



Global Drug Facility: Notes for applicants

Applications to the GDF must be made on the accompanying *GDF Application Form*. The following notes to the *GDF Application Form* provide additional information to assist countries in preparing applications, defining criteria and conditions for support, and also provide detailed notes to be used in conjunction with the *GDF Application Form*.

Please fill out the application form in French or English only.

Application Process

1. Upon receipt of the GDF Application Form, determine whether your programme meets the eligibility criteria and is able to meet the GDF terms and conditions for support. If it does, proceed with the application.
2. Please complete all sections of the application form. Incomplete applications will not be accepted.
3. Please submit the application form, together with all supporting documents, to the Stop TB Partnership Secretariat (see address below) with copies to the WHO Country and Regional Offices.
4. All copies of documents and attachments must be submitted in English or French.
5. The Stop TB Partnership Secretariat is unable to return originals of submitted documents and attachments to individual countries. Unless otherwise specified, documents may be shared with the GDF partners and collaborators.
6. The GDF application should be made in close collaboration with technical and financial partners committed to health and TB programmes and the country representatives of the Stop TB partners. The process should provide an opportunity for partners at the country level to commit them for additional support as well as being the basis for the GDF considering support.
7. The application form should follow the guidelines in this document and be forwarded to the Stop TB Partnership Secretariat on the enclosed form together with selected documentation.
8. An independent panel of experts: the GDF Technical Review Committee (TRC) will review applications, with recommendations forwarded to the Stop TB Partnership Co-ordinating Board for decision. Incomplete applications will be returned to countries for resubmission.
9. Decisions will be taken rapidly. Clarification and/or additional information may, however, be sought before implementation.

Please send the application form and supporting documents to the following address:

Global Drug Facility
Stop TB Partnership Secretariat
c/o World Health Organization
20, avenue Appia
CH-1211 Geneva 27
Switzerland
Fax: +41 22 791 4886 or + 41 22 791 4486
Email: gdf@who.int

Electronic submissions (e.g. on CD-ROM) are strongly encouraged in addition to hard copies.

Requirements for GDF support

Eligibility Criteria for support specific for grants of adult anti-tb drugs

- Estimated GNI per capita equal to or less than US\$ 3,000 per year.
- Highest priority will be given to countries with a GNP of less than US\$1,000 per year.

Eligibility Criteria for support specific for grants of paediatric anti-tb drugs

Countries fulfilling the following criteria are eligible for Paediatric anti-TB drug support from the GDF:

At least 85% of GDF funds should be spent on **low income countries (LICs¹)**, i.e. with a **GNI per capita < US\$ \$875 or less**.

No more than 10% of GDF funds should be spent on **lower middle income countries (LMICs²)**, i.e. **GNI per capita of US\$ 876 - \$3,465**

No more than 5% of GDF funds should be spent on **upper middle income countries (UMICs³)**, i.e. **GNI per capita of US\$ 3,466 - \$10,725** with priority given to those with a high disease prevalence, subject to these countries providing co-financing for their projects as to 20% in year 1 rising to 40% in year 4 (the same arrangements as per the Global Fund).

In the case of both LMICS and UMICs, contributions should be used to scale up existing programmes targeted principally at vulnerable groups (in accordance with the GDF definition).

The GDF Technical Review Committee will consider all applications received from countries that are LICs, LMICs and UMICs taking into account the above criteria.

GDF grants for paediatric formulations have been made possible through funding from UNITAID (www.unitaid.eu).

GDF Conditions

The following are the terms and conditions of **first term support**, concerning this supply of GDF drugs:

1. **All drugs supplied by GDF will ONLY be used:**
 - a. for treatment of TB patients;
 - b. free of charge to patients;
 - c. in treatment regimens following WHO guidelines;
 - d. in programmes following national guidelines for DOTS implementation;
 - e. in accordance with a multi-year plan for DOTS expansion and sustainability to reach the global targets for TB control.
2. **The applicant is responsible for the drugs beyond the agreed point of delivery.** The applicant will arrange for the payment or waiver of any import duty or tax, storage fees or insurance levied on drugs supplied by GDF in a timely fashion so that the drugs are released from customs and supplied for programmatic needs as required. The applicant is responsible for the in-country distribution and monitoring of drugs provided by GDF.
3. **Where registration is required**, GDF drugs will be expeditiously registered and the applicant will facilitate this process, so that drugs are released from registration and supplied for programmatic needs as required.
4. **For purposes of in-country registration by the National Drug Authority** (where applicable) of the anti-TB drugs to be supplied by GDF, the following actions are necessary:

