



## Annex B: LIST AND TECHNICAL SPECIFICATIONS OF PRODUCTS REQUESTED

### Eligibility criteria for submission of Bids for anti-tuberculosis medicines

Only bidders with products in compliance with the GDF Quality Assurance Policy (see <https://www.stoptb.org/suppliers/quality-assurance>) 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)<sup>1</sup>; or
- B. Products approved by a Stringent Regulatory Authority (SRA)<sup>2</sup>;
- 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)<sup>3</sup>. 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 <https://extranet.who.int/pqweb/medicines>) 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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<sup>1</sup> <https://extranet.who.int/pqweb/medicines>

<sup>2</sup> <https://extranet.who.int/pqweb/medicines>

<sup>3</sup> <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/expert-review-panel/>

**Schedule 1. Adult TB medicines**

<b>Item No.</b>	<b>Generic Code</b>	<b>General Description</b>	<b>Primary packaging</b>	<b>Secondary packaging</b>
Item No. 1	4-FDC/RHZE-150/75/400/275-(B)	Fixed-dose combination of Rifampicin 150mg/Isoniazid 75mg/Pyrazinamide 400mg/Ethambutol 275mg tablets	28 tablets/blister	pack of 24 blisters x 28 tablets
Item No. 2	3-FDC/RHE-150/75/275-(B)	Fixed-dose combination of Rifampicin 150mg/Isoniazid 75mg/Ethambutol 275mg tablets	28 tablets/blister	pack of 24 blisters x 28 tablets
Item No. 3	2-FDC/RH-150/75-(B)	Fixed-dose combination of Rifampicin 150mg /Isoniazid 75mg tablets	28 tablets/blister	pack of 24 blisters x 28 tablets
Item No. 4	Am-500-(A)	Amikacin 500 mg solution for injection in ampoule	1 ampoule	pack of 1x10 ampoules or 1x100 ampoules
Item No. 5	Amx/Clv-500/125-(B)	Amoxicillin/Clavulanic acid 500mg +125mg tablets	10 or 15 tablets/blister	pack of 10 blisters x 10 tablets or 1 blister x 15 tablets
Item No. 6	Bdq-100-(L)	Bedaquiline 100 mg tablets	188 tablets/HDPE container	pack of 188 tablets/HDPE container
Item No. 7	Cfz-100-(L/B)	Clofazimine 100 mg capsules or scored tablets	100 capsules/HDPE container or 10 capsules or scored tablets /blister	100 capsules/HDPE container or pack of 10 blisters x 10 capsules or scored tablets
Item No. 8	Cs-250-(B)	Cycloserine 250 mg capsules	10 capsules/blister	pack of 10 blisters x 10 capsules
Item No. 9	Dlm-50-(B)	Delamanid 50mg tablets	8 or 10 tablets/blister	pack of 6 blisters x 8 tablets or 10 blisters x 10 tablets
Item No. 10	E-400-(B)	Ethambutol 400mg tablets	28 tablets/blister	pack of 24 blisters x 28 tablets
Item No. 11	Eto-250-(B)	Ethionamide 250 mg film coated tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 12	H-300-(B)	Isoniazid 300mg tablets	28 tablets/blister	pack of 24 blisters x 28 tablets
Item No. 13	Imp/Cls-500/500-(V)	Imipenem/Cilastatin 500mg + 500mg powder for infusion in vials, without solvent	1 vial	pack of 1 x 10 vials or 1 x 100 vials
Item No. 14	Lfx-250-(B)	Levofloxacin 250 mg film coated tablets	10 tablets/blister	pack of 10 blisters x 10 tablets

<b>Item No.</b>	<b>Generic Code</b>	<b>General Description</b>	<b>Primary packaging</b>	<b>Secondary packaging</b>
Item No. 15	Lfx-500-(B)	Levofloxacin 500 mg film coated tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 16	Lzd-600-(B)	Linezolid 600 mg film coated or scored tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 17	Mfx-400-(B)	Moxifloxacin 400 mg film coated or scored tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 18	Mrp-1-(V)	Meropenem 1g powder for IV infusion in vials, without solvent	1 vial	pack of 1 x 10 vials or 1 x 100 vials
Item No. 19	Pa-200-(L)	Pretomanid 200mg tablets	26 tablets/HDPE container	pack of 26 tablets/HDPE container
Item No. 20	PAS-(Na)-4-(S)	P-amino-salicylate (PAS) sodium 4 g granules/powder in sachet	1 sachet	pack of 1 x 30 sachets or 25 sachets
Item No. 21	Pto-250-(B)	Prothionamide 250mg film coated tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 22	Pyr(B6)-100-(L)	Pyridoxine hydrochloride 100mg tablets	10 tablets/blister or 250 tablets/HDPE container	pack of 10 blisters x 10 tablets or 250 tablets/HDPE container
Item No. 23	Pyr(B6)-50-(B)	Pyridoxine hydrochloride 50mg tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 24	R-150-(B)	Rifampicin 150mg tablets or capsules	10 tablets or capsules/blister	pack of 10 blisters x 10 tablets or capsules
Item No. 25	R-300-(B)	Rifampicin 300mg tablets or capsules	10 tablets or capsules/blister	pack of 10 blisters x 10 tablets or capsules
Item No. 26	S-1-(V)	Streptomycin 1g powder for injection in vials, without solvent	1 vial	pack of 1x10 vials or 1x100 vials
Item No. 27	Z-400-(B)	Pyrazinamide 400mg tablets	28 tablets/blister	pack of 24 blisters x 28 tablets
Item No. 28	Z-500-(B)	Pyrazinamide 500mg tablets	28 or 10 tablets/blister	pack of 24 blisters x 28 tablets or 10 blisters x 10 tablets

