

Buying quality, affordable tuberculosis drugs through the Global Drug Facility:

A guide to the **Direct Procurement Service** for donors, non-governmental organizations and programme managers



Buying through the GDF:

straightforward, no-nonsense value

Why purchase anti-tuberculosis (TB) drugs through the Global Drug Facility (GDF) Direct Procurement (DP) Service?

Because the GDF DP Service offers a convenient, reliable source of affordable, quality anti-TB drugs tailored to meet specific programme needs.

GDF DP guarantees:

- **Competitive prices: significant savings**

The GDF secures affordable anti-TB drug prices through pooled procurement, standardization, prompt payment policies and innovative procurement strategies, and by linking demand for drugs to supply and outsourcing all its services on a competitive basis.

Moreover, the GDF's supply approach is equitable - no matter how big or small a client the same affordable prices are offered.

- **High quality: peace of mind**

The GDF requires that all drugs supplied are either prequalified under the World Health Organization (WHO) TB Prequalification Project or are approved for supply through a transparent, independent expert committee, pending prequalification.

In addition, all drug batches systematically undergo independent laboratory analysis and pre-shipment inspection prior to being shipped to the client.

- **Standardized products: A "one stop shop" for WHO-recommended drug formulations**

The GDF offers a standardized WHO-approved catalogue of anti-TB drugs and formulations, which is designed to promote the products prioritized by WHO Stop TB Department and in particular fixed-dose combination (FDC) tablets. Standardized formulations like FDCs reduce the number of tablets a patient needs to take, while avoiding mono-therapy and thereby reducing the risks of developing multidrug resistant TB (MDR-TB).

- **User-friendly packaging: health worker and patient focused**

GDF packaging options include: specially designed blister sheets and individual Patient Kits (containing a full course of treatment) both of which support effective drug management, as well as robust, ergonomically designed containers for loose tablets to protect the contents against damage and humidity.

- **A web-based ordering and tracking system: easy to use technology for efficiency and transparency**

GDF clients can track the status of their orders online from the point of manufacturing, through to quality control, shipment and delivery.

- **On-going technical support: a holistic approach to procurement**

The GDF assists programmes with common procurement issues such as selection, drug forecasting, quality assurance and registration prior to delivery. After delivery, the GDF provides follow-up drug management consultancy services during annual in-country missions.

What is Direct Procurement?

The GDF DP Service is a mechanism to assist governments and their partner organizations in purchasing quality, affordable first-line anti-TB drugs.

The aim of the GDF DP Service is to provide a reliable source of standardized, affordable drugs that will, in turn, save lives and avert traditional procurement bottlenecks. By securing low drug prices for each client, the DP Service generates additional programme savings that may be used for other aspects of TB control. This approach helps to maximize the impact of donor and government funding.

The GDF DP Service also strives to strengthen local capacity, specifically in the field of procurement. Clients participating in the GDF DP Service build relationships with established procurement agencies. This exposure allows clients the opportunity to adapt or apply proven procurement models to their national procurement programmes. In addition, GDF staff and the GDF procurement agent work with clients to develop or maintain a skill base for effective drug selection, forecasting and registration procedures.

How does DP work?

1) DP selection process

Prospective **procurement agents** are preselected through a widely advertised “Invitation for expressions of interest,” which ensures they meet certain mandatory criteria prior to being invited to participate in an international competition to offer their services to the GDF. Prospective **manufacturers** are preselected via processes that ensure all drugs to be supplied are either prequalified under the WHO TB Prequalification Project or are approved for supply through a transparent, independent expert committee, pending prequalification.

2) DP international competitive bidding process

The GDF Secretariat relies on public tenders and limited international competitive bidding processes following internationally recognized rules, to select manufacturers and procurement agents (including agents for quality control). This selection process occurs on a regular basis and ensures that the GDF supplies only quality assured drugs via efficient, reliable and competent contractual supply partners.

