Annex B: TECHNICAL SPECIFICATIONS OF E100DT, ITB - IDA/FLD/2021/001

Eligibility criteria for submission of bids for anti-tuberculosis drugs

Only bidders with products in compliance with the GDF Quality Assurance Policy (see http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp) are eligible to participate in the ITB.

The requirements are:

A. Products pre-qualified by WHO under the WHO Prequalification Programme (WHO PQP)[1]; or

B. Products approved by a Stringent Regulatory Authority (SRA)[2];

C. In the absence of products meeting the standards "A" and "B" as above, products recommended for use through a quality risk/benefit assessment process by the Expert Review Panel (ERP)[3]. These products are eligible for procurement for a limited period and under the following conditions:

1. The Finished Pharmaceutical Product (FPP) must be manufactured at an approved site as follows:
    - The site must have been inspected by WHO as a part of the WHO PQP (refer to http://apps.who.int/prequal/) and found to be operating at an acceptable level of compliance with WHO Good Manufacturing Practice (GMP) for the specific product; or
    - The site must have been inspected and found acceptable for the manufacture of the specific product by SRA defined as either: an International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) member country, an ICH observer or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement; or
    - The site must have been inspected and found acceptable for the manufacture of the specific product by inspectors of a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)
2. A product approval as described under either point "A" or "B" is pending, i.e. manufacturers have submitted relevant product dossiers and the dossiers have been accepted for assessment either by WHO PQP or SRA. Approvals under point "C" shall be limited to a maximum duration of 12 months in which manufacturers should obtain approval by WHO PQP or SRA.

Note: A bid submitted for a product for which the bidder has not received regulatory approval status as per GDF Quality Assurance policy and procedures, shall not be considered for the ITB evaluation.

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[1] https://extranet.who.int/prequal/content/prequalified-lists/medicines

[2] https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

[3] https://extranet.who.int/prequal/sites/default/files/documents/73_ERP_Feb2019.pdf

SCHEDULE NO. 2:

Oral solid dosage forms. Single dose formulations

ADULTS

1. ITEM No.1: Ethambutol 100 mg DT (blister)

General Description: Ethambutol 100mg dispersible tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets