

ANNEX B: LIST AND TECHNICAL SPECIFICATIONS OF PRODUCTS - 2016

Eligibility criteria for first-line anti tuberculosis drugs (FLD)

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

- A. Products shall be pre-qualified by WHO under the WHO Prequalification Programme (WHO PQP);
or
- B. Products shall be approved by a Stringent Regulatory Authority (SRA)
- C. In absence of products meeting the standards "A" and "B" above, products may be approved by GDF under the following option: Products shall be found acceptable to the GDF through a quality risk/benefit assessment process involving an Expert Review Panel (ERP). Products shall be eligible for this interim process 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 product³ 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 agreement⁴; 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)⁵
 2. A product approval as described under either points "B" or "C" 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 "D" 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 in accordance with the GDF Quality Assurance policy and procedures, shall not be considered for the ITB evaluation.

List of products are presented in 4 schedules as follows:

SCHEDULE NO. 1:

Oral solid dosage forms. Fixed dose combinations for adults and children.

ADULTS:

▪ **ITEM No. 1: 4FDC/ RHZE 150/75/400/275 (blister)**

General Description: Fixed-dose combination of Ethambutol 275mg/ Isoniazid 75mg/ Pyrazinamide 400mg/ Rifampicin 150mg coated tablets.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets.

▪ **ITEM No. 2: 3FDC/ RHE 150/75/275 (blister)**

General Description: Fixed-dose combination of Ethambutol 275mg/ Isoniazid 75mg/ Rifampicin 150mg coated tablets.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets.

▪ **ITEM No. 3: 2FDC/ RH 150/75 (blister)**

General Description: Fixed-dose combination of Isoniazid 75mg/ Rifampicin 150mg coated tablets or capsules

Primary packaging: 28 tablets or capsules/blister

Secondary packaging: pack of 24 blisters x 28 tablets or capsules

▪ **ITEM No. 4: 2FDC/ RH 150/150 (blister)**

General Description: Fixed-dose combination of Isoniazid 150mg/ Rifampicin 150mg coated tablets or capsules

Primary packaging: blister of 28 tablets or capsules

Secondary packaging: pack of 24 blisters x 28 tablets or capsules

▪ **ITEM No. 5: 2FDC/ RH 300/150 (blister)**

General Description: Fixed-dose combination of Isoniazid 150mg/ Rifampicin 300mg coated tablets or capsules.

Primary packaging: 28 tablets/blister or 10 capsules/blister

Secondary packaging: pack of 24 blisters x 28 tablets or pack of 10 blisters x 10 capsules

▪ **ITEM No. 6: 2FDC/ EH 400/150 (blister)**

General Description: Fixed-dose combination of Ethambutol 400mg/ Isoniazid 150mg coated tablets or capsules

Primary packaging: 28 tablets or capsules/blister

Secondary packaging: pack of 24 blisters x 28 tablets or capsules

CHILDREN:

▪ **ITEM No. 7: 3FDC/ RHZ 60/30/150 (blister)**

General Description: Fixed-dose combination of Isoniazid 30mg/ Pyrazinamide 150mg/ Rifampicin 60mg dispersible uncoated tablets.

Primary packaging: 28 tablets/blister or 6 tablets/strip

Secondary packaging: pack of 3 blisters x 28 tablets or pack of 14 strips x 6 tablets

▪ **ITEM No. 8: 2FDC/ RH 60/60 (blister)**

General Description: Fixed-dose combination of Isoniazid 60mg/ Rifampicin 60mg / dispersible uncoated tablets.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 3 blisters x 28 tablets

▪ **ITEM No. 9: 2FDC/ RH 60/30 (blister)**

General Description: Fixed-dose combination of Isoniazid 30mg/ Rifampicin 60mg/ dispersible uncoated tablets.

Primary packaging: 28 tablets/blister or 6 tablets/strip

Secondary packaging: pack of 3 blisters x 28 tablets or pack of 14 strips x 6 tablets

▪ **ITEM No. 10: 3FDC/ RHZ 75/50/150 (blister)**

General Description: Fixed-dose combination of Isoniazid 50mg/ Pyrazinamide 150mg/ Rifampicin 75mg dispersible uncoated tablets.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 3 blisters x 28 tablets

▪ **ITEM No. 11: 2FDC/ RH 75/50 (blister)**

General Description: Fixed-dose combination of Isoniazid 50mg/ Rifampicin 75mg dispersible uncoated tablets.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 3 blisters x 28 tablets

SCHEDULE NO. 2:

Oral solid dosage forms. Single dose formulations for adults and children

ADULTS:

- **ITEM No. 1: Ethambutol 400 mg (blister)**

General Description: Ethambutol 400mg coated tablets or capsules

Primary packaging: 28 tablets or capsules/blister

Secondary packaging: pack of 24 blisters x 28 tablets or capsules

- **ITEM No. 2: Isoniazid 300 mg (blister)**

General Description: Isoniazid 300mg tablets or capsule.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets

- **ITEM No. 3: Pyrazinamide 400 mg (blister)**

General Description: Pyrazinamide 400mg tablets or capsules

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets

- **ITEM No. 4: Pyrazinamide 500 mg (blister)**

General Description: Pyrazinamide 500mg tablets or capsules.