3) DP ordering process

Interested governments and their partner organizations may choose, at any time, to initiate the GDF DP ordering process by following these simple steps:

- **Verify eligibility.** Interested governments or partner organizations should first determine if they are eligible to use the GDF DP Service (see “Eligibility” insert).
- **Submit technical agreement.** Eligible clients should then complete and submit to the GDF a signed version of the DP Technical Agreement. Forms are available at:
www.stoptb.org/gdf/drugsupply/direct_procurement_process.asp
- **Place order.** Clients may then either place the DP order themselves or request that the GDF places the DP order on their behalf.
- **Make payment.** Clients will receive a pro-forma invoice from the GDF procurement agent, indicating all related costs, before their order is finalized. Once clients have accepted the proforma invoice, a contract will be sent for signature outlining all terms of supply, including the respective responsibilities of both parties. Clients sign and submit the contract to the GDF procurement agent and then execute payment.
- **Track order progress.** All clients receive a user ID and password giving them access to the GDF web-based order tracking system. This user ID enables clients to access information about, and track the status of, their orders. To facilitate the ordering process, the GDF procurement agent is available to answer client questions and provide technical support.

4) DP quality control

In addition to the drug quality assurance steps taken under the DP selection process, the GDF safeguards drug quality via the contracted services of a stringent, independent laboratory that tests batches of drugs in each order prior to delivery. The GDF also requires pre-shipment inspection of all orders to (a) ensure that packaging, labeling, content and shelf life meet the required standards of the GDF and its clients; and (b) ensure that each consignment corresponds to the order placed in terms of product type and quantity.

5) DP post-delivery support

Four to six months following delivery, the GDF Secretariat organizes a monitoring mission to assess adherence to the technical agreement and compliance with GDF Terms and Conditions of purchase. When needed, GDF monitoring teams work with programmes to identify strategies to strengthen drug management systems.

Eligibility

The following clients are eligible to use the GDF DP Service:

- Countries implementing DOTS in 90% or more of the population and NGOs supporting DOTS in these countries.
- Countries or NGOs approved by the GDF Technical Review Committee for a grant of free anti-TB drugs.
- Countries or NGOs approved for a grant for tuberculosis control by the Global Fund to Fight AIDS, Tuberculosis & Malaria (GFATM) Technical Review Panel.
- Organizations, donors and technical agencies supporting the above categories of countries or NGOs. Note: if a country, organization, or donor does **not** meet any of the above criteria, they are encouraged to contact the GDF for information on if and how they may become eligible to use the GDF DP Service.

Payment options

All offers will be made in US\$. The client is responsible for any currency exchange risk; any currency changes from the date the client transfers the funds in any of the acceptable currencies, to the date the funds are converted to the US\$ amount, will be on the client's account. Clients may choose to execute payment via **advance payment** or **bank guarantee**, unless otherwise agreed between the client and the GDF procurement agent.

- **Advance payment**
Client transfers an agreed upon sum to the procurement agent within 30 days of signature of a contract.
- **Bank guarantee**
Client submits a bank guarantee, issued by a reputable bank, or an irrevocable standby Letter of Credit, in an agreed upon sum to the procurement agent within 30 days of signature of a contract.

Terms and conditions of purchase

All DP clients of the GDF agree to the following terms and conditions:

- All drugs supplied by the 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; and
 - E. in accordance with a multi-year plan for DOTS expansion/implementation.
- The client is responsible for the drugs beyond the agreed point of delivery. The client will make arrangements for the payment or waiver of any import duty or tax, storage fees or insurance levied on drugs supplied by the GDF in a timely fashion so that the drugs are released from customs and supplied for programmatic needs as required. The client is responsible for the in-country distribution and monitoring of drugs provided by the GDF.
- Where registration is required, the client is responsible for registration issues in the country. GDF drugs will be expeditiously registered and the client will facilitate this process, so that drugs are released from registration and supplied for programmatic needs as required.
- 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:
 - A. The National TB Control Programme (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.
 - B. 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.
 - C. 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.
 - D. Where necessary, additional registration documents will be sent by the suppliers.
 - E. The NTP should indicate to GDF whether it is possible to ship and import the products while the registration process is ongoing.
- The client agrees, in principle, to an annual assessment of TB programme performance, including TB drug management, by an independent technical agency, and to share the complete assessment report with the GDF. The assessment will include a review of the adherence to GDF terms of supply, the provision of technical support for program management and drug management, and the finalization, together with the NTP, of the drug request for the following year of GDF supply, where relevant.
- The client will also provide the following reports to the GDF:
 - A. date of arrival of GDF-supplied drugs at port;
 - B. time taken to register drugs (if applicable);
 - C. date drugs received in central drugs store; and
 - D. latest available quarterly reports and a completed WHO TB Data Collection Form.

