



Procurement Manual for MDR-TB projects under the Green Light Committee mechanism



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1. Introduction

This manual explains the procurement procedures as agreed by World Health Organization / Global Drug Facility and the selected procurement agent and gives relevant background information on various supply-related aspects for the supply of second line anti-TB drugs for Green Light Committee multidrug-resistant TB (MDR-TB) approved programmes.

The Green Light Committee Initiative

The GLC Initiative, together with the Working Group on MDR-TB, promotes implementation of Stop TB Strategy in accordance with the Global Plan to Stop TB (2006–2015) and the Global MDR / extensively drug-resistant (XDR) -TB Response plan (2007–2008).

Established in 2000, the GLC Initiative is the mechanism that enables access to affordable, high-quality, second-line anti-TB drugs for the treatment of drug-resistant TB (DR-TB).

More information on GLC can be found at:

<http://www.who.int/tb/challenges/mdr/greenlightcommittee/en/>

The Global Drug Facility

The GDF is a mechanism to expand access to, and availability of, high-quality anti-TB drugs and diagnostics to facilitate global DOTS expansion or maintenance to support the Stop TB Strategy. The Secretariat is housed at WHO and coordinates the procurement of second line anti-TB drugs for the GLC approved projects.

More information on GDF can be found at: www.stoptb.org/gdf

Procurement agent:

The procurement agent is competitively selected and contracted by WHO/GDF and is responsible for the procurement of second-line anti-TB drugs for treating patients with MDR-TB, in the projects approved by GLC.

Following a competitive process an Agreement was signed between WHO/GDF and the IDA Foundation (IDA) in July 2007, which covers a 24-month period, to ensure an uninterrupted supply of high-quality products at the lowest price achievable through economies of scale.

IDA is a non-profit organization supporting health care in low-and middle-income countries by providing high-quality drugs and medical supplies at the lowest possible price. More information on IDA can be found at: www.ida.foundation.org

1.1. Quality Assurance: quality standards applied to manufacturers and finished pharmaceutical products

The products GDF procures are subject to internal quality assurance (QA) criteria (as of July 2009 GDF will harmonize its QA policy with that of the Global Fund).

Option A: WHO Prequalification (PQ)

All products need to be (i) manufactured at a site that has been inspected by WHO as a part of the WHO PQ Programme (<http://mednet3.who.int/prequal/>) and found operating at an acceptable level of compliance with WHO Good Manufacturing Practices (GMP) and (ii) approved for safety, quality and efficacy through WHO PQ dossier assessment. All products must also be in compliance with national regulatory standards.

OR

Option B: Stringent National Drug Regulatory Authority approval

All Products need to be (i) manufactured at a site located in a highly regulated country defined as an ICH¹(International Conference on Harmonization) member country, ICH observers and any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement or at a site approved by a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)² (ii) approved for safety, quality and efficacy by a regulatory authority of an ICH member country, ICH observer country or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC) No. 726/2004 or United States FDA tentative approval. All products must also be in compliance with national regulatory standards.

OR

Option C: Interim Assessment & Approval Process

Products shall be found acceptable to GDF when they are (i) manufactured at a site meeting the standards defined in options A (i) or B (i) above and (ii) approved through an Expert Review Committee (ERC) in an Interim Assessment & Approval Process. The ERC assesses products

¹For ICH members, observers or associated countries see www.ich.org

² www.picscheme.org

based on the information provided in a Pharmaceutical Product Questionnaire (PPQ) obtainable at <http://www.stoptb.org/gdf/drugsupply/> and the attached annexes. The product approval process described under either options A (ii) or B (ii) must be pending, i.e. manufacturers must have submitted complete product dossiers accepted for assessment. The Expert Review Committee is appointed by the WHO PQ Programme in collaboration with the Drug Management Sub-Committee of the Working Group on MDR-TB, on request by GDF. Any approval under option C shall be of limited duration, not exceeding 12 months as established by GDF at the time of manufacturer tender submissions.

In addition, IDA conducts in-house QA procedures in relation to their supply of pharmaceuticals and medical items. Before shipment, all consignments are visually inspected and samples are assessed on the basis of the manufacturer's Certificate of Analysis. Samples are retained for one year beyond the product's total shelf life to ensure proper follow-up in the case of complaints about quality being received later. For some products, packing and labelling specifications are developed by IDA's QA department to ensure consistency in packing, labelling and product information.

