

**PROCUREMENT MANUAL
FOR THE DOTS-PLUS PROJECTS
APPROVED BY THE
GREEN LIGHT COMMITTEE**

Edited by

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Marina Sereguina

Ron Wehrens



**World Health
Organization**

IDA

INTERNATIONAL DISPENSARY ASSOCIATION

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The International Dispensary Association (IDA) Foundation has been contracted by the World Health Organization (WHO) as the procurement agency responsible for the procurement, quality assurance and distribution of second-line anti-tuberculosis (anti-TB) drugs for treating patients with multidrug-resistant tuberculosis (MDR-TB), in the DOTS-Plus pilot projects approved by the Green Light Committee (GLC).

This manual explains the procurement procedures as agreed by WHO and IDA and gives relevant background information on various supply-related aspects.

An example of the electronic order form containing the most commonly used items is included and can be obtained on CD ROM from IDA (mdrtb@ida.nl).

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1. Glossary and abbreviations

airway bill

Document prepared by the shipper that provides details about the contents of the 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

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 Practice

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

GDP: Good Distribution Practice

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 nonproprietary name or under a new brand (proprietary) name.

GLC

Green Light Committee

GLC Secretariat

The function housed at WHO that assists with GLC operations and coordinates drug procurement by DOTS-Plus pilot projects.

GMP: Good Manufacturing Practice

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

IDA

International Dispensary Association

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. In this case, 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.

The seller must pay the costs and freight necessary to bring the goods to the named port of destination. In this case, 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. In this case, IDA calculates freight charges to the port 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. In this case, 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 (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 – a 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 proforma 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, strength, manufacturer and quality of the final product. The competent drug regulatory authority issues an official document.

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.

2. Frequently asked questions

1. What is the background of the IDA Foundation?

The IDA Foundation 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. In addition, IDA provides procurement agency services and offers consultancy and training on topics related to the various aspects of pharmaceutical supply management. IDA is based in the Netherlands and is ISO 9002-2000 and GDP certified. The quality of IDA products is verified in IDA's GcLP-approved laboratories.

More information on IDA can be found at: www.ida.foundation.org.

2. What is the purpose of the Green Light Committee?

GLC is a subgroup of the Stop TB Working Group on DOTS-Plus for MDR-TB. GLC has been established to review applications from potential DOTS-Plus pilot projects and determine whether they are in compliance with WHO's Guidelines for establishing DOTS-Plus pilot projects for the management of MDR-TB (WHO/CDS/TB/2000.279). Projects that are approved will benefit from second-line anti-TB drugs at concessional prices and from technical assistance from the GLC.

More information on GLC can be found at:
<http://www.who.int/tb/dots/dotsplus/management/en/index.html>

3. What is the relationship between WHO and IDA?

In 2001, an agreement was signed between WHO and IDA for the procurement, quality assurance and distribution of second-line anti-TB drugs for the projects approved by the GLC. The purpose of this agreement, which covers a 3-year period and was extended for 18 months, is to ensure an uninterrupted supply of high-quality products at the lowest price achievable through economies of scale.

4. When does IDA get involved?

Once the project has been approved, the GLC secretariat provides an official letter to IDA specifying the quantities of drugs approved and will facilitate contact between the project and IDA.

5. Which second-line anti-TB drugs are covered by the contract?

The contract covers all presentations of the following drugs:

Second-line anti-TB drugs	Abbreviations
amikacin	Am
capreomycin	Cm
ciprofloxacin	Cx
cycloserine	Cs
ethionamide	Et
kanamycin	Km
levofloxacin (Levaquin [®] /Tavanic)	L
ofloxacin	O
<i>p</i> -aminosalicylic acid	PASER
prothionamide	Pt

With the exception of levofloxacin (Levaquin[®]), which remains under patent until 2010, all these second-line anti-TB drugs are off patent and available in generic presentations.

Further details about these drugs can be found in the product information sheets included in this publication.

For the correct administration of these and other drugs and general treatment of tuberculosis patients, additional products, such as syringes, needles and water for injection, are required.

6. How is the quality of the drugs assured?

IDA's quality assurance (QA) process covers the entire supply chain, from manufacture of the raw materials to delivery of the finished product to the customer.

To ensure compliance with GMP requirements, suppliers and manufacturing sites are carefully selected and are regularly inspected by IDA pharmacists according to WHO guidelines. Each potential manufacturer is reviewed in terms of source of raw materials, stability studies, product specifications and all other relevant documentation. Samples of products are analysed for compliance to specifications. Once product–manufacturer combinations are approved by IDA's QA department, detailed specifications – including source of raw materials – are prepared to ensure that the product will later be manufactured to agreed specifications.