**Schedule 2. Pediatric TB medicines**

<b>Item No.</b>	<b>Generic Code</b>	<b>General Description</b>	<b>Primary packaging</b>	<b>Secondary packaging</b>
Item No. 1	3-FDC/RHZ-75/50/150-(B)	Fixed-dose combination of Rifampicin 75mg /Isoniazid 50mg/ Pyrazinamide 150mg dispersible tablets	28 or 10 tablets/blister	pack of 3 blisters x 28 tablets or 10 blisters x 10 tablets
Item No. 2	2-FDC/RH-75/50-(B)	Fixed-dose combination of Rifampicin 75mg/Isoniazid 50mg dispersible tablets	28 or 10 tablets/blister	pack of 3 blisters x 28 tablets or 10 blisters x 10 tablets
Item No. 3	Bdq-20-(L)	Bedaquilline 20 mg tablets or scored tablets	60 tablets/HDPE container	60 tablets/HDPE container
Item No. 4	Cfz-50-(L/B)	Clofazimine 50 mg capsules or scored tablets	100 capsules/HDPE container or 10 capsules or scored tablets /blister	100 capsules/HDPE container or pack of 10 blisters x 10 capsules or scored tablets
Item No. 5	Cs-125-(B)	Cycloserine 125 mg capsules	10 capsules/blister	pack of 10 blisters x 10 capsules
Item No. 6	Dlm-25-(B-DT)	Delamanid 25mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 7	E-100-(B)	Ethambutol 100mg tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 8	E-100-(B-DT)	Ethambutol 100mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 9	Eto-125-(B-DT)	Ethionamide 125 mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 10	H-100-(B)	Isoniazid 100mg tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 11	H-100-(B-DT)	Isoniazid 100mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 12	Lfx-100-(B-DT)	Levofloxacin 100 mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 13	Lzd-150-(B-DT)	Linezolid 150 mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 14	Mfx-100-(B-DT)	Moxifloxacin 100 mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 15	Z-150-(B-DT)	Pyrazinamide 150mg dispersible tablets	10 tablets/blister	pack of 10 blisters x 10 tablets

<b>Item No.</b>	<b>Generic Code</b>	<b>General Description</b>	<b>Primary packaging</b>	<b>Secondary packaging</b>
Item No. 16	Z-150-(DT)	Pyrazinamide 150mg dispersible tablets	100 tablets/HDPE container	100 tablets/HDPE container

### Schedule 3. Medicines with uncertain demand

<b>Item No.</b>	<b>Generic Code</b>	<b>General Description</b>	<b>Primary packaging</b>	<b>Secondary packaging</b>
Item No. 1	Lfx-750-(B)	Levofloxacin 750 mg film coated tablets	10 tablets/blister	pack of 10 blisters x 10 tablets
Item No. 2	Rbt-150-(L)	Rifabutin 150mg capsules	100 capsules/HDPE container	100 capsules/HDPE container
Item No. 3	Rpt-150-(B)	Rifapentine 150mg capsules	8 or 10 capsules/blister	pack of 3 blisters x 8 capsules or 10 blisters x 10 capsules
Item No. 4	Trd-250-(B)	Terizidone 250mg capsules	10 capsules/blister	pack of 10 capsules x 10 blisters

### Schedule 4. Adult TB medicines: Kit A

<b>Item No.</b>	<b>Generic Code</b>	<b>General Description</b>	<b>Specifications of the outer box</b>	<b>Specifications of the 4-FDC (RHZE) inner box</b>	<b>Specifications of the 2 FDC (RH) inner box</b>
Item No. 1	Cat I & III Kit A	General Description: Stop TB Cat. I + III Patient Kit type A containing - 6 blisters of 4FDC R150/H75/Z400/E275 (28 tablets/blister) - 12 blisters of 2FDC R150/H75 (28 tablets/blister)	Laminated, corrugated punched cardboard box Dimensions: • Length: 220mm ±5mm • Width: 115mm±5mm • Height: 130mm±5mm	Laminated, corrugated punched cardboard box Dimensions: • Length: 200mm ±5mm • Width: 50mm±5mm • Height: 120mm±5mm	Laminated, corrugated punched cardboard box Dimensions: • Length: 150mm ±5mm • Width: 60mm±5mm • Height: 85mm±5mm