IDA is GMP, GDP and ISO 9001:2000 certified.

WHO/GDF may also outsource independent quality control services for the products including batch sampling and testing and pre-shipment inspection with designated agents.

1.2. Products and prices

A product information table can be found in this publication, annex II (p 22). The "*Guidelines for the programmatic management of drug-resistant tuberculosis*" is also an essential publication which contains specific drug information (http://www.who.int/tb/publications/2006/who_hm_tb_2006_361/en/index.html).

For the correct administration of drugs and general treatment of TB patients, medicines to alleviate adverse effects of treatment and additional products, such as syringes, needles and water for injection, are required. (See chapter 11: Initial Evaluation, Monitoring of treatment and Management of adverse effects).

Generally, drugs should be stored in dry, well ventilated premises that offer protection from direct sunlight and dust. Temperature should normally be maintained between 15 and 25 °C.

However, some drugs require specific storage conditions, indicated by the manufacturers, to ensure that they retain their quality, safety and efficacy throughout their shelf life.

Specific details about storage conditions for each product can be found in the product information sheets included in this manual.

WHO has published guidance on good storage practices for pharmaceuticals; this document can also be accessed at www.who.int/medicines/library/qsm/trs908/trs908-9.pdf.

WHO partners, GDF and IDA continuously negotiate the best possible prices for the drugs concerned. Following an agreement between WHO and the manufacturer Eli Lilly, limited quantities of Capreomycin are offered at a preferential price to GLC-approved projects.

More information about the most recent prices can be found at:

http://www.stoptb.org/gdf/drugsupply/drugs_available.asp

These prices are the minimum prices GDF can currently offer. All prices are Ex-Works supplier's plant. Product prices for second-line drugs include a 7% margin that cover costs for quality control and procurement agent fees.

As the purchase price may fluctuate with international exchange rates and/or due to available sources and quantities required, definitive prices can be given by GDF/IDA only after receipt of a firm purchase order.

Transport insurance is arranged for all goods shipped by IDA; costs are 0.6% of the total value of goods freighted by air, sea and road.

Changes in pricing of drugs caused by a rise in exchange rate, a rise in import duties, a rise in transport costs, and a rise in the unit price charged to IDA by the manufacturer, will be passed on to the programme.

WHO has developed a tool for estimating drug needs and the corresponding budget for a specific cohort of patients, (SLD estimation and request tool) available on the GLC and GDF web sites.

2. Order procedures

The following section describes the steps for projects to follow to proceed with the procurement of the second-line drugs from the time of approval of the project by the GLC until the reception of the drugs in the recipient country.

2.1. Green Light Committee approval

The GLC Secretariat sends a letter to the country, copying GDF, to provide notification of the approval of a project(s). In addition GLC sends a Letter of Agreement (LoA) to Institutions whose project has been found in accordance with the Guidelines for the Programmatic Management of drug-resistant tuberculosis. This LoA outlines the benefits from a periodical review process by GLC and the access to preferential prices for the second-line drugs. The institution will indicate acceptance of such conditions by returning a countersigned original of this LoA to WHO. It should be noted that no second-line drugs can be ordered (as the procedures detailed below) until the LoA is signed.

2.2 Procurement form

The procurement form (Annex 1) must be completed and sent to GDF who will verify the provided information regarding regimens, drug quantities and other relevant procurement information such as: consignee details, documents needed for importation or status of drugs registration in the country.

Once validated, GDF will send an official request to IDA authorizing initiation of the procurement process for the project.

Programmes are strongly advised to calculate a reasonable buffer stock in their procurement order (to cover drug consumption for the whole expected delivery time). It is also recommended to place an order to cover drug needs for one year and request the delivery in two or more shipments, and to budget for drugs against adverse affects.³

³ This could be on average 10% of total drugs budget.

2.3. Order placement from the project to IDA

After all the above-mentioned documents have been received and revised by GDF, the GLC-approved programme is then requested to place the first firm drug order within 90 days. GDF must be copied on all correspondence between the project and IDA.