Current GDF agents

GDF procurement agent

The Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH purchases first-line anti-TB drugs from a limited number of suppliers for delivery to GDF approved countries. Contact/website: www.gtz.de

GDF quality control agent

GDF chose Intertek Technical Inspections as their quality control agent for pre-shipment inspection and sampling of batches of medicines for testing by GDF quality control laboratories. Intertek Technical Inspections, part of the FTS division of Intertek Group, provides services in the specific fields of inspection, expediting and quality assurance.

These activities are performed by a group of professionals supported by a coordination staff having a vast experience in dealing with different commodities, products, equipments and materials. Intertek Technical Inspections renders Third Party inspections to a wide range of customers, public and private organizations and government agencies. Intertek Technical Inspections performs surveillance activities at inspection sites, at loading and/or unloading, verifying the product conformity to the specified contractual requirements of the Client's purchase order, specifications, codes and standards. For more information, contact the focal point for GDF at Technical Inspections Milan – Italy: info.milan@intertek.com or visit their website at: www.intertek-ti.com

GDF testing laboratories

- **PROXY Laboratories**

Netherlands – E-mail: info@proxylab.nl; website: www.proxylab.nl/index.html

- **SGS India Pvt. Ltd.**

India – E-mail: Sanjeev_Arora@sgs.com; website: www.sgs.com

- **SGS Life Science Services – Lab Simon SA**

Belgium – E-mail: tome.najdovski@sgs.com; website: www.sgs.be

GDF freight forwarders

The following freight forwarder is used by GDF and sub-contracted by GTZ:

- **Geis SDV GmbH** – Contact/website: www.geis-group.com

GDF suppliers

The following suppliers have been contracted by the GDF procurement agent under Long Term Agreements to supply GDF drugs and related commodities.

- **Cadila**

Cadila is a research-based life sciences pharmaceutical company that manufactures human/veterinary formulations, active pharmaceutical ingredients, and vaccines and immunoglobins, and performs analytical research, phytochemistry, biotechnology, plant tissue culture, and biosynthesis. Cadila's manufacturing plant for anti-TB drugs is located in Ahmedabad, India. Contact/website: www.cadilapharma.com/

- **Lupin**

Lupin is a manufacturer of drugs that combat tuberculosis, bacterial infections, and cardiovascular disease, and supplies first line anti-TB drugs, which are manufactured at its plant in Aurangabad, India. Contact/website: www.lupinworld.com/

■ **Strides-Sandoz**

Strides-Sandoz is a partnership between a multi-national and an emerging global pharmaceutical company which develops products to fight TB, HIV/AIDS and Malaria. Contact/website: www.stridesarco.com/





■ **Svizera Europe (SE) - Svizera Labs Pvt Ltd (India)**

Svizera Europe, headquartered in the Netherlands, supplies first-line anti-TB drugs from its manufacturing facility, Svizera Pvt. Labs Ltd, in Mumbai, India.

Contact/website: www.svizera.org/

For information on the GDF quality assurance process and its relation to the suppliers listed above, please visit: www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp

Product Catalogue

Patient Kits	GDF has 2 types of patient Kits, one for Category I or III patients and one for Category II patients, which contain the full treatment for one patient of either category.	
1 st Line Adult Fixed Dose Combinations	Advances in the field of pharmacology have made it possible to develop quality combinations of up to four anti-TB drugs. In a single tablet, we are now able to deliver the two, three or four essential first-line drugs in the proper dosages, thus guaranteeing easy adoption of the WHO recommended regimens.	
1 st Line Single Formulations	The essential first-line drugs required to treat patients according to the WHO recommended regimens.	
1 st Line Injectibles	Additional supplies required to deliver first-line treatment for tuberculosis.	
Diagnostics Equipment	Diagnostic materials for use in laboratories.	
1 st Line Paediatric Drugs	The essential first-line drugs required to treat paediatric patients according to the WHO recommended regimens.*	
2 nd Line Drugs	The recommended anti-TB drugs for treating patients with multidrug-resistant TB (MDR-TB) according to WHO guidelines.	

