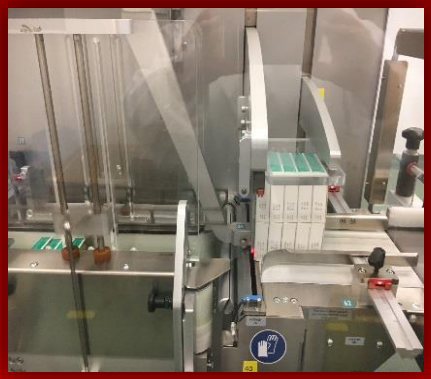
2019




# ANTI–TUBERCULOSIS MEDICINES TECHNICAL SPECIFICATIONS, SECOND LINE DRUGS: ITB-IDA/GDF-SLD/2019/002

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:**

**GROUP A**

## 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: Bedaquiline 100 mg (blister/container)

**General Description:** Bedaquiline 100 mg tablets.

**Primary packaging**: 10 tablets/blister or 100 tablets/HDPE container.

**Secondary packaging:** pack of 1 blister x 10 tablets or 100 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 1 blister x 10 tablets or 10 blisters x 10 tablets.

## CHILDREN

### 7. ITEM No. 7: 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.

### 8. ITEM No. 8: 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.

### 9. ITEM No. 9: Linezolid 100 mg/5 ml (bottle)

**General Description:** Linezolid 100 mg/5ml oral suspension.

**Primary packaging**: 1 bottle.

**Secondary packaging:** pack of 1 b ottle.

### 10. ITEM No. 10: Linezolid 150mg (blister/container)

**General Description:** Linezolid 150 mg scored or dispersible tablets.

**Primary packaging**: 10 tablets/blister/container

**Secondary packaging:** pack of 1 blister x 10 tablets or 100 tablets/HDPE container.

**SCHEDULE NO. 2:**

**GROUP B**

## ADULTS

### 11. ITEM No.1: Cycloserine 250 mg (blister)

**General Description:** Cycloserine 250 mg capsules.

**Primary packaging**: 10 capsules/blister.

**Secondary packaging:** pack of 10 blisters x 10 capsules.

### 12. ITEM No. 2: Clofazimine 100 mg (blister/container)

**General Description:** Clofazimine 100 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.

### 13. ITEM No. 3: Terizidone 250mg (blister)

**General Description:** Terizidone 250mg capsules.

**Primary packaging**: 10 capsules/blister.

**Secondary packaging:** pack of 10 capsules x 10 blisters.

## CHILDREN

### 14. ITEM No.4: Cycloserine 125 mg (blister)

**General Description:** Cycloserine 125 mg capsules.

**Primary packaging**: 10 capsules/blister.

**Secondary packaging:** pack of 10 blisters x 10 capsules.

### 15. ITEM No.5: 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.

**SCHEDULE NO. 3:**

**GROUP C**

## ADULTS

### 16. 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.

### 17. 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.

### 18. 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.

### 19. ITEM No. 4: 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.

### 20. ITEM No. 5: 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.

### 21. 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.

### 22. 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.

### 23. ITEM No. 8: 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.

### 24. ITEM No. 9: 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.

## CHILDREN

### 25. ITEM No. 10: 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.

## SCHEDULE NO. 4:

## OTHER ADD-ON AGENTS

# ADULTS

### 26. ITEM No. 1: 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.

### 27. ITEM No.2: Amoxicillin / Clavulanic acid 875 mg + 125 mg (blister)

**General Description:** Amoxicillin/Clavulanic acid 875mg +125mg tablets.

**Primary packaging**: 10 tablets/blister.

**Secondary packaging:** pack of 10 blisters x 10 tablets.

### 28. ITEM No. 3: Capreomycin 1g (vial)

**General Description:** Capreomycin 1 g powder for injection in vial, without solvent.

**Primary packaging:** 1 vial.

**Secondary packaging:** pack of 1 or 1x 10 vials.

### 29. ITEM No. 4: Kanamycin 1g (vial)

**General Description:** Kanamycin 1g powder for injection in vial, without solvent.

**Primary packaging:** 1 vial.

**Secondary packaging:** pack of 1 or 1x10 vials.

### 30. ITEM No. 5: Kanamycin 1g (ampoule)

**General Description:** Kanamycin 1g solution for injection in ampoule.

**Primary packaging:** 1 ampoule.

**Secondary packaging:** pack of 1 or 1x10 ampoules.

## 31. ITEM No. 6: Water for Injection 5ml ampoule/vial

**General Description:** Water for injection, sterile, 5mL ampoules/vial

**Primary packaging:** ampoule/vial

**Secondary packaging**: pack of 100 ampoules

## 32. ITEM No. 7: 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.

## 33. ITEM No. 8: 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.

## CHILDREN

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

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

**Primary packaging**: 1 bottle.

**Secondary packaging:** pack of 1 bottle.

### 35. ITEM No. 10: Capreomycin 500 mg (vial)

**General Description:** Capreomycin 500 mg powder for injection in vial, without solvent.

**Primary packaging:** 1 vial.

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

### 36. ITEM No. 11: Kanamycin 500mg (vial)

**General Description:** Kanamycin 500mg powder for injection in vial, without solvent.

**Primary packaging:** 1 vial.

**Secondary packaging:** pack of 1 or 1x10 vials.

### 37. ITEM No. 12: Kanamycin 500mg (ampoule)

**General Description:** Kanamycin 500mg solution for injection in ampoule.

**Primary packaging:** 1 ampoule.

**Secondary packaging:** pack of 1 or 1x10 ampoules.