The primary contact persons at IDA and WHO regarding issues concerning procurement are:

IDA:

Mr Vicente Segovia (Program Management)

E-mail: vsegovia@idafoundation.org

Tel: +31 20 403 7 159

Fax: +31 20 403 1 854

WHO/GDF:

Ms Paloma Lerga (Technical Officer)

Ms Maria Sarquella (Procurement Officer)

E-mail: lergap@who.int /

sarquellam@who.int

Tel: +41 22 791 25 08 (direct line)

The manager of the GLC-approved project is responsible for ensuring the official regulatory approval of products to be supplied in any order through fast-track registration procedures or registration waivers. IDA is not responsible for the registration of drugs in the countries but is required to facilitate the process.

Countries requesting drugs are also responsible for ensuring that the products supplied comply with the country's legislation on patent registration or restrictions.

Lastly, programmes are also responsible for the drugs beyond the agreed point of delivery. They must make arrangements 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. Programmes are responsible for the in-country distribution.

A number of countries have signed host agreements with WHO whereby WHO benefits from simplified import procedures and is exempt from taxes as well as some of the importation requirements (e.g. drug registration)⁴.

⁴ The host agreement between the country and WHO defines, among other things, which "privileges and immunities" and other exemptions WHO will enjoy in the country concerned. This is specific to each country/organization, has the status of International Treaty and is registered as such in the United Nations Treaty Series. **WHO does not have host agreements with all the countries where it holds an office.**

2.4. Quotation

After receipt of an order from a project, IDA prepares a quotation and sends it tot the project within 10 working days.

2.5. Acceptance and Confirmation

Upon receipt, review and acceptance of IDA's quotation, the project confirms by sending a purchase order and, if applicable, by transferring payment specified in the quotation to IDA's bank account.

Special note: In the case of UNITAID⁵ Grant recipient projects, GDF will place the order with the procurement agent once the transaction is confirmed by GDF's Finance unit.

2.6. Final order placement from IDA to the manufacturers

Once payment is received by IDA, the agent will confirm the order and delivery schedule.

The standard lead time for deliveries of ordered second-line drugs is approximately 5 months. Second-line anti-TB drugs are not kept in stock by any of the drug manufacturers. For small, urgent orders and accelerated lead time is possible subject to availability of second-line drugs in the rotating stockpile held by IDA.

2.7. Order Management System

The OMS is a web based order tracking system that allows registered users to follow the status of their orders. Projects will receive a username and password as soon as a firm order has been placed by IDA (as per 2.6 above).

⁵ UNITAID aims to improve access to treatments against HIV/AIDS, malaria and tuberculosis for the populations of developing countries, by getting lower prices of quality medicines and diagnostics which are still too expensive for these countries, and speed up their availability and delivery in the field (see: www.unitaid.eu)

Through the OMS, the projects are informed about each step in the supply process, including order placement, receipt of payment, expected delivery dates, as well as the relevant shipping details and necessary documentation.

3. Glossary and abbreviations

Airway bill : Document prepared by the freight forwarder that provides details about the contents of the air shipment, the route and carrier, and the shipping charges.

Batch: A defined quantity of any drug product processed in a single process or series of processes that can reasonably be expected to be uniform in character and quality.

Batch number: A distinctive combination of numbers and/or letters that specifically identifies a batch on labels, batch records, the Certificate of Analysis, etc.

Bill of lading: Document certifying that the goods are in the charge of the carrying vessel. The document is issued by the shipper and signed by the master of the vessel.

Certificate of Analysis: Certificate provided by the manufacturer giving the test results from a particular batch. The batch number, manufacturing and expiry dates, and all test results that are part of the release specification should be included in this Certificate of Analysis.

Certificate of Insurance: Certificate proving that the shipment has been insured.

Certificate of Origin: Document stating that the product in question has been produced by the manufacturer in the country concerned.

Certificate of Pharmaceutical Product: Certificate issued by the drug regulatory authorities in the country of origin that indicates whether the product has a marketing authorization (registration) in the country of origin and certifies that the manufacturer complies with the WHO-GMP guidelines and is regularly inspected (with indication of frequency).

DOTS - Directly Observed Treatment Short-Course.

A key pillar of the internationally recommended strategy for TB control.