Packing and labelling specifications are developed by IDA's QA department to ensure consistency in packing, labelling and product information.

After approval, extensive monitoring of product quality continues; all batches are sampled, visually inspected and assessed on the basis of the manufacturer's Certificate of Analysis. A considerable number of batches are subjected to re-analysis in IDA's QA laboratory. 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.

This process applies only to generic products and not to Eli Lilly products supplied to IDA.

In addition, the WHO prequalification project is now including the second-line anti-TB drugs in the list of drugs which should be assessed by WHO. In the future, only drugs approved by WHO should be supplied to GLC-approved projects.

More information on the WHO prequalification project can be found at <http://mednet3.who.int/prequal/>

7. How are the prices determined?

In line with its contract with WHO, IDA continuously negotiates the best possible prices for the drugs concerned. A 7% margin is then added to the purchase price to cover IDA's operational costs. As the purchase price may fluctuate with international exchange rates, available source and quantities required, the prices at which IDA ultimately offers the drugs are likely to change. Definitive prices can be given only after receipt of a firm purchase order.

Following an agreement between WHO and the manufacturer Eli Lilly, limited quantities of capreomycin and cycloserine are offered at a reduced price to GLC-approved projects.

8. When should the drugs be ordered from IDA?

IDA will start procurement in response to approved, confirmed and prepaid orders. In this way, optimal drug shelf lives are guaranteed. Delivery times depend on quantities required and the availability of the drugs. It is strongly recommended that orders be placed as early as possible, allowing at least 4 months for the drugs to be delivered.

Second-line anti-TB drugs are not kept in stock by either IDA or any of the drug manufacturers, including Eli Lilly.

9. Will the drugs be registered in my country?

Countries may require that drugs be registered before their importation is allowed. Some of the second-line anti-TB drugs have already been registered with drug regulatory authorities in several countries.

Projects based in countries requiring registration should inform IDA at the earliest possible stage. IDA can then facilitate transfer of the required information and documentation from the manufacturer to the registration authority in the country of destination.

Drug registration is the responsibility of the project manager. WHO and IDA will both facilitate this process. In several countries, registration can take up to about 2 years.

In countries other than the Russian Federation, drugs may be exempt from registration if they are requested directly from WHO. In fact, WHO has signed host agreements with the governments of most countries allowing the Organization to import drugs without preliminary registration.

Details of registration status are given in the product information sheets included in this publication.

10. How will the international transport of the goods be arranged?

IDA can arrange transport by the following methods:

- ***Air freight***

The fast and predictable transfer times make air freight is by far the safest mode of transport and it is therefore recommended for the relatively sensitive and valuable second-line anti-TB drugs. IDA's close cooperation with the world's largest airlines and forwarding agencies ensures reliable transportation.

- ***Sea freight***

On request, small-volume consignments can be shipped by sea in extra-strong wooden cases. However, the risks of delay, theft and damage mean that this method is not commonly used for the supply of second-line anti-TB drugs. For larger consignments, however, sea transport by container may be a better option. A so-called reefer container can be arranged to ensure refrigerated conditions during shipment.

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

11. Which documents can IDA provide?

The following documents can be provided by IDA:

- GMP/marketing licence
- Certificate of Pharmaceutical Product
- Certificate of Origin
- Certificate of Analysis
- Packing list
- Invoice
- Airway bill (for air freight)
- Bill of lading (for sea freight)
- Free Gift Certificate
- Certificate of Insurance

In addition to the export documents provided with the consignment, copies are also sent to:

- invoice address
- delivery address
- clearing address.

12. What are the payment conditions?

IDA requires payment in advance. For orders over €500 000, payment can also be made by Letter of Credit: please consult with IDA before opening the Letter of Credit.

As soon as payment is received or a Letter of Credit has been approved by IDA's Financial Department, the procurement process can be started.

13. What storage conditions are needed for the drugs?

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, specified by the manufacturers, to ensure that they retain their quality, safety and efficacy throughout their shelf life.

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.

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

14. Who are the contact persons?

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

IDA:

Mrs Marieke Korsten/Vicente Segovia
E-mail: mkorsten@idafoundation.org /
vsegovia@idafoundation.org
Tel: +31 20 403 7 159
Fax: +31 20 403 1 854

WHO:

Mrs Fabienne Jouberton
Procurement Officer
E-mail: joubertonf@who.int
Tel: +41 22 791 18 81 (direct line)
Fax: +41 22 791 42 68

3. Order procedures

Your request can be submitted to IDA (for the attention of Mrs Korsten and Mr Segovia. Please send a copy of the request to Mrs Jouberton. (For addresses, see p. 9)

The following information is required:

- The GLC-assigned project approval number
- The products and quantities required (which must be in line with the GLC approval)
- Full delivery address details
- Full details of the paying organization
- Full details of the forwarding agent or consignee (optional)
- Your reference number for the request
- Preferred mode of transport (air or sea)
- Preferred arrival date
- Required documents
- Registration requirements in the country of destination.