¹ As defined by the World Bank Atlas Method

² Ibid

³ Ibid

- The NTP is required to provide GDF with the contact details of the persons at the National Drug Authority and the NTP/Ministry of Health responsible for drug registration in country. This information will be provided to our suppliers.
 - A copy of the Guidelines for Submission to the National Drug Authority, along with an indication of the time required for registration should be provided to GDF for the suppliers; Further, it should be indicated whether it is possible to obtain a waiver to registration or if a fast-track mechanism for dossiers exists in country. If so, the terms or conditions under which either of these provisions could be exercised should be provided to GDF to be shared with suppliers.
 - Suppliers will submit dossiers (where possible) in accordance with the Guidelines provided. The National Drug Authority should review the documents and inform the suppliers if they are sufficient for the purposes of registering all anti-TB drugs to be shipped. If all requirements are not met, the suppliers should be informed of any additional documentation that is required.
 - Where necessary, additional registration documents will be sent by the suppliers.
 - The NTP should indicate to GDF whether it is possible to ship and import the products while the registration process is ongoing.
5. **Regular assessments of the NTP performance**, including anti-TB drug management, will be carried out by an independent technical agency, and the complete assessment report provided to GDF. The applicant will also provide the following reports to the Stop TB Partnership secretariat:
- a. a regular annual report on TB programme performance in accordance with WHO guidelines;
 - b. quarterly reports on case finding, smear conversion and treatment outcomes;
 - c. date of arrival of GDF drugs at port;
 - d. time taken to register drugs (if applicable); and
 - e. date drugs received in central drugs store.
6. **Proven sustained political commitment:**
- a. Where a budget line or earmarked public sector funds for anti-TB drugs do not exist, Government beneficiaries must establish a multi-year budget line for anti-TB drugs or earmark multi-year public sector funds for anti-TB drugs with annual increases in dedicated funds and furthermore demonstrate expenditure of the dedicated funds during the period of GDF support.
 - b. Where a budget line or earmarked public sector funds for anti-TB drugs do exist, Government beneficiaries must make annual increases in dedicated funds for anti-TB drugs and demonstrate expenditure of the dedicated funds during the period of GDF support.
7. **Additionality:** Government beneficiaries must provide annually to the GDF, evidence that GDF anti-TB drugs and/or related supplies are additional to what would have been provided by the recipient government, other donors and agencies (including non-governmental organizations) in the absence of the GDF Grant. To this end, the evidence will include, but not be limited to, the following:
- a. Baseline data with respect to the annual number of courses of treatment being provided by all non-GDF sources – national government and other donors – during the year prior to the arrival of GDF-supplied drugs in the country;
 - b. The annual number of courses of treatment being provided by all non-GDF sources – national government and other donors – following the arrival of GDF supplied drugs in the country.
 - c. Where this information does not exist, and where the Government has exhausted all reasonable avenues in its efforts to obtain this information, the Government will provide estimates supported by the empirical evidence used to arrive at these estimates.
8. **Co-financing and technical cooperation** are available from other governments/donors for non-drug aspects of the multi-year plan (including DOTS expansion).