Primary packaging: 28 tablets/blister

Secondary packaging: pack of 24 blisters x 28 tablets

- **ITEM No. 5: Rifampicin 150 mg (blister)**

General Description: Rifampicin 150mg tablets or capsules.

Primary packaging: 10 tablets or capsules/blister

Secondary packaging: pack of 10 blisters x 10 tablets or capsules

- **ITEM No. 6: Rifampicin 300 mg (blister)**

General Description: Rifampicin 300mg tablets or capsules.

Primary packaging: 10 tablets or capsules/blister

Secondary packaging: pack of 10 blisters x 10 tablets or capsules

- **ITEM No. 7: Rifabutin 150 mg (blister/HDPE container)**

General Description: Rifabutin 150mg capsules.

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

Secondary packaging: 1 HDPE container or pack of 10 blisters x 10 capsules.

CHILDREN

- **ITEM No.8: Isoniazid 100 mg (blister)**

General Description: Isoniazid 100mg tablets.

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

- **ITEM No.9: Ethambutol 100 mg (blister)**

General Description: Ethambutol 100mg tablets.

Primary packaging: 10 tablets/blister

Secondary packaging: pack of 10 blisters x 10 tablets

**SCHEDULE NO. 3:
Stop-TB patient's kits.**

▪ **ITEM No. 1: Cat I & III Kit A**

General Description: Stop TB Cat. I + III Patient Kit A containing

- 6 blisters x 4FDC R150/H75/Z400/E275 (28 tablets/blister)
- 12 blisters x 2FDC R150/H75 (28 tablets/blister)

Technical Specifications:

Specifications of the outer box	Laminated, corrugated punched cardboard box Dimensions: <ul style="list-style-type: none"> • Length: 220mm ±5mm • Width: 115mm±5mm • Height: 130mm±5mm
Specifications of the 4-FDC inner box	Laminated, corrugated punched cardboard box Dimensions: <ul style="list-style-type: none"> • Length: 200mm ±5mm • Width: 50mm±5mm • Height: 120mm±5mm
Specifications of the RH inner box	Laminated, corrugated punched cardboard box Dimensions: <ul style="list-style-type: none"> • Length: 150mm ±5mm • Width: 60mm±5mm • Height: 85mm±5mm

▪ **ITEM No. 2: Cat I & III Kit C**

General Description: Stop TB Cat. I+III Patient Kit C containing

- 6 blisters x 4FDC R150/H75/Z400/E275 (28 tablets/blister)
- 6 blisters x 2FDC R150/H150 (28 tablets/blister)

Technical Specifications:

Specifications of the outer box	Laminated, corrugated punched cardboard box Dimensions: <ul style="list-style-type: none"> • Length: 220mm ±5mm • Width: 90mm±5mm • Height: 130mm±5mm
Specifications of the 4-FDC inner box	Laminated, corrugated punched cardboard box Dimensions:

	<ul style="list-style-type: none"> • Length: 200mm ±5mm • Width: 50mm±5mm • Height: 120mm±5mm
Specifications of the RH inner box	<p>Laminated, corrugated punched cardboard box</p> <p>Dimensions:</p> <ul style="list-style-type: none"> • Length: 180mm ±5mm • Width: 30mm±5mm • Height: 90mm±5mm

SCHEDULE NO. 4:

Parenteral injectable and other related products

- **ITEM No. 1: Streptomycin 1g injectable (vial)**

General Description: Streptomycin 1g powder for injection with or without solvent water for injection 5mL ampoule

Primary packaging: vial

Secondary packaging: pack of 50 or 100 vials

- **ITEM No. 2: Water for Injection 5mL ampoule**

General Description: Water for injection, sterile, 5mL ampoules

Technical Specifications:

5mL water for injection, sterile, free from pyrogens

Primary packaging: ampoule or vial

Secondary packaging: pack of 100 ampoules

- **ITEM No. 3: Hypodermic AD syringe with re-use prevention feature, 5 ml with needle (21 G, 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" and 23G 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 particular storage conditions as appropriate.

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

Technical Specifications for Safety boxes: 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.

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

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 particular storage conditions as appropriate.

- **ITEM No. 5: Safety Box for used syringes and needles, 5L**

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

Technical Specifications for Safety boxes: 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.