

**MDR-TB PROCUREMENT REQUEST FORM AND TECHNICAL AGREEMENT (MPTA)**

*Request from*

|  |  |
| --- | --- |
| **Name of Institution** |  |
| **Address** |  |

(hereinafter “Client”)

*Submitted to*

|  |
| --- |
| **Global Drug Facility, Stop TB Partnership Secretariat, c/o World Health Organization** |
| **20, avenue Appia, 1211 Geneva 27, Switzerland** |

(hereinafter “WHO/GDF”)

**SECTION A. REQUEST FORM**

**Treatment and enrolment**

|  |  |
| --- | --- |
| *No of patients currently on treatment* |  |
|  |
| *Enrolment* | *Number of patients* |
| *Planned enrollment, Year, QTR* |  |
| *Planned enrollment, Year, QTR* |  |
| *Planned enrollment, Year, QTR* |  |
| *Planned enrollment, Year, QTR* |  |

Please indicate planned enrolment for one year by quarter starting from the time this form is completed

**Treatment regimens**

|  |  |
| --- | --- |
| **Treatment Regimen (TR)\*** | **Number of Patients on the TR** |
| 1.  |  |
| 2.  |  |
| 3.  |  |

\*EXAMPLE: 8 Z-Km(Cm)-Lfx-Eto-Cs/ 12 Z-Lfx-Eto-Cs

While the preferred option for procurement is orders for full regimens (split deliveries possible), this form can be used to order partial regimens or to complement full regimen (partial supply to adjust based on stock on hand, consumption, new patients) .

Please indicate this by ticking the appropriate box:

**[ ]  this is a request for full regimen**

**[ ]  this is a request for partial regimen (subject to GF approval, if applicable)**

*Please provide the authorization from the Global Fund*

**[ ]  this is a request to complement full regimen** (partial supply)

I*n case of request for partial supply, a detailed quantification should be provided providing details on stock needs, available stock, and, therefore, the gap, which needs to be procured.*

PRODUCTS AND QUANTITIES REQUESTED

For programs implementing WHO treatment guidelines, GDF provides quality assured anti-TB medicines and related commodities as listed in GDF’s product catalogue at [*http://www.stoptb.org/gdf/drugsupply/drugs\_available.asp*](http://www.stoptb.org/gdf/drugsupply/drugs_available.asp). GDF quality assurance policy can be found at [*http://www.stoptb.org/gdf/drugsupply/quality\_sourcing\_process.asp*](http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp)

It is recommended to place a request for medicines at least 6 months before the Preferred Delivery Date.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Medicine | Form | Procured from GDF\* | Dose | Units per day\*\* | No. of days patient will take medicine | Total units/ Patient | Total No. of patients receiving medicine | Total Request/Units | Adjusted Request/ Units1 |
|  |  |  |  | **A** | **B** | **C=A x B** | **D** | **E=C x D** | **F** |
| *Example: calculation* | *Tab* | *YES* | *250mg* | *2 tablets/day* | *120 days* | *240 tablets* | *10 patients* | *2400 tablets* | *2200 tablets* |
| Kanamycin | Vial | YES |   |   |   |   |   |   |   |
| Capreomycin | Vial | YES |   |   |   |   |   |   |   |
| Amikacin | Amp | YES |   |   |   |   |   |   |   |
| Moxifloxacin 2 | Tab | YES |   |   |   |   |   |   |   |
| Levofloxacin | Tab | YES |   |   |   |   |   |   |   |
| Ethionamide | Tab | YES |   |   |   |   |   |   |   |
| Prothionamide | Cap | YES |   |   |   |   |   |   |   |
| Cycloserin | Tab | YES |   |   |   |   |   |   |   |
| PASER  | Sachet | YES |   |   |   |   |   |   |   |
| P-aminosalicylate sodium 60% (PAS)  | Jar/ Sachet | YES |   |   |   |   |   |   |   |
| Other products (insert additional lines) |   | YES |   |   |   |   |   |   |   |

\*- In case of partial regimen request, mark NO in this cell.

\*\*-Units: tablets, capsules, vials/injections, sachets

**1** Adjusted Total Request is the final request of the programme. The adjusted request **need not** match the Total Request/Units, as this provides flexibility to countries, taking into account other aspects which may affect the order, such as current stock positions, , consumption patterns and other aspects. Information on the aspects considered can be provided in the "**Comments**" section below.

**2** Kindly inform, if applicable, whether only moxifloxacin from Bayer due to patent protection in

 your country can be procured, by ticking the box below:

[ ]  Yes, we can procure only Bayer’s moxifloxacin. Before the supply of Bayer’s product can be initiated, GDF will

 request the Client to provide a confirmation in writing to this effect.

