















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 21 (Q3 2019)




Pediatric Friendly Formulations


Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Clofazimine 50mg capsule, dispersible tablet	Remain in EOI; remove capsule formulation; keep dispersible formulation	Clofazimine is a Group B medicine in the WHO DRTB Recommendations. ¹ One SRA-approved supplier of a capsule formulation, one ERP-recommended supplier of a tablet formulation. The preferred formulation is a dispersible tablet.	
Cycloserine 125mg capsule	Remain in EOI	Cycloserine is a Group B medicine in the WHO DRTB Recommendations. ¹ There is one WHO-Prequalified (PQ) supplier.	
Ethambutol 100mg chewable or dispersible tablet	Remain in EOI	Ethambutol is WHO-recommended in the treatment of DSTB. ² It is a Group C medicine in the WHO DRTB Recommendations. ¹ There is one WHO PQ supplier.	
Ethionamide 125mg dispersible tablet	Remove from EOI	Ethionamide is a Group C medicine in the WHO DRTB Recommendations. ¹ There are now two WHO PQ suppliers and this formulation is no longer eligible for the ERP.	
Isoniazid 100mg chewable or dispersible tablet	Remain in EOI	Isoniazid is recommended in the WHO LTBI Guidance 2018. ³ There is one ERP-recommended supplier.	
Levofloxacin 100mg dispersible tablet	Remain in EOI	Levofloxacin is a Group A medicine in the WHO DRTB Recommendations. ¹ It is recommended in the WHO Hr-TB Guidance 2018. ⁴ One WHO PQ supplier and one ERP-recommended supplier.	
Linezolid 150mg dispersible tablet	Remain in EOI Remain in Priority List	Linezolid is a Group A medicine in the WHO DRTB Recommendations. ¹ There are currently no quality-assured suppliers. Priority rationale - Product is needed to complete pediatric DRTB regimens.	
Rifapentine 150mg dispersible tablet	Add to EOI	TPMAT suggested that a 150mg dispersible tablet formulation be added for pediatric use.	

Adult Formulations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Clofazimine 100mg capsule, or scored tablet	Remain in EOI; remove capsule formulation; keep tablet formulation	Clofazimine is a Group B medicine in the WHO DRTB Recommendations. ¹ One SRA-approved supplier and 2 ERP-recommended suppliers. The preferred formulation is a scored tablet.	
Bedaquiline 100mg tablet	Remain in EOI	Bedaquiline is a Group A medicine in the WHO DRTB Recommendations. ¹ There is one SRA-approved supplier.	
Delamanid 50mg tablet	Remain in EOI	Delamanid is a Group C medicine in the WHO DRTB Recommendations. 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 quality-assured supplier.	
Rifapentine 150mg tablet	Remove from EOI	Rifapentine is WHO-recommended for use in LTBI. ³ There is one quality-assured supplier. TPMAT recommends removing this product in favour of a more child-friendly, dispersible formulation	
Rifapentine 300mg tablet	Remain in EOI Remain in Priority List	Rifapentine is WHO-recommended for use in LTBI. ³ It is being studied in different LTBI regimens. 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). ² There is one WHO PQ supplier.	
Rifampicin / Isoniazid 75mg / 50mg, dispersible tablet	Remain in EOI	WHO-recommended for DSTB in children (continuation phase). ² One WHO PQ supplier and one ERP-recommended supplier.	
Isoniazid / Rifapentine 150mg / 150mg dispersible tablet	Remove from EOI	There is no quality-assured supplier of this formulation. There is insufficient data in children to support the development of this formulation. TPMAT suggested to focus on a child-friendly formulation of Rifapentine 150mg until more information is available on dosing in children.	

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Isoniazid / Rifapentine 300mg / 300mg capsule or tablet	Remain in EOI Remain in Priority List	WHO-recommended for the 3HP regimen for LTBI. ³ No quality-assured suppliers.	

Products Prioritized for ERP ad-hoc Review

Products 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 21 ERP EOI

The final ERP Round 21 EOI was published on the Global Fund website on 26th August 2019 (Reference Number: GF/ERP/Round 21/08-2019).

¹ WHO consolidated guidelines on drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2019.

² Guidelines for the treatment of drug-susceptible tuberculosis and patient care, 2017 update. Geneva: World Health Organization; 2017.

³ Latent TB Infection: Updated and consolidated guidelines for programmatic management. Geneva: World Health Organization; 2018.

⁴ WHO treatment guidelines for isoniazid-resistant tuberculosis: Supplement to the WHO treatment guidelines for drug-resistant tuberculosis. Geneva: World Health Organization; 2018