In addition to the above, the following are the terms and conditions of GDF support for **second term grantees** (after initial three year grant):

9. **Adherence** to the GDF terms and conditions during the first-term grant, and compliance as well as demonstrated progress towards meeting the GDF TRC and monitoring mission recommendations.
10. **Progress made in DOTS expansion** during the initial three years of the GDF grant. For countries with nationwide coverage this will mean sustaining the nationwide coverage and enhancing DOTS implementation as defined by the Stop TB Strategy.
11. **Achievement** of an acceptable level of treatment success rates in DOTS implemented areas as determined by the GDF TRC. Consideration will be given to countries that have not achieved the desirable treatment success rates but have shown steady improvements in their results.
12. **Drugs procured from non-GDF sources** should be of proven quality (a document from the drug regulatory authority of the exporting country showing that the supplier follows *Good Manufacturing Practices* should be provided to the GDF).
Medium to long term plans to ensure proven quality should also be provided.
13. **NTP agreement to move towards** standardized formulations and presentation of anti-TB drugs, i.e. in line with those products in GDF catalogue

GDF Priorities

In the event that GDF has limited resources, it may not be possible to support all countries submitting applications. Applications will be prioritized, based on objective criteria, by an independent GDF Technical Review Committee.

Duration of Support

GDF grants are for a period of three years (regular support, including buffer). Supply of drugs for the second and third years of support does not require resubmission of an application, but is dependent on the following:

- a. submission of quarterly and annual reports on case findings and treatment outcomes for patients treated in DOTS programmes
- b. submission of information on customs clearance: (i) date of arrival of GDF drugs at port (ii) date GDF drugs received in central drugs store/NTP store (iii) time taken to register GDF drugs (if applicable)
- c. a satisfactory annual report from an independent monitoring agency which will among other things, assess financial flows for TB, drug management, program performance and adherence to GDF terms and conditions of support
- d. availability of resources.

Notes to the GDF Application Form

The application form is divided into eight sections (A, B, C, D, E, F, G and H). Each section requires the applicant to complete boxes or tables. In addition, applicants are asked to attach additional documents. Applicants are requested to fill in the application form, paying close attention to these accompanying notes.

Section A. Application details

- In the contact information table, please provide the name of the country making the application, and details of the contact person.
- For **Tables A and B**, please list the regimens used for each category of treatment. For example, 2RHZE/4R₃H₃, which means two months daily of rifampicin, isoniazid, pyrazinamide and ethambutol followed by four months of isoniazid and rifampicin given three times a week. Please be sure to specify if the treatment is daily, 3x/week, or 2x/week. (R=rifampicin; H=isoniazid; Z=pyrazinamide; E=ethambutol; S=streptomycin). Please use parentheses to denote the use of FDC formulations where applicable, for example, 2(RHZE)/4(RH)₃.

- In column A, please estimate the **total** number of patients planned to be treated in accordance with the DOTS strategy (as per the multi -year plan for DOTS expansion, to reach the global targets for TB control).
- In column B, please estimate the number of patients planned to be treated in accordance with the DOTS strategy, that you would treat using drugs from GDF grant.
- In **Table C**, please provide a breakdown by age of paediatric patients to receive prophylaxis using drugs from all sources (third column) and those receiving prophylaxis using drug supplied by GDF (fourth column).

Section B. Background information

Please answer all questions as fully as possible. In case of approval, the information provided will help the GDF assess future compliance of the applicant country with the condition of support related to proven sustained political commitment and financial sustainability of the NTP program.

- For question B.3, Annex I is found in the Word file accompanying the application form materials.
- For questions in section B.4, please provide information on Global Fund status.

Section C. Products

The following products are currently available from the Global Drug Facility.

Adult Products	Type of packaging
Rifampicin 150mg/ Isoniazid 75mg/Pyrazinamide 400mg/Ethambutol 275mg Film Coated Tablets (4-drug fixed dose combination) (RHZE 150/75/400/275)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
Rifampicin 150mg/Isoniazid 75mg Film Coated Tablets (2-drug fixed dose combination) (RH150/75)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
Rifampicin 150 mg/Isoniazid 75 mg/ Ethambutol 275 mg (RHE 150/75/275)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
Rifampicin 150mg/Isoniazid 150mg Film coated Tablets (2-drug fixed dose combination) (RH150/150)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
Ethambutol 400mg/Isoniazid 150mg Film Coated Tablets (2-drug fixed dose combination) EH(400/150)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
Isoniazid 300mg Film Coated Tablets (H300)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
Pyrazinamide 400mg Film Coated Tablets (Z400)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
Ethambutol 400 mg Film Coated Tablets (E400)	Blister <input type="checkbox"/> Loose <input type="checkbox"/>
1 g of Streptomycin Sulfate (S 1)	Vials
Water for injection of Streptomycin Sulfate, 5 ml	Vials
Hypodermic syringes (auto disabling)	YES <input type="checkbox"/> NO <input type="checkbox"/>

