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

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This procurement manual is a revision of the previous publication "PROCUREMENT MANUAL FOR THE DOTS-PLUS PROJECTS APPROVED BY THE GREEN LIGHT COMMITTEE" edited by the World Health Organization in 2006. (WHO/HTM/TB/2003.328 Rev.2)

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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 ICH[1](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 (EC9 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