IDA will then send the proforma invoice including:

- Prices (in US dollars)
- Name of the manufacturers
- Overview of registration (if required)
- Estimated delivery time
- Payment conditions
- Freight charges
- Insurance charges.

IDA will then await your confirmation and payment. As soon as these have been received, a firm delivery schedule will be given. Changes in quantities or products are not possible after receipt of your order confirmation.

Upon receipt of the drugs, IDA will perform quality control tests to verify that the drugs comply with the agreed standards.

After goods have been released by IDA's quality control laboratories, they will be prepared for shipment. As soon as transport arrangements have been made, IDA will send the documents required for customs clearance.

4. Product information sheets

Product Information Sheet

Amikacin, 500 mg/ml, 2-ml ampoules

Pharmaceutical information

Use: for different types of infections, including MDR-TB

Group: aminoglycoside, similar to streptomycin, kanamycin, capreomycin

Available from IDA	Country of origin	Pack size		Shelf-life	Registered in
Gland Pharma	India	100 ampoules	E/F/S	24 months	India

Price indication: US\$ 24.00 /100 ampoules, ex-works

Conditions of storage:

Below 25 °C, protected from light

Abbreviations:

E – English

F – French

R – Russian

S – Spanish

Minimum order (batch size) 2000 x 100 amps

Product Information Sheet

Capreomycin, vials, 1 g dry powder for injection

Pharmaceutical information

Use: should be used only for the treatment of MDR-TB

Group: aminoglycoside, similar to streptomycin, kanamycin, amikacin

Available from IDA	Country of origin	Pack size	Labelling	Shelf-life	Registered in
Eli Lilly	Germany	vial	E	24 months	Armenia, Australia, Kazakhstan, Latvia, Peru, Poland, Russian Federation, Spain
Eli Lilly	Germany	vial	R	24 months	Russian Federation

Price indication: US\$ 1.07/vial, ex-works (Eli Lilly price)*

Conditions of storage:
Below 25 °C

Abbreviations:

E – English

F – French

R – Russian

S – Spanish

* Depends of availability of Eli Lilly product against concessional price. Non-concessional price is US\$ 3.21

Product Information Sheet

Cycloserine, 250-mg capsules

Pharmaceutical information

Use: only for second-line treatment of MDR-TB

Group: separate group, unrelated to other MDR-TB drugs except terizidone

Remarks: relatively unstable product – adherence to storage conditions as specified on label is important (dry place, below 25 °C)

Available from IDA	Country of origin	Pack size	Labelling	Shelf-life	Registered in
Macleods	India	100 capsules	E/F/S	24 months	India
Macleods	India	60 capsules	R	24 months	Russian Federation
Macleods	India	60 capsules	E/F/S	24 months	Kazakhstan, Nepal, Sri Lanka, Viet Nam
Eli Lilly	Greece	100 capsules	E	18 months	Armenia, Australia, Estonia, France, Hong Kong SAR, Israel, Kazakhstan, Latvia, Lithuania, Malaysia, Malta, Peru, Poland, Romania, Russian Federation, United Arab Emirates, United Kingdom, USA
Eli Lilly	Greece	100 capsules	R	18 months	Russian Federation

Price indication: US\$ 52.50/100 capsules, ex-works (Mc Leods)

US\$ 14.55/100 capsules, ex-works (Eli Lilly)

Conditions of storage:
In a dry place, below 25 °C

Abbreviations:

E – English
F – French
R – Russian
S – Spanish

Product Information Sheet

Ethionamide, 250-mg tablets

Pharmaceutical information

Use: should be used only for the treatment of MDR-TB

Group: thioamide group, similar to prothionamide

Available from IDA	Country of Origin	Pack size	Labelling	Shelf-life	Registered in
Macleods	India	100 tablets	E/F/S	36 months	Kazakhstan, Malta, Nepal, Peru, Ukraine, Viet Nam
Macleods	India	100 tablets	R	36 months	Russian Federation

Price indication: US\$ 10.20/100 tablets, ex-works

Conditions of storage:

Below 25 °C, protected from light

Abbreviations:

E – English

F – French

R – Russian

S – Spanish

Product Information Sheet

Prothionamide, 250-mg tablets

Pharmaceutical information

Use: should be used only for the treatment of MDR-TB

Group: thioamide group, similar to ethionamide

Available from IDA	Country of Origin	Pack size	Labelling	Shelf life	Registered in
Fatol	Germany	100 tablets	E	60 months	Germany
Fatol	Germany	100 tablets	R	60 months	Russian Federation

Price indication: US\$ 12.57/100 tablets, ex-works

Conditions of storage:

Below 25 °C, protected from light

Abbreviations:

E – English

R – Russian

Product Information Sheet

Kanamycin, vials, 1 g dry powder for injection

Pharmaceutical information

Use: should be used only for MDR-TB, but is also used for sexually transmitted infections in Portuguese-speaking African countries.

Group: aminoglycoside, similar to amikacin, streptomycin, capreomycin

Remarks: 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.

Available from IDA	Country of origin	Pack size	Labelling	Shelf life	Registered in
Rotexmedica	Germany	50 vials	E/F/S	36 months	Hong Kong SAR, Myanmar, Romania

Price indication: US\$ 18.46/50 vials, ex-works

Conditions of storage:
Below 25 °C, protected from light

Abbreviations:

E – English

F – French

R – Russian

S – Spanish

Product Information Sheet

Ofloxacin, 200-mg tablets

Pharmaceutical information

Use: for different types of infections, including MDR-TB

Group: fluoroquinolone, similar to ciprofloxacin, norfloxacin, levofloxacin

Available from IDA	Country of origin	Pack size	Labelling	Shelf-life	Registered in
Macleods	India	60 tablets	R	36 months	Russian Federation
Microlabs	India	100 tablets	E/F/S	36 months	India

Price indication: US\$ 3.50/100 tablets, ex-works

Conditions of storage:

In a dry place, below 25 °C

Abbreviations:

E – English

F – French

R – Russian

S – Spanish

Product Information Sheet

PASER sachet equivalent to 4 g aminosalicylic acid

Pharmaceutical information

Use: should be used only for the treatment of MDR-TB

Group: separate class, unrelated to any other MDR-TB drugs

Available from IDA	Country of origin	Pack size	Labelling	Shelf-life	Registered in
Jacobus	USA	30 x 4-g sachets	E/F/S	24 months	USA
Jacobus	USA	30 x 4-g sachets	R	24 months	Russian Federation

Price indication: US\$ 47.50/30 sachets, ex-works

Conditions of storage:

In a dry place below 15 °C (in a refrigerator or freezer)

Abbreviations:

E – English

F – French

R – Russian

S – Spanish

5. IDA E-Catalogue MDR-TB products (May 2004)

Electronic order form (example)

Qty	Product description	Unit		Price indication in USD ex-works Amsterdam	Total estimated value (in USD)	Total volume (in cm ³)	Total weight (in kg)	Price indication in another currency ex-works Amsterdam	Total estimated value (in another currency)
	amikacin 500 mg/2-ml injection	100	ampoules	24.00					
	capreomycin 1g powder for injection	1	vials	1.07					
	cycloserine 250-mg tablets	100	capsules	14.55					
	ethionamide 250-mg tablets	100	tablets	10.20					
	prothionamide 250-mg tablets	100	tablets	12.57					
	kanamycin 1 g powder for injection	50	vials	18.46					
	ofloxacin 200-mg tablets	100	tablets	3.50					
	PASER sachet, equivalent to 4 g aminosalicylic acid **	30	sachets	47.50					

** to be kept in a cold chain

Order Details	
About this order	
Name of the project:	
Reference number of the project:	
Your reference number of the request:	
Date of the order submission:	
Date of approval by GLC:	
Must the requested products be registered in your country?	
Mode of transportation? (AIR, SEA)	
Preferred arrival date:	
Is part-shipment allowed?	
Required documents:	
Additional remarks:	
About your organization	
Did you order from IDA before? If Yes, your Customer number:	
Name:	
Contact person:	
Address:	
City:	
Country:	
Tel:	
Fax:	
E-mail:	
Additional remarks:	
About the destination of this consignment	
Name:	
Contact person:	
Address:	
City:	
Country:	
Tel:	
Fax:	
E-mail:	
Additional remarks:	
About the forwarding agent (if applicable)	
Name:	
Contact person:	
Address:	
City:	
Country:	
Tel:	
Fax:	
E-mail:	
Additional remarks:	
About the payment for the consignment	
Will payment be made by your organization? (Y/N)	
If No: Details of the financing organization:	
Name:	
Contact person:	
Address:	
City:	
Country:	
Tel:	
Fax:	
E-mail:	
Additional remarks:	