 [ ]  No, we can procure moxifloxacin from any source.

**Comments:**

**SECTION B. CONSIGNEE and contact DETAILS**

Please ensure that full contact details are provided below, including full mailing address, telephone, fax, and email.

|  |  |
| --- | --- |
| **Country:** |  |
| **Contact Person** |  |
| **Position:** |  |
| **Organization:** |  |
| **Address:** |  |
| **Telephone:** |  |
| **Fax:** |  |
| **Email:** |  |

|  |  |
| --- | --- |
| 1. Full contact details of person/authority responsible for **tracking anti-TB medicines order**
 | Name:Position:Organization:Address:Telephone:Fax:e-mail:  |
| 1. Full contact details of person responsible for **registration** of the products to be delivered.
 | **Dossier for the application must be sent to:**Name:Position:Organization:Address:Telephone:Fax:e-mail: |
| 1. Full contact details of **Notifying party** (person/authority responsible for medicines shipment authorization)Note: Above person will be contacted via email when shipment is ready to be shipped. **Authorization will be required before the shipment is dispatched.**
 | Name:Position:Organization:Address:Telephone:Fax:e-mail: |

**SECTION C: DELIVERY & IMPORTATION DETAILS**

The Preferred date(s) of Delivery specified by the Programme should indicate when the Programme needs GDF medicines to arrive in-country to ensure sufficient stock of anti-TB medicines are maintained at the central, regional and peripheral Programme levels. GDF will undertake best efforts to arrange for accommodation of the requested delivery date(s). GDF will provide updates on the Estimated Time of Arrival (ETA) as such information becomes available.

|  |  |
| --- | --- |
| 1. Period in which medicines will be used
 |  |
| 1. Preferred delivery date (date the medicines required, considering standard leadtime 4-6 months from receipt of funds )
2. **Note:** In case split shipments are required, a preferred delivery date for each of the shipments should be indicated (please note comment above).
 |  |
| 1. Preferred port of delivery
 |  |
| 1. Preferred mode of shipment
 | **[ ]  Air [ ]  Sea [ ]  Overland** |
| 1. Documentation needed to accompany consignment.

Standard documentation includes airway bill/bill of lading, invoice and packing list). Should you require further documentation, please check the appropriate box.  | [ ]  Airway bill/bill of lading [ ]  Certificate of analysis (analytical batch certificate) [ ]  Certificate of origin [ ]  Packing list [ ]  Invoice [ ]  Gift certificate [ ]  Other documents or requirements (such as original documents, etc) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Please confirm that no special pre-shipment inspections are required in addition to the pre-shipment inspection that will be carried out by the GDF agent.
 | [ ]  **NO**, GDF inspections are sufficient[ ]  **YES**, Special pre-shipment inspection requirements Please specify: |
| 1. Advance notice required by customer before delivery

**Note:** Standard shipping and quality documents are usually only available 2 weeks before goods are shipped. If more advance notice is required, this will result in longer lead times for the order. |     week(s) |
| 1. Special requirements concerning markings on outer cartons.
 |     |
| 1. Details of additional requirement such as language labelling requirements
 |     |
| 1. Can shipments arrive outside of regular working hours (09.00 - 17.00 h / Mon - Fri). If no, please state the hours.
 | Yes [ ]  No [ ]  |
| 1. What is the source of the funds being used to purchase these medicines/products (i.e. Global Fund, Government, etc)?
 |  |

**SECTION D: REGISTRATION DETAILS**

Information on medicines registration is **critical** to ensure timely delivery of medicines. Please ensure that the section below is complete with accurate, up-to-date information.

|  |  |
| --- | --- |
| 1. Is **medicines registration required for the products to be delivered**?Time required for medicine registration?
 | Yes [ ]  No [ ] Number of weeks required for registration:     |
| 1. Can **importatio**n of medicines into the country be made **prior to or during registration** (where applicable)?
 | Before [ ]  During [ ]  Neither [ ]   |
| 1. If registration is required: Registration d**ossier** for the application to be sent to:
 | Name:Title:Organization:Address:Telephone:Fax:Email: |
| 1. If registration is required:
	1. Is it possible to obtain a **waiver to registration**?
	2. Does a **fast-track mechanism** exist for the registration of the products to be delivered?
 | Yes [ ]  No [ ] Number of weeks required for waiver: Yes [ ]  No [ ] Number of weeks to fast-track: **List of documents required:*****for waiver:***- - - ***for fast-track registration:***- - -  |
| 1. Other important information concerning medicines registration that may affect GDF medicines shipments.
 |     |

