TB Procurement and Market-Shaping Action Team (TPMAT) Recommendations on Products to Include and Prioritize on the Global Fund's (GF) Expert Review Panel (ERP) Expression of Interest (EOI) Round 31 (Q3 2025)

Paediatric Friendly Formulations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Bedaquiline 20mg, tablet (scored and dispersible)	Remain in EOI Add to Priority List	Bedaquiline is recommended by WHO for use in children of all ages and is part of multiple DR-TB regimens including BEAT-TB regimens, endTB regimens, all-oral shorter regimens and Group A for all-oral longer regimens. ^{1,2} There is one SRA approved supplier, second expected supplier to file in Q4 2025.	
Clofazimine 50mg tablet or dispersible tablet	Remain in EOI	Clofazimine is recommended by WHO for use in children of all ages and is part of multiple DR-TB regimens including some BEAT-TB regimens, some endTB regimens, all-oral shorter regimens and Group B for all-oral longer regimens. ¹ There is one SRA approved supplier of a capsule formulation and one WHO Prequalified (PQ) supplier of a tablet formulation.	
Cycloserine 125mg capsule	Remain in EOI	Cycloserine is recommended by WHO for use in children of all ages and is Group B for DR-TB all-oral longer regimens. ¹ There is one WHO PQ supplier.	
Delamanid 25mg tablet or dispersible tablet	Remain in EOI	Delamanid is recommended by WHO for use in children of all ages and is part of multiple DR-TB regimens including BEAT-TB regimens, some endTB regimens, and Group C for all-oral longer regimens. ^{1,2} There is one SRA approved supplier.	
Rifapentine 150mg, tablet (scored and dispersible)	Remove from EOI	Rifapentine is recommended by WHO for use in children off all ages as part of the 3HP regimen for TB Preventive Therapy. ³ There are two suppliers that are quality-assured by WHO PQ. The product is no longer eligible for the ERP EOI.	

TPMAT recommendations to Global Fund Expert Review Panel's EOI Round 31

Adult Formulations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Clofazimine 100mg tablet, (must be scored)	Remain in EOI	Clofazimine is recommended by WHO for use as part of multiple DR- TB regimens including some BEAT-TB regimens, some endTB regimens, all-oral shorter regimens and Group B for all-oral longer regimens. ^{4,2} There is one SRA approved supplier of a capsule formulation, one WHO PQ supplier of a tablet formulation (not scored) and one WHO PQ supplier of a capsule formulation.	~
Delamanid 50mg tablet	Remain in EOI Remain in Priority List	Delamanid is recommended by WHO for use as part of multiple DR-TB regimens including BEAT-TB regimens, some endTB regimens, and Group C for all-oral longer regimens. ^{4,2} There is one SRA approved supplier and one WHO PQ supplier. Additional suppliers are needed for supply security due to exclusivity in some jurisdictions.	
Pretomanid 200mg tablet	Remain in EOI	Pretomanid is recommended by WHO for use as part of multiple DRTB regimens including the BPaLM and BPaL regimens. ⁴ There are two WHO PQ suppliers and one ERP recommended supplier. The product will be removed from the ERP EOI when a third supplier receives WHO PQ.	
Rifabutin 150mg tablet or capsule	Remain in EOI	For use when rifampicin cannot be used due to drug-drug interactions. There is one WHO PQ supplier that is not currently producing and one SRA supplier producing limited amounts. Additional suppliers are needed to increase supply security.	
Rifampicin 150mg capsule	Remain in EOI	Severe shortage of quality-assured active pharmaceutical ingredient globally limiting the availability of finished product. Open for new finished product suppliers or WHO PQ suppliers with new API sources. The product will be kept in the ERP EOI while the shortage is resolving and will be removed when the backlog has decreased significantly.	
Rifampicin 300mg capsule	Remain in EOI	Severe shortage of quality-assured active pharmaceutical ingredient globally limiting the availability of finished product. Open for new finished product suppliers or WHO PQ suppliers with new API sources. The product will be kept in the ERP EOI while the shortage is resolving and will be removed when the backlog has decreased significantly.	\checkmark



