.

1. Background

- 1.1 General and brief information on the political or geographic region in which the project will be carried out, including its size, population and general governance structure;
- 1.2 Brief description of the health care system in the region and the TB control programme (including the lines of authority and responsibility):
 - a. Administrative structure and role of the public (governmental) and private sectors in the provision of TB related health care services
 - b. Relationship of the TB control programme to the rest of the healthcare system
 - c. TB situation and TB control in prisons
- 1.3 Epidemiology of TB in the country and project region;
- 1.4 Epidemiology of HIV in the country and project region;
- 1.5 Reasons for the emergence of drug resistant TB in the region and the applicant's assessment of the relative importance of each reason;
- 1.6 Brief description of the existing pharmaceutical regulations including registration of anti-TB drugs in the country.

2. Existing TB control programme

Successful implementation of the DOTS strategy is one of the primary criteria in determining whether or not a project is capable of handling the complex issues associated with diagnosis and treatment of drug-resistant TB.

- 2.1 DOTS programme performance in the country/region with aggregate data and regional/sector (for example prison-civilian) breakdown whenever possible according to standard WHO case registration, reporting, and cohort analysis formats and definitions;
- 2.2 Quarterly reports generated by the DOTS based TB control programme for at least last two years.
- 2.3 Among all TB cases, percentage of re-treatment TB cases, percentage of chronic TB cases percentage of pulmonary smear-negative and extra-pulmonary TB cases;
- 2.4 Strategies and methods for case finding and contact tracing;
- 2.5 Treatment strategy for TB cases (regimens and method for determining what regimen a patient receives);
- 2.6 Description of treatment delivery for the intensive and continuation phases of treatment.
- 2.7 Defaulter tracing system and measures to assure adherence to treatment;
- 2.8 Drug supply mechanism (including funding source and any problems associated with distribution, such as stock-outs);
- 2.9 Number and type (nurse, physician, laboratory technician, etc.) of professional staff involved including their roles and responsibilities.

3. Information on drug-resistant TB in the area and past use of second-line drugs

- 3.1 Any available drug resistance surveillance data for the country and/or the area(s) where this project will be implemented. Data should be separated for new patients and re-treatment patients. Whenever possible, data for re-treatment cases should be separated for each of the re-treatment subgroups: Failures of Category I, Relapses after Category I, Return after Default from Category I, Failures of Category II, Relapses after Category II, and Return after Default from Category II;
- 3.2 In case representative drug resistance surveillance data are not available, any available drug resistance data from the project area should be provided with a clear explanation of the nature of the group of patients represented by the data;
- 3.3 Drug resistance profile of the proposed treatment cohort if known;
- 3.4 Full description of the management of drug-resistant TB cases within the TB control programme prior to the application to the GLC;

- 3.5 Availability and use of second-line drugs in the country and project area prior to the application to the GLC, such as availability for purchase with or without doctor's prescription, on the open (legal) or black market, outside the TB control programme and in the private medical sector.

4. Government Commitment and Partnerships

The governing authorities, leadership of the health department, and the leadership of the TB control programme in the region must be firmly committed to TB control as this is one of the most important elements for the success of TB prevention and control activities. This section should include:

- 4.1 Evidence of commitment to TB control such as the budget for TB services and changes in the budget in recent years, development of TB services and supportive social services in recent years, and recent responses of the authorities to the TB situation. Commitment of funds or contributions in kind to support the project from the local government or health system authority;
- 4.2 Verification that diagnosis, treatment, and follow-up of drug-resistant TB is provided free of charge to the patients, including ancillary tests and medications;
- 4.3 Name of local, national and international collaborating agencies, partners, consultants including their roles, commitment and responsibilities;
- 4.4 Commitment of the TB control system to regulate and account for the distribution of second line anti-TB drugs according to specific guidelines;
- 4.5 Anticipated long-term strategy to manage drug-resistant TB in the region/country.