Patient Kits

Recommended

Product	Description	Unit Price (US\$)
Cat I & III Kit A	Stop TB Cat. I+III Patient Kit A 6 blisters (168) 4-FDC tablets (R150/H75/Z400/E275) 12 blisters (336) 2-FDC tablets (R150/H75)	\$18.15
Cat II Kit A1	Stop TB Cat. II Patient Kit A1 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275) 56 vials of Streptomycin 1gr 60 vials of water for injection 5ml 60 2-stroke auto-disabling syringes & needles 15 blisters (420) 3-FDC tablets (R150/H75/E275)	\$54.94
Cat II Kit A2	Stop TB Cat. II Patient Kit A2 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275) 56 vials of Streptomycin 1gr 60 vials of water for injection 5ml 60 syringes & needles 15 blisters (420) 3-FDC tablets (R150/H75/E275)	\$45.80

Other Patient Kits available

Product	Description	Unit Price (US\$)
Cat I & III Kit B	Stop TB Cat. I+III Patient Kit B 6 blisters (168) 4-FDCs (R150/H75/Z400/E275) 18 blisters (504) 2-FDC tablets (E400/H150)	\$22.54
Cat I & III Kit C	Stop TB Cat. I+III Patient Kit C 6 blisters (168) 4-FDCs (R150/H75/Z400/E275) 18 blisters (504) 2-FDC tablets (R150/H150)	\$14.26
Cat II Kit B1	Stop TB Cat. II Patient Kit B1 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275) 56 vials of Streptomycin 1gr 60 vials of water for injection 5ml 60 2-stroke auto-disabling syringes & needles 15 blisters (420) 2-FDC tablets (R150/H75) 10 blisters (280) tablets E400	\$52.27
Cat II Kit B2	Stop TB Cat. II Patient Kit B2 9 blisters (252) 4-FDC tablets (R150/H75/Z400/E275) 56 vials of Streptomycin 1gr 60 vials of water for injection 5ml 60 syringes & needles 15 blisters (420) 2-FDC tablets (R150/H75) 10 blisters (280) tablets E400	\$43.13

1st Line Adult Fixed Dose Combinations (FDC)

Product	Description	Tablets per unit	Unit Price (US\$)	Avg. cost per tablet
4-FDC	Rifampicin 150 mg / Isoniazid 75 mg / Pyrazinamide 400 mg / Ethambutol 275 mg - Pack of loose tablets	1000	\$48.11	\$0.048
4-FDC-B	Rifampicin 150 mg / Isoniazid 75 mg / Pyrazinamide 400 mg / Ethambutol 275 mg - Box of 24 blister sheets	672	\$35.93	\$0.053
3-FDC	Rifampicin 150 mg / Isoniazid 75 mg / Ethambutol 275 mg tablets - Pack of loose tablets	1000	\$41.80	\$0.042
3-FDC-B	Rifampicin 150 mg / Isoniazid 75 mg / Ethambutol 275 mg tablets - Box of 24 blister sheets	672	\$30.64	\$0.046
2-FDC RH 150/75	Rifampicin 150 mg / Isoniazid 75 mg - Pack of loose tablets	1000	\$20.65	\$0.021
2-FDC RH 150/75-B	Rifampicin 150 mg / Isoniazid 75 mg - Box of 24 blister sheets	672	\$17.79	\$0.026
2-FDC RH 150/150	Rifampicin 150 mg / Isoniazid 150 mg - Pack of loose tablets	1000	\$23.40	\$0.023
2-FDC RH 150/150-B	Rifampicin 150 mg / Isoniazid 150 mg - Box of 24 blister sheets	672	\$19.03	\$0.028
2-FDC EH 400/150	Ethambutol 400 mg / Isoniazid 150 mg - Pack of loose tablets	1000	\$22.92	\$0.023
2-FDC EH 400/150-B	Ethambutol 400 mg / Isoniazid 150 mg - Box of 24 blister sheets	672	\$17.07	\$0.025

1st Line Single Formulations

Product	Description	Tablets per unit	Unit Price (US\$)	Avg. cost per tablet
E400	Ethambutol 400 mg - Pack of loose tablets	1000	\$20.17	\$0.020
E400-B	Ethambutol 400 mg - Box of 24 blister sheets	672	\$14.82	\$0.022
H300	Isoniazid 300 mg - Pack of loose tablets	1000	\$6.83	\$0.007
H300-B	Isoniazid 300 mg - Box of 24 blister sheets	672	\$6.20	\$0.009
Z400	Pyrazinamide 400 mg - Pack of loose tablets	1000	\$10.04	\$0.010
Z400-B	Pyrazinamide 400 mg - Box of 24 blister sheets	672	\$8.70	\$0.013

1st Line Injectibles

Product	Description	Unit Price (US\$)
S1	Streptomycin 1gr - Box of 50 vials	\$3.89
W	Water for injection, 5ml - Box of 100 vials	\$9.78
S&N-AD	Auto-disabling syringes with integrated needles - Box of 100 syringes/needles	\$19.05
S&N	Syringes with by packed needles - Box of 100 syringes/needles	\$4.09