TPMAT recommendations to Global Fund Expert Review Panel's EOI Round 31

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Rifampicin / Isoniazid, 75 mg / 50 mg, dispersible tablet	Remain in EOI	Severe shortage of quality-assured active pharmaceutical ingredient globally limiting the availability of finished product. Open for new finished product suppliers or WHO PQ suppliers with new API sources. The product will be kept in the ERP EOI while the shortage is resolving and will be removed when the backlog has decreased significantly.	
Rifampicin / Isoniazid / Pyrazinamide 75mg / 50mg / 150mg, dispersible tablet	Remain in EOI	Severe shortage of quality-assured active pharmaceutical ingredient globally limiting the availability of finished product. Open for new finished product suppliers or WHO PQ suppliers with new API sources. The product will be kept in the ERP EOI while the shortage is resolving and will be removed when the backlog has decreased significantly.	
Rifampicin / Isoniazid, 150 mg / 75 mg, tablet	Remain in EOI	Severe shortage of quality-assured active pharmaceutical ingredient globally limiting the availability of finished product. Open for new finished product suppliers or WHO PQ suppliers with new API sources. The product will be kept in the ERP EOI while the shortage is resolving and will be removed when the backlog has decreased significantly.	Ø
Rifampicin / Isoniazid / Ethambutol, 150 mg / 75 mg / 275 mg, tablet	Remain in EOI	Severe shortage of quality-assured active pharmaceutical ingredient globally limiting the availability of finished product. Open for new finished product suppliers or WHO PQ suppliers with new API sources. The product will be kept in the ERP EOI while the shortage is resolving and will be removed when the backlog has decreased significantly.	
Rifampicin / Isoniazid / Pyrazinamide / Ethambutol, 150 mg / 75 mg / 400 mg / 275 mg, tablet	Remain in EOI	Severe shortage of quality-assured active pharmaceutical ingredient globally limiting the availability of finished product. Open for new finished product suppliers or WHO PQ suppliers with new API sources. The product will be kept in the ERP EOI while the shortage is resolving and will be removed when the backlog has decreased significantly.	

TPMAT recommendations to Global Fund Expert Review Panel's EOI Round 31

Rifapentine / Isoniazid / Moxifloxacin 300 mg / 75 mg / 100mg, tablet	Remain in EOI Remain in Priority List	A new FDC to support the introduction and scale-up of shorter regimens for DSTB as recommended by WHO (e.g., the Study 31 Regimen). ⁵ New supplier expected to submit in Q3 2025.	
Rifapentine / Isoniazid / Moxifloxacin / Pyrazinamide 300 mg / 75 mg / 100mg / 375 mg, tablet	Remain in EOI Add to Priority List	A new FDC to support the introduction and scale-up of shorter regimens for DSTB as recommended by WHO (e.g., the Study 31 Regimen). ⁴ New supplier expected to submit in Q3 2025.	

In-vivo Diagnostics Tests

Diagnostics Test	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
TB antigen skin tests	Remain in EOI	Three antigen-based skin tests were recommended by WHO in	
		2022. ⁶ One ERP recommended supplier of this product.	

Products Prioritized for ERP ad-hoc Review

Product in the above tables highlighted in green are eligible for the ERP ad-hoc Review process, meaning they can be reviewed by the ERP as soon as they meet the submission criteria and do not have to wait until the next ERP Round to be reviewed. These high priority products are needed to complete or improve regimens and have no quality-assured suppliers or the quality-assured supply is insufficient to meet current demand.

Final Round 31 ERP EOI

The final ERP EOIs are available here:

- https://www.theglobalfund.org/media/a1dkp11l/psm_2025-07-round-31-invitation-to-manufacturers_invitation_en.pdf
- https://www.theglobalfund.org/media/2bibz2o2/psm_2025-07-15-invitation-to-manufacturers-adhoc_invitation_en.pdf

¹ WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022.

² Key updates to the treatment of drug-resistant tuberculosis: rapid communication, June 2024. Geneva: World Health Organization; 2024.

³ WHO consolidated guidelines on tuberculosis: Module 1: prevention – tuberculosis preventive treatment, second edition. Geneva: World Health Organization; 2024.

⁴ WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-resistant tuberculosis treatment, 2022 update. Geneva: World Health Organization; 2022.

⁵ WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-susceptible tuberculosis treatment. Geneva: World Health Organization; 2022.

⁶ WHO consolidated guidelines on tuberculosis. Module 3: diagnosis. Tests for tuberculosis infection. Geneva: World Health Organization; 2022.