5. Organization, Management and Coordination

Roles and responsibilities of each participating component of the TB control system, including specific individuals, must be delineated to prevent overlap and to ensure all aspects of the project are covered. Local institutions, the general medical services, and the social services system as well as outside donors or collaborators should be integrated into the project. This section should provide a detailed description of:

- 5.1 Number of patients planned for enrollment. Anticipated start date and duration of the project;
- 5.2 Local facilities of the TB control system (including specialized units) that will be involved in the treatment of patients with drug-resistant TB and the roles and responsibilities;
- 5.3 Local personnel in the TB control system who will be responsible for the treatment of patients affected by drug-resistant TB, and their training/experience in the management of such cases and use of second-line anti-TB drugs;
- 5.4 Local facilities outside the TB control system that will be involved in the management of patients with drug-resistant TB, including roles and responsibilities of each (e.g., prisons, general medical services, social services, psychiatric facilities, alcohol and drug abuse treatment programmes, social services, etc.);
- 5.5 Infection control measures;
- 5.6 Plan for the monitoring and supervision of the project by the project itself and by any external organizations;
- 5.7 Training programme for health care personnel, laboratory technicians, and information systems/data management personnel;
- 5.8 Plan for sustainability beyond the project period;
- 5.9 Collaboration established with the prison system for management of the drug-resistant TB.

6. Case finding, diagnosis and definitions

This section should clearly describe case-finding strategies to be employed for enrolling patients in the project cohort. Some projects have already identified patients with drug-resistant TB waiting to be treated; others may plan to enroll patients as they are diagnosed in the future.

- 6.1 Case finding strategies and methods; including policies for use of culture and DST (flow charts are encouraged, including which drugs will be tested and at what stage in the diagnostic assessment).
- 6.2 Inclusion/exclusion criteria for selecting, out of all cases with drug-resistant TB identified by the project, those to be enrolled in the project cohort, including a description of health care institutions/bodies in charge of elaborating and applying the criteria (for example, the responsible clinician, an expert committee, etc.).
- 6.3 Case definitions for patients with DR-TB with brief description for each and rationale behind using them within a framework of this project (at minimum, the case definitions in the new Guidelines are strongly recommended).
- 6.4 Detailed definitions of DR-TB treatment outcomes (at minimum, the case definitions in the new Guidelines are strongly recommended).
- 6.5 HIV testing policy and percentage of HIV-infected persons among those with DR-TB.

7. Laboratory Aspects

Although drug-resistant TB may be suspected on clinical grounds, it is diagnosed with certainty only by the bacteriology laboratory. Ultimately, definitive treatment is based on accurate, timely DST results.⁴ Well-functioning bacteriology laboratory services that provide, at minimum, accurate, timely drug susceptibility testing, at minimum, for isoniazid and rifampicin are mandatory. The application should describe:

- 7.1 Laboratory network and main laboratories that will serve the project (national or regional reference laboratory(ies), culture laboratory(ies), microscopy services, for example), including the number and types of personnel, the number of sputum specimens processed, the techniques used for culture and DST, bio-safety procedures;
- 7.2 Schedule, frequency, and extent of bacteriological evaluation of patients during treatment and follow up;
- 7.3 Quality control and quality assurance systems and supervisory activities of the local reference laboratory(s), results of the most recent quality assurance evaluations of sputum smears, cultures and DSTs; structure of supervision in the laboratory network;
- 7.4 Collaboration with an international reference laboratory and the quality assurance system associated with this laboratory;
- 7.5 Process and infrastructure for specimens collection, transport and referral;
- 7.6 Information management (recording and reporting) system.