**SECTION E. TECHNICAL AGREEMENT (TA)**

1. *CONDITIONS OF SUPPLY*
* General conditions
	+ GDF procures only quality assured medicines.
	+ All medicines and commodities shall be provided to patients free of charge.
	+ Standard production lead times are 4-6 months after receipt of funds.
	+ No approval from Green Light Committee, either global or regional, is needed. However, GDF may provide a copy of this document to the responsible regional or global Green Light Committee(s) for their advice; this is particularly relevant for Global Fund supported procurements.
* Procurement processes
	+ WHO/GDF works with procurement agent(s) (PA) to coordinate the purchasing and logistics of WHO/GDF order(s) under this MPTA (MDR-TB Procurement Request Form and Technical Agreement). The execution of this MPTA can be initiated only after signing of a commercial contract between the PA and the Client and receipt of the prepayment of funds by PA, or as agreed in writing between the PA and the Client.
	+ The Client will be responsible for payment or obtaining waiver of any applicable duties, any import requirements, as well as to facilitate product registration in cooperation with manufacturers or obtaining relevant waivers, in-country storage, distribution and monitoring of all supplies, unless otherwise agreed with the PA and/or WHO/GDF
	+ The Client understands the importance of quality medicines. Applicants submitting a MPTA for partial regimens understand that it is their direct responsibility to ensure that other medicines provided are of assured quality and they are fully accountable for the care of their patients. In the case of Global Fund supported procurements, prior written agreement of the Global Fund is required if the funds are to support partial regimens.
* Monitoring and technical assistance
	+ WHO/GDF reserves the right to conduct monitoring mission(s) by an independent technical agency on the use of medicines and related commodities delivered under this document. The Client agrees to interact with experts which WHO/GDF may notify and from which WHO/GDF may request assessments, such as but not limited to WHO Regional TB Advisors, regional Green Light Committee (rGLC) representatives, WHO Regional Supply Officers and Country Supply Officers. The assessment report will be shared with the Client.
	+ The Parties may also consult on and mutually agree on implementation of technical assistance on MDR-TB medicines management.
* Special provisions
	+ Any serious adverse effects that come to the Client’s attention and that may be related to the use of the medicines are to be reported to the national pharmacovigilance centre or, in the absence of a national pharmacovigilance centre, to the national medicines regulatory authority in a timely manner in accordance with local legislation or other applicable requirements.
	+ If the Client does not represent an established international NGO, publicly known to be active in MDR-TB patient treatment (PIH, MSF, International HIV/AIDS Alliance or similar), a UN organization or the government entity in tuberculosis related affairs of the respective country, the Client needs to provide a letter of endorsement from the National TB Program or similar entity. In case this cannot be provided, the Client needs to submit relevant explanation to allow for GDF decision on this procurement. In submitting the letter or explanation, the Client agrees that GDF may contact its Partners for additional information without further consent by the Client.
	+ In case specific off label medicines for MDR-TB treatment are requested according to WHO treatment guidelines, such as Group 5 drugs, GDF might request Client to sign specific liability waiver which needs to be submitted before the supply of these products can commence.
	+ In case of request for Bedaquiline, and according to the WHO Interim Policy Guidance on Bedaquiline[[1]](#footnote-1), the drug may be used as part of an MDR-TB treatment regimen provided the following five conditions are met:
* Treatment administered under closely monitored conditions
* Proper patient inclusion
* Patients informed consent obtained
* Adherence to principles of designing a WHO- recommended MDR-TB regimen
* Pharmacovigilance and proper management of AEs and prevention of drug-drug interactions

*2. FINAL PROVISIONS*

For applicable WHO/GDF General Terms and Conditions, please refer to the GDF webpage: *http://www.stoptb.org/gdf/drugsupply/resource\_materials.asp*

1. *SUBMISSION AND SIGNATURE*

 **Please sign below and send it to the following address:**

**Global Drug Facility**

**Stop TB Partnership Secretariat, c/o World Health Organization**

**20, avenue Appia, CH-1211 Geneva 27, Switzerland**

**Tel.: +41 22 791 12508, Fax: +41 22 791 4886,**

**Email: gdfprs@who.int**

|  |  |
| --- | --- |
|  |  |
| Signature: |  |
|  |  |
| Name:  |  |
| Title: (Authorised Official) |  |
| Date: |  |

1. <http://www.who.int/mediacentre/news/notes/2013/bedaquiline_mdr_tb_20130613/en/> [↑](#footnote-ref-1)