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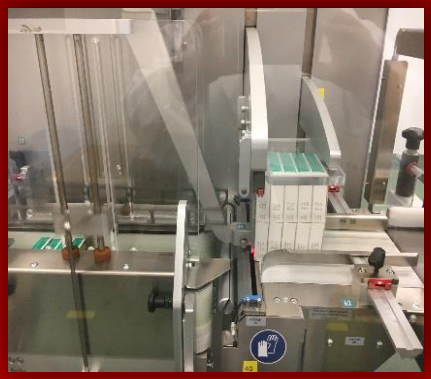

ANTI–TUBERCULOSIS MEDICINES TECHNICAL SPECIFICATIONS, SECOND LINE DRUGS – ITB -IDA/SLD/2018/002

GLOBAL DRUG FACILITY

STBP | Stop TB Partnership

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.

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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%20ERP_Feb2016_1.pdf

A. SECOND LINE DRUGS

SCHEDULE NO. 1:

Oral solid dosage forms. Fluoroquinolones

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.

SCHEDULE NO. 2: Second-line injectable agents

5. ITEM No. 1: Amikacin 500 mg (ampoule)

General Description: Amikacin 500 mg solution for injection in ampoule

Primary packaging: 1 ampoule

Secondary packaging: pack of 10, 50 or 100 ampoules

6. ITEM No. 2: Capreomycin 500 mg (vial)

General Description: Capreomycin 500 mg powder for injection in vial.

Primary packaging: 1 vial

Secondary packaging: pack of 1, 10 or 100 vials

7. ITEM No. 3: Capreomycin 1g (vial)

General Description: Capreomycin 1 g powder for injection in vial.

Primary packaging: 1 vial

Secondary packaging: pack of 1, 10 or 100 vials

8. ITEM No. 4: Kanamycin 500 mg (vial/ampoule)

General Description: Kanamycin 500 mg powder/solution for injection in vial/ampoule, without solvent.

Primary packaging: 1 vial/ampoule.

Secondary packaging: pack of 1, 10, 50 or 100 vials/ampoules.

9. ITEM No. 5: Kanamycin 1g (vial/ampoule)

General Description: Kanamycin 1g powder/solution for injection in vial/ampoule, without solvent.

Primary packaging: 1 vial/ampoule.

Secondary packaging: pack of 1, 10, 50 or 100 vials/ampoules.

10. ITEM No. 6: Streptomycin 1g (vial)

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

Primary packaging: 1 vial

Secondary packaging: pack of 1, 10, 50 or 100 vials

SCHEDULE NO. 3:

Oral solid dosage forms. Other core second-line agents for adults and children

ADULTS

11. 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.

12. ITEM No. 2: 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.

13. ITEM No.3: Cycloserine 250 mg (blister)

General Description: Cycloserine 250 mg capsules.

Primary packaging: 10 capsules/blister

Secondary packaging: pack of 10 blisters x 10 capsules.

14. ITEM No. 4: Linezolid 600 mg (blister)

General Description: Linezolid 600 mg film coated or scored tablets.

Primary packaging: 10 tablets/blister

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

15. ITEM No. 5: Clofazimine 100 mg (blister/container)

General Description: Clofazimine 100 mg capsules or scored tablets.

Primary packaging: 10 capsules/blister or 50 capsules/HDPE container.

Secondary packaging: pack of 10 blisters x 10 capsules or 50 capsules/HDPE container.

16. ITEM No. 6: Terizidone 250mg (blister/container)

General Description: Terizidone 250mg capsules.

Primary packaging: 10 capsules/blister or 50 capsules/HDPE container.

Secondary packaging: pack of 10 capsules x 10 blisters or 50 capsules/HDPE container.

CHILDREN

17. ITEM No. 7: Ethionamide 125 mg (blister)

General Description: Ethionamide 125 mg tablets.

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets.

18. ITEM No. 8: Clofazimine 50 mg (blister/container)

General Description: Clofazimine 50 mg soft capsules or scored tablets.

Primary packaging: 10 capsules/blister or 50 capsules/HDPE container.

Secondary packaging: pack of 10 blisters x 10 capsules or 50 capsules/HDPE container.

SCHEDULE NO. 4:

Other add-on agents for adults and children

ADULTS

19. ITEM No. 1: 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.

20. ITEM No. 2: 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 1 x 25 sachets.

21. ITEM No. 3: 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.

22. ITEM No. 4: 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.

23. ITEM No. 5: Amoxicillin / Clavulanic acid 500 mg + 125 mg (blister)

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

Primary packaging: 10 or 15 tablets/blister

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

24. ITEM No.6: Amoxicillin / Clavulanic acid 875 mg + 125 mg (blister)

General Description: Amoxicillin/Clavulanic acid 875mg +125mg film-coated tablets.

Primary packaging: 8 or 10 tablets/blister

Secondary packaging: pack of 2 blisters x 8 tablets or 10 blisters x 10 tablets.

25. ITEM No. 7: Pyridoxine 50 mg (blister)

General Description: Pyridoxine hydrochloride 50mg tablets.

Primary packaging: 10 or 25 tablets/blister

Secondary packaging: pack of 1 blister x 10 tablets or 2 blisters x 25 tablets.

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

General Description: Pyridoxine hydrochloride 100mg tablets.

Primary packaging: 10 tablets/blister or 250 tablets/HDPE container.

Secondary packaging: pack of 10 blisters x 10 tablets or 250 tablets /HDPE container.

CHILDREN

27. ITEM No. 9: Amoxicillin / Clavulanic acid 125 mg + 31.25 mg (bottle)

General Description: Amoxicillin/Clavulanic acid 125mg +31.25mg powder for suspension in bottle.

Primary packaging: 1 bottle

Secondary packaging: pack of 1 bottle, 100ml.

28. ITEM No. 10: Amoxicillin / Clavulanic acid 250 mg + 125 mg (blister)

General Description: Amoxicillin/Clavulanic acid 250mg +125mg film coated tablets.

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 1 or 2 blisters x 10 tablets.