Annex B: LIST AND TECHNICAL SPECIFICATIONS OF PRODUCTS, SECOND LINE DRUGS, ITB - IDA/SLD/2020/002

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 as following:

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.

---

[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. 1:

WHO-RECOMMENDED GROUP A AND B MEDICINES

ADULTS

1. ITEM No. 1: Levofloxacin 250 mg (blister)

General Description: Levofloxacin 250 mg film coated tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

2. ITEM No. 2: Levofloxacin 500 mg (blister)

General Description: Levofloxacin 500 mg film coated tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

3. ITEM No. 3: Levofloxacin 750 mg (blister)

General Description: Levofloxacin 750 mg film coated tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

4. ITEM No. 4: Moxifloxacin 400 mg (blister)

General Description: Moxifloxacin 400 mg film coated or scored tablets

Primary packaging: 10 tablets/blister.

Secondary packaging: pack of 10 blisters x 10 tablets

5. ITEM No. 5: Bedaquline 100 mg (container)

General Description: Bedaquline 100 mg tablets

Primary packaging: 188 tablets/HDPE container

Secondary packaging: pack of 188 tablets/HDPE container

6. ITEM No. 6: Linezolid 600 mg (blister)

General Description: Linezolid 600 mg film coated or scored tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

7. ITEM No. 7: Cycloserine 250 mg (blister)

General Description: Cycloserine 250 mg capsules

Primary packaging: 10 capsules/blister

Secondary packaging: pack of 10 blisters x 10 capsules

8. ITEM No. 8: Clofazimine 100 mg (blister/container)

General Description: Clofazimine 100 mg capsules or scored tablets

Primary packaging: 10 capsules or scored tablets/blister or HDPE container

Secondary packaging: pack of 10 blisters x 10 capsules or scored tablets or 100 capsules or scored tablets /HDPE container

SCHEDULE NO. 2:

WHO-RECOMMENDED GROUP C MEDICINES

ADULTS

9. ITEM No. 1: Ethionamide 250 mg (blister)

General Description: Ethionamide 250 mg film coated tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

10. ITEM No. 2: Delamanid 50 mg (blister)

General Description: Delamanid 50mg tablets

Primary packaging: 8 or 10 tablets/blister

Secondary packaging: pack of 6 blisters x 8 tablets or 10 blisters x 10 tablets

11. ITEM No. 3: Prothionamide 250 mg (blister)

General Description: Prothionamide 250mg film coated tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

12. ITEM No. 4: PAS Acid 4 g (sachet)

General Description: P-aminosalycilic (PAS) acid 4 g granules in sachet

Primary packaging: 1 sachet

Secondary packaging: pack of 1 x 30 sachets

13. ITEM No. 5: PAS Sodium 4 g (sachet)

General Description: P-amino-salicylate (PAS) sodium 4 g granules/powder in sachet

Primary packaging: 1 sachet

Secondary packaging: pack of 1 x 30 sachets or 25 sachets

14. ITEM No. 6: Amikacin 500 mg (ampoule)

General Description: Amikacin 500 mg solution for injection in ampoule

Primary packaging: 1 ampoule

Secondary packaging: pack of 1x10 ampoules or 1x100 ampoules

15. ITEM No. 7: Streptomycin 1g (vial)

General Description: Streptomycin 1g powder for injection in vials, without solvent

Primary packaging: 1 vial

Secondary packaging: pack of 1x10 vials or 1x100 vials

16. ITEM No. 8: Pretomanid 200mg (container)

General Description: Pretomanid 200mg tablets

Primary packaging: 26 tablets/HDPE container

Secondary packaging: pack of 26 tablets/HDPE container

17. ITEM No. 9: Imipenem/Cilastatin 500 mg + 500 mg (vial)

General Description: Imipenem/Cilastatin 500mg + 500mg powder for infusion in vials, without solvent

Primary packaging: 1 vial

Secondary packaging: pack of 1 x 10 vials or 1 x 100 vials

18. ITEM No. 10: Meropenem 1 g (vial)

General Description: Meropenem 1g powder for IV infusion in vials, without solvent

Primary packaging: 1 vial

Secondary packaging: pack of 1 x 10 vials or 1 x 100 vials

19. ITEM No. 11: Amoxicillin / Clavulanic acid 500 mg + 125 mg (blister)

General Description: Amoxicillin/Clavulanic acid 500mg +125mg tablets

Primary packaging: 10 or 15 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets or 1 blister x 15 tablets

SCHEDULE NO. 3:

PRODUCTS WITH UNCERTAIN DEMAND

ADULTS

20. ITEM No. 1: Terizidone 250mg (blister)

General Description: Terizidone 250mg capsules

Primary packaging: 10 capsules/blister

Secondary packaging: pack of 10 capsules x 10 blisters

21. ITEM No. 2: Water for Injection 10mL (ampoule/vial)

General Description: Water for injection, sterile, 10mL ampoules

Primary packaging: ampoule or vial

Secondary packaging: pack of 100 ampoules or vials

22. ITEM No. 3: Hypodermic AD syringe with re-use prevention feature, 5 ml with needle (21G, 22G or 23G) and Safety Box for used syringes, 5L

General Description of syringes: Hypodermic automatic disabling (AD) syringes with re-use prevention feature, capacity of 5mL, sterile, with needle on top or bi-packed for reconstitution and injection.