8. Treatment and Follow-up Strategy

This section should clearly describe all aspects of treatment with anti-TB drugs within the proposed project and post-treatment follow-up, including:

- 8.1 Use of standardized, empiric, or definitive treatment regimens and rationale behind their use;⁵
- 8.2 Treatment regimens and algorithms for their design for both intensive and continuation phases;
- 8.3 Criteria to change the treatment regimen from intensive to continuation phases and other modifications in the regimen;
- 8.4 Experience of the medical staff in using second-line anti-TB drugs,

⁴ Treatment that is based on the best educated guess or probability of drug resistance in an individual patient is considered empiric treatment, for example, a patient in whom category II treatment is failing but whose sputum DST results have not yet been reported.

⁵ Standardized treatment means the same drug regimen is used for all patients (for example, category I treatment for new pulmonary cases). Empiric treatment means drugs for an individual patient are selected based on the best guess or probability of drug susceptibility. Definitive (or individualized) treatment means drugs are selected based on DST results. These definitions refer to general concepts and not necessarily to individual clinical circumstances. A treatment regimen may mix these approaches, for example, in programmes that test for resistance to some drugs but not others.

- 8.5 Transfer of patients and patient information from inpatient to outpatient settings and in the reverse direction, transfers between the prison and the civilian sectors, between long-term care or specialized housing facilities, sanatoria, other regions, and other hospitals;
- 8.6 Monitoring for the effectiveness of treatment with bacteriological and other tests;
- 8.7 Management of patients with associated problems such alcohol or drug abuse, homelessness, diabetes mellitus, and HIV infection;
- 8.8 Availability and use of surgery for diagnosis and treatment.

9. Side effects monitoring and management

Second line drugs cause side effects much more frequently than first line drugs. The side effects must be detected promptly and managed skillfully to ensure adequate treatment. The application should include a detailed plan to monitor for and manage adverse drug reactions:

- 9.1 Schedule for monitoring for adverse reactions including the clinical evaluations and laboratory tests to be performed at baseline and periodically;
- 9.2 Experience of the medical staff in managing side-effects or training activities planned;
- 9.3 Ancillary drugs and other therapies available to manage side effects;
- 9.4 Strategy and algorithms for the management of the most frequently occurring/expected side effects.

10. Treatment delivery and adherence

Applications should describe existing and proposed strategies and measures to assure adherence to the long duration of treatment. Important note: at present 100 percent DOT is required by the GLC.

- 10.1 Ensuring complete treatment and follow up of all patients (case management), especially when patients are transferred from inpatient to ambulatory care or, more generally, from one treatment location to any other location;
- 10.2 Provision of social support services needed by patients;
- 10.3 Plan for follow up of patients defaulting treatment.

11. Drug management

This part of the application should describe how the drugs will be managed and accounted for from the time they are received from the shipping agent until each tablet or capsule or vial has been received by the patient.

- 11.1 Management system for second-line anti-TB drugs to be procured as a result of this application, including importation, distribution, storage, monitoring, reporting, and accountability;
- 11.2 Second-line anti-TB drugs registered in the country (name, form, generic name, and manufacturer),
- 11.3 Second-line anti-TB drugs produced or available in the country other than through the GLC mechanism.

12. Information Systems and Data Management

The project must train all necessary participants to record and report the required information accurately and completely, at a minimum, the data specified in the *Guidelines*, including supervision and quality assurance, and report these data to WHO annually.

- 12.1 System of data recording and management in the hospital, dispensary, out-patient setting for the clinical management of each patient (specify the data to be recorded in a standard format in the medical record and in computerized electronic database).
- 12.2 Laboratory data recording and reporting system.
- 12.3 Format for aggregate quarterly and annual reporting.