DOTS-Plus: A case management strategy under development, designed to manage MDR-TB using second-line drugs within the DOTS strategy in low- and middle-income countries.

Expiry date: Designates the date up to and including which the product is expected to remain within specifications if stored correctly. The expiry date for every batch is established by adding the shelf life to the manufacturing date.

Free gift certificate: Certificate declaring that the shipment is a gift from an organization in another country.

GcLP: Good control Laboratory Practices: That part of quality assurance which ensures that control laboratory standards comply with the requirements of the marketing authorization (registration).

GDP: Good Distribution Practices: That part of quality assurance which ensures that products are consistently stored, transported and handled under suitable conditions as required by the marketing authorization (registration) or product specification.

Generic product: A pharmaceutical product, usually intended to be interchangeable with the innovator product, generally manufactured without a licence from the innovator company and marketed after the expiry of the patent or other exclusivity rights relating to the innovator product. A generic product may be marketed either under the approved non-proprietary name or under a new brand (proprietary) name. (WHO definition)

GMP: Good Manufacturing Practices: An industry term for technical procedures undertaken under recognized standards to ensure that products are consistently produced and controlled and are appropriate for their intended use and product specification or as required by the Marketing Authorization.

Incoterms: Standard trade definitions most commonly used in international sales contracts; devised and published by the International Chamber of Commerce. See web site www.iccwbo.org. The most commonly used terms are:

CFR – Cost and Freight (... named port of destination) – means that the seller delivers when the goods pass the ship's rail in the port of shipment. The seller must pay the costs and freight necessary to bring the goods to the named port of destination *but* the risk of loss of or damage to

the goods, as well as any additional costs due to events occurring after the time of delivery, are transferred from the seller to the buyer. For the GLC approved projects, IDA calculates freight charges to the port of destination.

CIF – Cost, Insurance and Freight (... named port of destination) – means that the seller delivers the goods to the carrier nominated by him but the seller must in addition pay the cost of carriage necessary to bring the goods to the named port of destination.

For the GLC approved projects, IDA calculates freight charges to the port of destination, including freight insurance of 0.6% of the total value of the goods.

CIP – Carriage and Insurance Paid to (... named place of destination) – means that the seller delivers the goods to the carrier nominated by him but the seller must in addition pay the cost of carriage necessary to bring the goods to the named place of destination. The buyer bears all risks and any additional costs occurring after the goods have been so delivered. For the GLC approved projects, IDA calculates freight charges to the place of destination, including freight insurance of 0.6% of the total value of the goods.

CPT – Carriage Paid To (... named place of destination) means that the seller delivers the goods to the carrier nominated by him but the seller must in addition pay the cost of carriage necessary to bring the goods to the named place of destination. The buyer bears all risks and any other costs occurring after the goods have been so delivered. For the GLC approved projects, IDA calculates freight charges to the port of destination.

EXW – Ex Works – means that the seller delivers when the goods are placed at the disposal of the buyer at the seller's premises or another named place (works, factory, warehouse, etc.) not cleared for export and not loaded on any collecting vehicle.

FCA – Free Carrier (... named place) – means that the seller delivers the goods, cleared for export, to the carrier nominated by the buyer at the named place. IDA does not calculate extra freight charges or insurance to ship the goods to any port in the Netherlands or Belgium or to any airport in the Netherlands.

Innovator pharmaceutical product: The first product authorized for marketing in a country with a stringent regulatory authority⁶ (normally as a patent drug) on the basis of documented efficacy, safety and quality.

Invoice: Final documentation giving the exact amount to be paid, which is sent to the buyer once the goods have been packed.

Letter of credit: An interbank document, issued by the buyer's bank, stating that a certain sum of money is available for the seller to claim from the bank as soon as the consignment is shipped and the required documents, as specified in the letter of credit, are presented.

MDR-TB- Multidrug-resistant tuberculosis

Specific form of TB caused by a bacillus resistant to at least Isoniazid and Rifampicin, the two most powerful anti-TB drugs.

Packing list: List of the contents of the order, including weight, volume, number of boxes and expiry dates, drawn up after the goods have been packed.

Patent: A title granted by public authorities that confers a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear, full description of it, and claims this monopoly.

