
















## 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 24 (Q3 2021)


### 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. <sup>1,2</sup> 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. <sup>1</sup> 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. <sup>1</sup> There is one WHO PQ supplier.	
Delamanid 25mg tablet or dispersible tablet	Remain in EOI Remain in Priority List	Delamanid is a Group C medicine in the WHO DRTB recommendations for longer regimens and has an indication for children. <sup>1,2</sup> There is no quality-assured supplier commercially available.	
Ethambutol 100mg dispersible tablet	Remain in EOI	Ethambutol is WHO recommended in the treatment of DSTB. <sup>3</sup> It is also a Group C medicine in the WHO DRTB Recommendations for longer regimens and is used in shorter regimens. <sup>1</sup> There is one WHO PQ supplier.	
Isoniazid 100mg dispersible tablet	Remove from EOI	Isoniazid is WHO recommended in different LTBI regimens and in DRTB in the shorter regimen. <sup>1,4</sup> There are two WHO PQ suppliers and this product no longer qualifies for the ERP EOI.	
Linezolid 150mg dispersible tablet	Remain in EOI Remain in Priority List	Linezolid is a Group A medicine in the WHO DRTB Recommendations in the longer regimen. <sup>1</sup> There is no quality-assured supplier.	




Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Pyridoxine 10mg tablet, preferably scored	Add to EOI	WHO recommended as prevention for certain individuals at higher risk of isoniazid-induced peripheral neuropathy. <sup>4</sup> Can also be used for treatment of isoniazid-induced peripheral neuropathy. <sup>4</sup>	
Rifapentine 150mg dispersible tablet	Remain in EOI	Recommended in children down to 2 years of age for 3HP for LTBI. <sup>4</sup>	

## 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. <sup>1</sup> There is one SRA approved supplier.	
Clofazimine 100mg tablet, preferably 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. <sup>1</sup> 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 Add to Priority List	Delamanid is a Group C medicine in the WHO DRTB Recommendations for longer regimens. <sup>1</sup> There is one SRA approved supplier. Priority rationale – A second supplier has submitted and been accepted by WHO PQ and is now eligible for ERP review. A second supplier of delamanid could alleviate supply constraints and put pressure on price.	
Pretomanid 200mg tablet	Remain in EOI	WHO recommended for specific DRTB indication under operational research conditions. <sup>1</sup> There is one SRA approved supplier.	
Pyridoxine 50mg scored tablet	Add to EOI	WHO recommended as prevention for certain individuals at higher risk of isoniazid-induced peripheral neuropathy. <sup>4</sup> Can also be used for treatment of isoniazid-induced peripheral neuropathy. <sup>4</sup>	
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.	

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Rifapentine 300mg tablet	Remain in EOI Remain in Priority List	Rifapentine is WHO recommended for both 3HP and 1HP regimens for LTBI. <sup>4</sup> It is also being studied to shorten DS-TB treatment. This formulation would reduce the daily pill burden compared to the current formulation available. There is no quality assured supplier.	

## 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). <sup>3</sup> There is one WHO PQ supplier. Priority rationale – A second supplier is needed to increase supply security.	
Rifampicin / Isoniazid 75mg / 50mg, dispersible tablet	Remain in EOI	WHO recommended for DSTB in children (continuation phase). <sup>3</sup> There is one WHO PQ supplier and one ERP-recommended supplier.	
Isoniazid / Rifapentine 300mg / 300mg tablet or scored tablet	Remain in EOI Add to Priority List	WHO recommended for 3HP regimen for LTBI. <sup>4</sup> One ERP-recommended supplier. There are no SRA or WHO PQ suppliers. Priority rationale – A second supplier is needed to increase supply security and availability.	

## 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 24 ERP EOI

The final ERP Round 24 EOI is available here: [https://www.theglobalfund.org/media/10377/psm\\_2021-09-27\\_invitation-to-manufacturers\\_en.pdf](https://www.theglobalfund.org/media/10377/psm_2021-09-27_invitation-to-manufacturers_en.pdf)

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

<sup>2</sup> Rapid communication on updated guidance on the management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2021.

<sup>3</sup> Guidelines for the treatment of drug-susceptible tuberculosis and patient care, 2017 update. Geneva: World Health Organization; 2017.

<sup>4</sup> WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment. Geneva: World Health Organization; 2020.