Annexes

The annexes of the application should contain all letters of support and relevant data related to the project. Fax or scanned copies are acceptable with the electronic submission, but the original paper letters of support must be received by the GLC secretariat before an application can be approved. Specifically, this section should contain the following items in separate annexes:

1. Original letters of:
 - a. endorsement for the project from National TB Programme, Ministry of Health (or appropriate authority, such as Ministry of Justice), and local health authorities. For regional or local projects, letters would be appropriate from these same individuals plus letters from the corresponding authorities at the state, provincial, or regional level.
 - b. commitment from representatives of **each** organization involved in the potential project verifying the organization's proposed role and responsibilities.
2. The budget (in USD) and documentation of funding committed.
3. Drug Resistance Survey results or other DST data not included in the main body of the application.
4. Results of quality assurance programmes performed for each laboratory (and each procedure) involved.
5. Data collection and reporting forms to be used.
6. Programme evaluation data for the present TB control programme and according to standard WHO/IUATLD reporting system for case registration, reporting, and cohort analysis.
7. Drug procurement request for second-line anti-TB drugs to complete treatment of the proposed cohort including, the generic name, formulation, unit dose, number of unit doses, daily dosage, number of patients per each drug, total quantity for the full period of treatment and the timing for shipment of the drugs (drugs should be shipped no more than every quarter and no less than every year (see below form for drug procurement request). Changes to the procurement request after GLC approval requires satisfactory justification to be assessed by the GLC. Please consult *Guidelines* and the *Procurement manual*⁶ for GLC approved projects while preparing this annex.
8. and following: Other annexes may be included as needed.

⁶ http://www.who.int/tb/publications/dotsplus_management/en/index.html

Projects are strongly advised to consult the Procurement manual and contact Global Drug Facility (GDF) for additional details on preparation to the drug procurement using the GLC mechanism.

Form for Drug Procurement Request (duplicate this form as needed)

Name and location of the Project _____

Duration of the project (years) _____. Total size of the cohort _____

No. patients per quarter (3 months) _____ or per year _____

Regimen ⁷ :		Number of patients on this regimen:
Drug	Unit dose if different than shown	Number of unit doses for each drug for all patients to be treated with this regimen
Kanamycin 1 gm vial		
Amikacin 1 gm vial		
Capreomycin 1 gm vial		
Ofloxacin 200 mg		
Other fluoroquinolone and dose:		
Ethionamide 250 mg		
Prothionamide 250 mg		
Cycloserine 250 mg		
Terizidone 250 mg		
PASER 4 gr. Sachet		
Other		
Regimen:		Number of patients on this regimen:
Kanamycin 1 gm vial		
Amikacin 1 gm vial		
Capreomycin 1 gm vial		
Ofloxacin 200 mg		
Other fluoroquinolone and dose:		
Ethionamide 250 mg		
Prothionamide 250 mg		
Cycloserine 250 mg		
Terizidone 250 mg		
PASER 4 gr. Sachet		
Other		
TOTAL FOR ALL PATIENTS / ALL REGIMENS		
Kanamycin 1 gm vial		
Amikacin 1 gm vial		
Capreomycin 1 gm vial		
Ofloxacin 200 mg		
Other fluoroquinolone and dose:		
Ethionamide 250 mg		
Prothionamide 250 mg		
Cycloserine 250 mg		
Terizidone 250 mg		
PASER 4 gr. Sachet		
Other		

⁷ Regimens may be indicated using the standardized coding system in the Guidelines, analogous to standardized short-course chemotherapy (2HRZE/4HR), for example, 6KQTCP/18QTCP.

ADDRESS AND SCHEDULE FOR SUBMITTING APPLICATIONS

Completed applications should be delivered to:

**World Health Organization
Stop TB Department
Green Light Committee of the Working Group on DOTS-Plus for multi-drug resistant tuberculosis
20 Avenue Appia
CH-1211
Geneva 27
SWITZERLAND**

Electronic copy of the application itself, annexes and all supporting documents should be sent to the following email address: dotsplus@who.int

Incomplete applications will not be reviewed by the committee until all information requested is submitted.

The GLC Secretariat (dotsplus@who.int) can be contacted with any question regarding the application.

Applications are due on 20th day of January, March, May, July, September, and November. The GLC meets and will discuss each application on approximately the 20th of the following month.

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