Proforma invoice: Includes such information as the price of the products, shipping and insurance charges (if applicable), total value, detailed description of the products offered and terms of payment. The pro-forma invoice is sent by the supplier to the buyer to confirm the purchase order.

Quotation: Offer made by the supplier to the prospective buyer; it includes prices, quantities, payment conditions and delivery conditions. It does not imply any obligation to the supplier on the part of the prospective buyer.

Registration (or marketing authorization): A process enabling a State to control which products are going to be commercialized in its territory and which are not, selecting them on the basis of need and of the safety of a given active ingredient, and also selecting the dosage form,

⁶ Including inter alia USA; EU/EEA countries; Japan

strength, manufacturer and quality of the final product. The competent drug regulatory authority issues an official document (registration certificate or product licence or marketing authorization).

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Shelf life: The period of time during which a drug product is expected, if stored correctly, to remain within specifications as determined by stability studies on a number of batches of the product. The shelf life is used to establish the expiry date of each batch.

4. Annexes

4.1. Annex 1: Procurement Form

PROCUREMENT FORM

SECTION A. CONSIGNEE DETAILS

Country:	
Consignee:	
Position:	
Address:	
Telephone:	
Fax:	
Email:	

SECTION B. DRUG REQUEST FORM FOR A 2 YEAR DOTS-PLUS PROJECT

Number of patients to be treated	Treatment Regimen For MDR-TB patient
Total Patients:	
# Patients approved by GLC:	

Drug Product	Units/Day	No. of Days (Months) Patient will take the drug	Total Units/Patient	Total No. of Patients Receiving the Drug	Total Request
Kanamycin 1 gr vial					
Capreomycin 1 gr vial					
Amikacin 500 mg/2 ml					
Ofloxacin 200 mg tabs					
Levofloxacin 250 mg					
Ethionamide 250 mg tabs					
Prothionamide 250 mg tabs					
Cycloserin 250 mg tabs					
P-aminosalicylic acid (PAS) 4 gr. Sachet					
others products can be added					

* units: tablets, capsules, vials, sachets

Signature _____

Date _____

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SECTION C. CONTACT & DELIVERY DETAILS

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

1) Name and full contact details of person/authority responsible for tracking anti-TB drug order (if different from above)	
2) Name and address of contact person/authority responsible for drug registration issues.	
3) PERSON/AUTHORITY TO BE NOTIFIED (name, postal address, telephone, fax, email) Note: Above person will be contacted via email when shipment is ready to be shipped. **Authorization will be required before the shipment is dispatched.	
4) Advance notice required by customer before delivery	week(s)
5) Preferred date(s) of delivery ⁽⁷⁾	
6) A) Preferred port of delivery <u>and</u> B) Preferred mode of shipment (air or sea)	
7) Special requirements concerning markings on outer cartons. ⁽⁸⁾	
8) 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 special requirements <input type="checkbox"/> Special requirements as described below:
9) 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. Note: the Clean Report of Findings requires an additional inspection, time allotment, and cost.	<input type="checkbox"/> Airway bill/bill of lading <input type="checkbox"/> Certificate of analysis (analytical batch certificate) <input type="checkbox"/> GMP Certificate <input type="checkbox"/> Certificate of origin <input type="checkbox"/> Packing list <input type="checkbox"/> Gift certificate <input type="checkbox"/> Invoice <input type="checkbox"/> Clean report of findings <input type="checkbox"/> Other documents or special requirements (Please specify) _____
10) Details of additional requirement such as language labelling requirements	

Signature _____

Date _____

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⁽⁷⁾ GDF expressly disclaims responsibility for any delays or defaults resulting from the acts or omissions of procurement or shipping agents, as well as for any delays or defaults caused by other conditions beyond its reasonable control, including, but not limited to *force majeure*, Government restrictions (including the denial or cancellation of any export, import or other necessary permit or license), wars, insurrections, fires, floods, or failure of any supplier or subcontractor substantially to meet its obligations to GDF.

⁽⁸⁾ The standard outer packaging information includes: supplier, product name and colour coding, batch number and expiry date.

SECTION D: REGISTRATION DETAILS

Information on drug registration is **critical** to ensure timely deliver of drugs. Please ensure that the section below is complete with accurate, up to date information.

