

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 25 (Q2 2022)

Paediatric Friendly Formulations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Bedaquiline 20mg tablet or dispersible tablet, preferably scored	Remain in EOI	Bedaquiline is a Group A medicine in the WHO DRTB recommendations and is included in both longer regimens and shorter regimens and for use in children. ^{1,2} There is one SRA approved supplier.	
Clofazimine 50mg tablet or dispersible tablet	Remain in EOI	Clofazimine is a Group B medicine in the WHO DRTB recommendations for longer regimens and is included in the shorter regimens. ^{1,2} 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 a Group B medicine in the WHO DRTB Recommendations for longer regimens and is included in some modified shorter regimens. ^{1,2} There is one WHO PQ supplier.	
Delamanid 25mg tablet or dispersible tablet	Remain in EOI Remove from Priority List	Delamanid is a Group C medicine in the WHO DRTB recommendations for longer regimens and has an indication for children. ^{1,2} There is one SRA approved supplier. The product remains under patent and there are no other known products in development.	
Ethambutol 100mg dispersible tablet	Remove from EOI	Ethambutol is WHO recommended in the treatment of DSTB. ² It is also a Group C medicine in the WHO DRTB Recommendations for longer regimens and is used in shorter regimens. ^{1,2} There are two WHO PQ suppliers of this product and it is no longer eligible for inclusion in the ERP EOI. GF also indicated this product no longer qualifies for the ERP EOI.	
Linezolid 150mg dispersible tablet	Remain in EOI Remove from Priority List	Linezolid is a Group A medicine in the WHO DRTB Recommendations in the longer regimen. ^{1,2} There are two suppliers recommended for procurement by the ERP.	

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Rifapentine 150mg dispersible tablet, scored	Remain in EOI	Recommended in children down to 2 years of age for 3HP for LTBI. ^{3,2} There are no quality-assured suppliers of this product.	

Adult Formulations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Bedaquiline 100mg tablet	Remain in EOI	Bedaquiline is a Group A medicine in the WHO DRTB Recommendations and is included in both longer regimens and shorter regimens. ¹ There is one SRA approved supplier and one supplier recommended for procurement by the ERP.	
Clofazimine 100mg tablet, (must be scored)	Remain in EOI	Clofazimine is a Group B medicine in the WHO DRTB Recommendations for longer regimens and is included in the shorter regimens. ¹ 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	Delamanid is a Group C medicine in the WHO DRTB Recommendations for longer regimens. ¹ There is one SRA approved supplier and one supplier recommended for procurement by the ERP.	
	Remove from Priority List	The product remains under patent and there are no other known products in development.	
Pretomanid 200mg tablet	Remain in EOI	WHO recommended for DRTB as part of the BPaLM and BPaL regimens for fluoroquinolone-susceptible and fluoroquinolone-resistant DRTB, respectively. ^{4,1} There is one SRA approved supplier.	
Rifabutin 150mg capsule or tablet	Remain in EOI	For use when rifampicin cannot be used due to drug-drug interactions. There is one WHO PQ supplier.	
Rifapentine 300mg tablet, scored	Remain in EOI	Rifapentine is WHO recommended for both 3HP and 1HP regimens for LTBI and for treatment of DS-TB. ^{3,5} There is one supplier recommended for procurement by the ERP and another supplier is in the WHO PQ pipeline and planning to submit to the ERP.	
	Remove from Priority List		

Fixed-Dose Combinations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Rifampicin / Isoniazid / Pyrazinamide 75mg / 50mg / 150mg, dispersible tablet	Remain in EOI Remain in Priority List	WHO recommended for DSTB in children (intensive phase). ⁵ There is one WHO PQ supplier. Priority rationale – A second supplier is needed to increase supply security.	
Rifampicin / Isoniazid 75mg / 50mg, dispersible tablet	Remove from EOI	WHO recommended for DSTB in children (continuation phase), LTBI and in the shorter regimen for TB meningitis. ² There are two WHO PQ suppliers of this product and it is no longer eligible for inclusion in the ERP EOI. GF also indicated this product no longer qualifies for the ERP EOI.	
Isoniazid / Rifapentine 300mg / 300mg, capsule or tablet or scored tablet	Remain in EOI Remove from Priority List	WHO recommended for 3HP regimen for LTBI. ³ There is one WHO PQ supplier and one supplier recommended for procurement by the ERP. Two quality-assured suppliers are now available. This product is no longer a priority for additional suppliers.	

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 25 ERP EOI

The final ERP EOIs are available here:

- GF/ERP/Round 25/06-2022: https://www.theglobalfund.org/media/12133/psm_2022-06-29-round25_invitation-to-manufacturers_en.pdf
- GF/ERP/Ad-Hoc/06-2022: https://www.theglobalfund.org/media/12134/psm_2022-06-29_invitation-to-manufacturers-adhoc_en.pdf

¹ WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2020.

² WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022.

³ WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment. Geneva: World Health Organization; 2020.

⁴ Rapid communication: key changes to the treatment of drug-resistant tuberculosis. Geneva: World Health Organization; 2022 (WHO/UCN/TB/2022.2).

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