Diagnostics Equipment

Product	Description	Unit Price (US\$)
Equipment starter kit A	Contains all materials needed to fully equip a new (or refurbish an existing) laboratory unit to perform smear microscopy.	contact GDF
Consumables kit A	Contains dissolved reagents (min. shelf life 3 years) and all other consumables like microscope slides, filter paper, immersion oil, etc. needed to prepare 1000 slides.	contact GDF
Microscope kit	Contains one high quality biological microscope, as well as one mirror unit, one lamp stand, one rechargeable battery and a charger.	contact GDF
Sputum containers	1000 sputum containers	contact GDF

1st Line Paediatric Drugs*

Product	Description	Unit Price (US\$)
RH(60/60)	Rifampicin 60mg/Isoniazid 60mg, Tablets, Dispersible (2-drug fixed dose combination)	contact GDF
RH(60/30)	Rifampicin 60mg/Isoniazid 30mg, Tablets, Dispersible (2-drug fixed dose combination)	contact GDF
RHZ(60/30/150)	Rifampicin 60mg/Isoniazid 30mg/Pyrazinamide 150mg, Tablets, Dispersible	contact GDF
H100	Isoniazid 100mg Tablets, Breakable	contact GDF
Z150	Pyrazinamide 150mg Tablets, Breakable	contact GDF

2nd Line Drugs*

Product	Description	Unit Price (US\$)
Capreomycin	Capreomycin, 1 gr powder for inj., 1 vial	contact GDF
Cycloserin	Cycloserin 250 mg, pack of 100 capsules	contact GDF
Ethionamide	Ethionamide 250 mg, pack of 100 tablets	contact GDF
Kanamycin	Kanamycin, 1 gr powder for inj., 50 vials	contact GDF
Ofloxacin	Ofloxacin 200 mg, pack of 100 tablets	contact GDF
PASER	PASER 4 gr granules, pack of 30 sachets	contact GDF
Prothionamide	Prothionamide 250 mg, pack of 100 tablets	contact GDF

Notes

The paediatric products indicated are those available at this time. However, as other WHO recommended paediatric products – i.e. Ethambutol 100mg - and formulations - e.g. child-friendly/dispersible - become available, these will be added to the GDF catalogue.

Prices

These are the minimum prices GDF can currently offer. All prices are FCA Mumbai or Amsterdam. Under certain circumstances such as production capacity constraints or conflicting default lead times in relation to the required delivery date of a particular order, *prices for some products will occasionally be higher.*

Other costs

Costs for quality control, pre-shipment inspection, transport (air freight or sea freight) and insurance, *are not included in the listed product prices*, except for Streptomycin, Water for Injection and Syringes and Needles, where the quality control costs are already included in the Catalogue Price.

What is the GDF?

The Global Drug Facility (GDF) is one of the success stories in the fight against tuberculosis (TB), a curable infectious disease that claims more than 5,000 lives every day. Launched in 2001, the GDF has developed a new approach to promoting access to quality, affordable anti-TB drugs by working with programmes to identify strategies that improve drug management and ensure rational drug use, thereby strengthening capacity. In just over five years the GDF has supplied more than 9 million patient treatments to over 70 countries. The GDF has achieved this through its three services:

- (i) a *Grant Service* whereby first-line adult and paediatric anti-TB drugs are granted to eligible and approved countries that are donor-dependent for their drug needs;
- (ii) a *Direct Procurement Service* for governments, donors and NGOs to purchase drugs for use in DOTS programmes in countries that have sufficient finances but lack adequate procurement capacity, including a robust quality assurance system; and
- (iii) a *Technical Support Service* whereby the Grant and Direct Procurement Services are combined with technical assistance for (a) in-country drug management and anti-TB drug monitoring and (b) support to global efforts to improve TB drug quality assurance, primarily via WHO's TB prequalification programme.

To promote local capacity and accountability, the GDF coordinates annual, independent monitoring missions to review programme progress and assess adherence to GDF terms and conditions. When needed, monitoring teams, composed of TB and drug management experts, work with programmes to identify strategies that will strengthen drug management, ensure rational drug use and effective distribution.

GDF contact:

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

The Stop TB Partnership Secretariat is administered by the World Health Organization.

Notes