1. Is drug registration required ? Time required for drug registration?	Yes <input type="checkbox"/> No <input type="checkbox"/> Number of weeks:
2. Can importation and distribution of drugs in the country be made prior to or during registration (where applicable)?	Before <input type="checkbox"/> During <input type="checkbox"/>
3. If registration is required: a) Is it possible to obtain a waiver to registration ? b) Does a fast-track mechanism exist for drug registration?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> If Yes, approximately how long does it take: _____
4. Can shipments arrive outside of normal working hours? If no, state the hours .	Yes <input type="checkbox"/> No <input type="checkbox"/>
5. Other important information concerning drug registration that may affect GDF drugs shipments.	

Global Drug Facility
Stop TB Partnership Secretariat
c/o World Health Organization
20, avenue Appia
CH-1211 Geneva 27
Switzerland
Tel.: +41 22 791 2508
Fax: +41 22 791 4886

Signature _____

Date _____

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4.2. Annex 2: Product Information Table

Drug	Use	Drug class	Available from IDA	Country of origin	Pack size	Labelling	Shelf life	Conditions of storage:
Amikacin, 500 mg/ml, 2-ml vials (Am)	For different types of infections, including MDR-TB	Aminoglycoside, similar to streptomycin, kanamycin, capreomycin	Medochemie	Cyprus	10 Vials	E/F/S/R	36 months	In a dry place, below 25 °C, protected from light
Capreomycin, vials, 1 g dry powder for injection (Cm)	Should be used only for the treatment of MDR-TB	Aminoglycoside, similar to streptomycin, kanamycin, amikacin	Eli Lilly	Germany	vial	E/R	24 months	In a dry place, below 25 °C, protected from light
Cycloserine, 250-mg capsules (Cs)	Only for second-line treatment of MDR-TB	Analogue of D-alanine	Macleods	India	100 capsules	E/F/S/R	24 months	Relatively unstable product – adherence to storage conditions as specified on label is important In a dry place, below 25 °C
Ethionamide, 250-mg tablets (Eto)	Should be used only for the treatment of MDR-TB	Carbothioamide group, similar to prothionamide	Macleods	India	100 tablets	E/F/S/R	36 months	In a dry place, below 25 °C, protected from light
Prothionamide, 250-mg tablets (Pto)	Should be used only for the treatment of MDR-TB	Carbothioamide group, similar to ethionamide	Fatol	Germany	100 tablets	E/R	60 months	In a dry place, below 25 °C, protected from light
Kanamycin, vials, 1 g dry powder for injection (Km)	Should be used only for MDR-TB, but is also used for sexually transmitted infections in Portuguese-speaking African countries.	Aminoglycoside, similar to amikacin, streptomycin, capreomycin	Rotexmedica	Germany	50 vials	E/F/S	36 months	For stability reasons, the product is supplied as dry powder in the form of kanamycin acid phosphate. Before use, 4 ml water for injection should be added. In a dry place, below 25 °C, protected from light
Ofloxacin, 200-mg tablets (Ofx)	For different types of infections, including MDR-TB	Fluoroquinolone, similar to ciprofloxacin, norfloxacin, levofloxacin	Macleods Microlabs	India India	100 tablets 100 tablets	E/F/S/ R	36 months	In a dry place, below 25 °C, protected from light
PASER sachet equivalent to 4 g aminosalicilic acid	Should be used only for the treatment of MDR-TB	salicylic acid; anti-folate	Jacobus	USA	30 x 4-g sachets	E/R	24 months	In a dry place below 15 °C (in a refrigerator or freezer)
Levofloxacin, 250 mg tablets (Lvx)	For different types of infections, including MDR-TB	Fluoroquinolone, similar to ciprofloxacin, ofloxacin,	Macleods	India	100 tab blister	E/F/S/P	24 months	In a dry place below 25 °C, protected from light
Moxifloxacin 400 mg tablets, (Mfx)	For different types of infections, including MDR-TB	Fluoroquinolone, similar to ciprofloxacin, ofloxacin, levofloxacin	Bayer	Europe	5 tablets, blister	E	60 months	In a dry place below 25 °C, protected from light

E / F / S / P / R = English / French / Spanish / Portuguese / Russian