Patient kits	
<p style="text-align: center;">Cat I & III Patient kit (Type A): Full treatment for a Cat I or Cat III patient for 6 months: 2(RHZE)/4(RH) Oral drugs in blister packs in a single patient box</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>
<p style="text-align: center;">Cat I & III Patient kit (Type B): Full treatment for a Cat I or Cat III patient for 8 months: 2(RHZE)/6(EH) Oral drugs in blister packs in a single patient box</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>
<p style="text-align: center;">Cat I & III Patient kit (Type C): Full treatment for a Cat I or Cat III patient for 6 months (intermittent continuation phase): 2(RHZE)/4(RH)₃ Oral drugs in blister packs in a single patient box</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>
<p style="text-align: center;">Cat II Patient Kit (Type A1): Full treatment for Cat II Patient for 8 months: 2S(RHZE)/1(RHZE)/5(RHE) Oral drugs in blister packs, vials of Streptomycin and water for injection, sterile auto-disabling syringes</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>
<p style="text-align: center;">Cat II Patient Kit (Type B1): Full treatment for Cat II Patient for 8 months: 2S(RHZE)/1(RHZE)/5(RH)E Oral drugs in blister packs, vials of Streptomycin and water for injection, sterile auto-disabling syringes</p>	YES <input type="checkbox"/> NO <input type="checkbox"/>

Paediatric Products⁴	Type of packaging
<p style="text-align: center;">Rifampicin 60mg/Isoniazid 30mg/ Pyrazinamide 150mg, Tablets, Dispersible (3-drug fixed dose combination) RHZ(60/30/150)</p>	Loose <input type="checkbox"/>
<p style="text-align: center;">Rifampicin 60mg/Isoniazid 30mg, Tablets, Dispersible (2-drug fixed dose combination) RH(60/30)</p>	Loose <input type="checkbox"/>
<p style="text-align: center;">Rifampicin 60mg/Isoniazid 60mg, Tablets, Dispersible (2-drug fixed dose combination) RH(60/60)</p>	Loose <input type="checkbox"/>
<p style="text-align: center;">Isoniazid 100mg Tablets, Breakable (H100)</p>	Loose <input type="checkbox"/> Blister <input type="checkbox"/>
<p style="text-align: center;">Pyrazinamide 150mg Tablets, Breakable (Z150)</p>	Loose <input type="checkbox"/> Blister <input type="checkbox"/>

⁴In circumstances when a country uses Ethambutol or Streptomycin as part of their paediatric treatment, if approved, the programme can access adult formulated Ethambutol (E 400) and/or Streptomycin (S1) until such a time when paediatric formulation for these products become available.

SECTION D. Procedure and timeline for supply of drugs

- Please fill in the tables with requested consignee information, delivery and importation details, and registration information.

SECTION E. Terms and conditions of GDF support

Please read the terms and conditions of GDF support listed in section E carefully, and sign each page of the application form to show agreement with these terms and conditions. Please also check the box agreeing with GDF terms and conditions.

SECTION F. Supporting Documents Required

- Please indicate the supporting documents you have provided by clearly labelling each with a reference number.
- The GDF often receives requests from countries who would like to see examples of well written/successful applications and supporting documents. If you are not willing to allow the GDF to publish your documents, please indicate which documents.

Please submit the following 9 (nine) documents.

1. Completed application form

- The application form should be completed as accurately as possible in order to minimize the amount of clarification necessary and expedite the review process.

2. A covering letter explaining why GDF drugs are needed

- This letter should specify why GDF drugs are needed and why drugs have not been secured through other mechanisms.