Technical Specifications for syringe and needle:

5mL Sterile, Auto Disable Syringe with 0.2ml graduation, in polypropylene, with Re-Use prevention feature, conform to ISO 7886-4, CE Marked Certificate with needle 21G x 1 1/2", 22G x 1" 1.5" and23G x 1" 1.5" mounted on top or bi-packed, stainless steel, plastic base and protecting cap. Packed in a sterile pack.
Packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterile peel-off pack. Product information on the individual pack: name of the manufacturer; type of product and main characteristics; expiry date; lot number; the word "sterile" or equivalent harmonized symbol, the words "check the integrity of the individual sterilization protection before use" (if space allows), "for single use", CE marking. Information for storage conditions as appropriate.

General Description of Safety boxes: Safety box for used syringes/needles, 5L

Technical Specifications for Safety box:

Puncture resistant containers for collecting and disposing of minimum 100 used AD syringes/ needles. Complies with WHO Performance specification E10/IC.2.
Packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For construction at the field level.

23. ITEM No. 4: Hypodermic AD syringes with re-use and sharp injury prevention (RUP/SIP) features, 5ml with needle (21G, 22G or 23G) and Safety Box for used syringes, 5L

General Description of syringes: Hypodermic automatic disabling (AD) syringes with re-use prevention and sharp injury prevention features, capacity of 5mL, sterile, with attached retractable needle or bi-packed for reconstitution and injection.

Technical Specifications for syringes:

5mL sterile Auto Disable Syringe with 0.2 ml graduation, in polypropylene, with Re-Use Prevention and Sharp Injury Prevention, conform to ISO 7886-4, with CE Marked Certificate, with retractable or bi-packed needle 21G x1" or 1 ¼", 23G x 1 ¼" and 23G x 1, Packed in a sterile blister pack.
Packaging: 100 pieces in a box. Each syringe and needle packed in an individual sterilized peel-off pack. Product information on the individual pack: name of the manufacturer; type of product and main characteristics; expiry date; lot number; the word "sterile" or equivalent harmonized symbol, the words "check the integrity of the individual sterilization protection before use" (if space allows), "for single use", CE marking. Information for storage conditions as appropriate.

Technical Specifications for Safety box:

Puncture resistant containers for collecting and disposing of minimum 100 used AD syringes/ needles. Complies with WHO Performance specification E10/IC.2.
Packaging: 25 boxes in one carton flat-packed for ease of shipment and storage. For construction at the field level.

SCHEDULE NO. 4:

PRODUCTS FOR PEDIATRIC M/XDR TB TREATMENT

24. ITEM No. 1: Levofloxacin 100 mg DT (blister)

General Description: Levofloxacin 100 mg dispersible tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

25. ITEM No. 2: Moxifloxacin 100 mg DT (blister)

General Description: Moxifloxacin 100 mg dispersible tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

26. ITEM No. 3: Bedaquline 20 mg (container)

General Description: Bedaquiline 20 mg tablets or scored tablets

Primary packaging: 60 tablets/HDPE container

Secondary packaging: 60 tablets/HDPE container

27. ITEM No. 4: Linezolid 100 mg/5 ml (bottle)

General Description: Linezolid 100 mg/5ml oral suspension

Primary packaging: 1 bottle

Secondary packaging: pack of 1 bottle

28. ITEM No. 5: Linezolid 150mg (blister)

General Description: Linezolid 150 mg scored or dispersible tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

29. ITEM No. 6: Cycloserine 125 mg (blister)

General Description: Cycloserine 125 mg capsules

Primary packaging: 10 capsules/blister

Secondary packaging: pack of 10 blisters x 10 capsules

30. ITEM No. 7: Clofazimine 50 mg (blister/container)

General Description: Clofazimine 50 mg capsules or scored tablets

Primary packaging: 10 capsules/blister or 100 capsules/HDPE container

Secondary packaging: pack of 10 blisters x 10 capsules or 100 capsules/HDPE container

31. ITEM No. 8: Ethionamide 125 mg DT (blister)

General Description: Ethionamide 125 mg dispersible tablets

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

32. ITEM No. 9: Amoxicillin / Clavulanic acid 250 mg + 62.5 mg (bottle)

General Description: Amoxicillin/Clavulanic acid 250mg +62.5mg powder for suspension in bottle.

Primary packaging: 1 bottle.

Secondary packaging: pack of 1 bottle.