



IDA Foundation: procuring second-line drugs to treat MDR-TB through the GLC mechanism

IDA acts as exclusive procurement agent for the Global Drug Facility (GDF), housed at the World Health Organization (WHO), to support the supply of affordable and quality assured second-line TB products to over 50 Green Light Committee (GLC) approved projects around the world. In close cooperation with GDF, IDA, as a not-for-profit organisation, is pro-actively working on improving product quality, lead times and ensuring affordability. Our key activities and actions are listed below, all of which are aimed at continuously enhancing projects supervised by GLC.

Quality Assurance

Second-line TB products supplied to GLC approved projects need to be safe, effective and appropriately labelled. There are currently only a limited number of manufacturers able to supply second-line TB products with sufficient guarantees of safety and efficacy.

IDA has 35 years experience in quality assurance of essential medicines, including assessment of manufacturing site compliance with GMP and the assessment of product dossiers for quality, safety and efficacy. IDA is therefore well placed to implement GDF's overall quality assurance (QA) system, which establishes the eligibility of second-line TB products to be supplied to GLC-approved projects. As a principle, IDA recognizes the assessments of the WHO Prequalification Programme (PQ) as well as those of Stringent Regulatory Authorities (SRA); in these cases IDA only requests additional product information for verification purposes such as shelf-life, packing specifications, labelling and method of analysis. In the absence of WHO PQ and SRA options, IDA participates in the GDF interim quality assessment process whereby second-line drugs are evaluated against defined criteria by Interim Review Committees (IRC) whose Members are appointed by WHO PQ and the DMSC (Drug Management Sub-Committee) of the MDR-TB Working Group, on the request of GDF. These criteria are drawn from the Pharmaceutical Product Questionnaire developed by the Inter-Agency Pharmaceutical Coordination Group as well as the expert inputs of IDA's Quality Assurance Department.

Documentation relating to batches of second-line TB products delivered to IDA's warehouse is assessed according to clearly defined specifications and batches are subjected to randomized (in the case of new products: 100 %) re-analysis by a WHO-prequalified laboratory for quality control purposes. The consignments are also subject to a pre-shipment physical inspection by IDA staff in the Netherlands.

Affordability

It is IDA's mission to deliver quality assured essential medicines at the lowest possible price. Aggregated high volume warrants access to competitive prices. In our aim to strengthen affordability of second-line TB products IDA, in consultation with GDF, is deploying the following initiatives:

- *Sourcing new suppliers* by publishing periodically, through GDF, an invitation to submit Expressions of Interest (EOI) for the supply of second-line TB products. Submissions which do not fulfil the quality criteria of WHO PQ or an SRA will be assessed under the aforementioned interim quality assessment process in order to provide for fast track approval of new products. This process serves as an interim complement until sufficient products are prequalified under the WHO PQ Programme or approved by a SRA. EOI's will, in principle, be followed by international tenders issued by IDA.
- *Negotiating better prices* on the basis of increasing volume, prompt payment policies and standardization. IDA's Purchasing Department requests quotations from all approved and eligible suppliers for every sales quotation. This way IDA can negotiate the most favourable terms. IDA maintains access to actual raw material prices for price control purposes.
- *Ensuring transparency*: All prices of second line TB products delivered by IDA for GDF/GLC are published on GDF's website (www.stoptb.org/gdf).





Availability

Given current lead times of manufacturers of second-line TB products, IDA in close cooperation with GDF, is taking the following initiatives to ensure faster deliveries where needed:

- *Stockpile*; in close cooperation with GDF, IDA is currently building up a strategic stockpile of second-line TB products in its warehouses in the Netherlands. The stockpile is financed by GDF with funds provided by UNITAID (www.unitaid.eu). The initial stockpile is based on treatments for 800 patients. However, given the rapid expansion of the various projects and challenging lead times for some products, GDF and IDA are now making preparations to increase the stockpile to 5,800 patients. IDA will ensure all provisions for sufficient cool storage. As the stockpile reaches its target level, urgent deliveries can be handled in a more effective way.
- *Increasing production capacity and improving lead times*; current and potential suppliers are contacted by IDA and requested to update us continuously about their second-line TB developments on product and production capacity level. IDA also advocates to its suppliers the importance of increasing production capacity through regular meetings and advises on API reserves.



Customer Service

Close customer contact is highly valued at IDA. A team of 19 professionals is involved in Procurement Services for GDF. Our Customer Service Desk is regionally clustered, ensuring active response to country-specific issues. The Desk is supervised by a dedicated Head Coordinator for GLC approved second-line TB projects, supported by a Deputy Coordinator. Specialists in our Purchase, Logistics and Quality Departments provide key internal support to order processing, stock management, quality assurance and registration issues. Regional IDA offices and a network of agents may provide local support. Given the increase of the second-line TB order volumes, IDA is currently expanding its Service Desk and optimizing working procedures to ensure continued rapid response to our clients and partners under the GLC projects. IDA is now providing electronic data directly into GDF's order management tool enabling recipients to track and trace orders.

For further information, please feel free to contact us.



IDA Foundation

Slochterweg 35
1027 AA Amsterdam
P.O. Box 37098
1030 AB Amsterdam
The Netherlands

Service Desk

phone: + 31 20 4033051
fax: + 31 20 4031854
e-mail: service@idafoundation.org
www.idafoundation.org