3. Multi-year DOTS Expansion Plan

- Please attach the latest development plan for TB. The TB development plan should be based on the principles of the Stop TB Strategy. Such plan should be based on a program review or program analysis at the end of the previous plan period. The plan should have clear objectives (see WHO guidelines for national programs, second edition, WHO 1997) and clear targets. Countries scaling up should have a timeframe which indicates how many new districts and provinces are added under DOTS over time during the plan period. The plan should describe in detail all activities which are needed to achieve the objectives. Roughly these are the activities described in the WHO framework for TB control: diagnostic services, treatment services, monitoring system, supervision, training, IEC, drug supply (and supply of diagnostics), quality control for direct microscopy, program coordination meetings, advocacy and resource mobilisation activities. Ensure that there is included in this plan a description of storage and distribution facilities that would be used for the GDF drugs.
- For example:
 - General introduction*
 - Epidemiological characteristics, including age breakdown (e.g., children aged less than 5 years old)
 - TB profile in country
 - Health sector*
 - Overall government health policies and strategies
 - TB infrastructure (*with an organizational chart*)—Structure of the government health services and how they relates to TB services, including hospital network, laboratory network, TB register, drug supply
 - Ongoing or planned health reforms (e.g. decentralization, integration of functions, changes in financing) and their impact on TB services
 - TB drug supply management*
 - Description of method(s) of forecasting drug requirements

- How often the forecasts are made or adjusted, if they are made through central level estimates or by accumulation of health centre figures, and title of person submitting the estimates for financial approval.
- What is the national recommendation for months stock-on-hand?
- What is the total health budget and what is the TB budget; how much comes from the national budget, what comes from donors, and what is the shortfall?
- Which products are produced nationally and which are imported?
- Description of tendering process.
- Description of the registration and product selection process, including time and cost.
- Description of the pre-qualification and importing process, including sampling and testing.
- A list of drugs routinely used, including formulations, standards, and packaging.

d. Status of DOTS implementation

- DOTS expansion by population unit
- Objectives, specific activities, and year-by-year DOTS coverage plan
- Indication of resources available and additional resources required
- Notifications, treatment outcomes, DOTS coverage
- Major constraints to DOTS
- Current budget

4. A copy of a recent TB evaluation or review

- Please provide a copy of the most recent independent assessment of the national TB control programme, performed by a competent organization.

5. A policy document which outlines national TB treatment policy

- Please provide a copy of the technical and operational guidelines for DOTS used by the national TB programme. These guidelines must include:
 - (a) diagnostic guidelines;
 - (b) case definitions;
 - (c) treatment guidelines, including regimens, dosages and formulations;
 - (d) drug management system; and
 - (e) monitoring guidelines, including indicators, definitions, and forms.

6. Annual report on case-notifications and treatment outcomes

- Please attach the most recent WHO Global TB Control Data Collection Form. If this has not yet been submitted, please submit it to the WHO regional office, with a copy provided to the GDF.

7. Evidence of support from partners

- Please provide evidence that national/international partners and/or donors support this application to the GDF. This could be demonstrated in one of several ways, for example;
 - (a) application submitted on behalf of the interagency coordinating committee (or equivalent);
 - (b) letter of support from partners; or
 - (c) partners as co-signatories of the application.

8. A drug management plan

- Please provide a document showing the flow of drugs from the port of arrival (air/sea port) until they are used in the health centre. Please include the name of the responsible authority at each level of the drug distribution chain.

9. A drug quality plan

- Please provide a document describing the NTP plans to ensure proven quality of drugs in the medium to long term.

SECTION G. Country Visit Dates

- In order to assist countries that have applied for GDF support, representatives of the Stop TB Partnership Secretariat, as well as Stop TB partners conduct country visits following review of applications. Please propose suitable dates for such a visit. **Please note, a country visit will not be needed if the applicant for paediatric drugs is an existing GDF supported country. If the applicant has never received GDF support, a Country Visit will be necessary within one month of Grant approval for paediatric anti-TB drugs.**

SECTION H. SUSTAINABILITY

These questions will assist GDF and the Technical Review Committee to understand the applicant's strategy to meet its anti-TB drugs needs in the absence of GDF.