
















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 22 (Q1 2020)

Paediatric Friendly Formulations



Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Bedaquiline 20mg tablet or dispersible tablet	Add to EOI	Bedaquiline is a Group A medicine in the WHO DRTB Recommendations as part of the all-oral longer regimen and as part of the all-oral shorter regimen. ^{1,2} Will be needed for children once results of studies are available.	
Clofazimine 50mg dispersible tablet	Remain in EOI	Clofazimine is a Group B medicine in the WHO DRTB Recommendations and is included in the all-oral shorter regimen. ^{1,2} 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.	
Delamanid 25mg tablet or dispersible tablet	Add to EOI	Delamanid is a Group C medicine in the WHO DRTB Recommendations for the all oral longer regimen and has an indication for children aged 3 years or more. ¹ No quality-assured supplier commercially available.	
Ethambutol 100mg chewable or dispersible tablet	Remain in EOI	Ethambutol is WHO-recommended in the treatment of DSTB. ³ It is a Group C medicine in the WHO DRTB Recommendations. ¹ There is one WHO PQ supplier.	
Isoniazid 100mg dispersible tablet	Remain in EOI	Isoniazid is recommended in the WHO LTBI Guidance 2018. ⁴ There is one ERP-recommended supplier.	
Levofloxacin 100mg dispersible tablet	Remove from EOI	There are 2 WHO PQ suppliers for this product. Product no longer meets eligibility for inclusion on the ERP.	
Linezolid 150mg dispersible tablet	Remain in EOI Remain in Priority List	Linezolid is a Group A medicine in the WHO DRTB Recommendations. ¹ No quality-assured supplier. Priority rationale - Product is needed to complete pediatric DRTB regimens.	


Rifapentine 150mg dispersible tablet	Remain in EOI	TPMAT, in consultation with PADO-TB, suggested this formulation as it could be used in multiple regimens going forward. Rifapentine, as part of the 3HP regimen, is WHO-recommended in children down to 2 years of age for LTBI. ⁴	
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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. ¹ There is one SRA-approved supplier.	
Clofazimine 100mg scored 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 and 2 ERP-recommended suppliers. The preferred formulation is a scored tablet.	
Delamanid 50mg tablet	Remain in EOI	Delamanid is a Group C medicine in the WHO DRTB Recommendations. ¹ There is one SRA-approved supplier.	
Pretomanid 200mg tablet	Add to EOI	Pretomanid, under operational research as part of the BPaL regimen, is included in the WHO Rapid Communication on DRTB from December 2019. ²	
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	Remain in EOI Remain in Priority List	Rifapentine is WHO-recommended for use in LTBI. ⁴ It is being studied in different LTBI regimens and to shorten DSTB treatment. This formulation would reduce the daily pill burden compared to the current formulation available. 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). ³ There is one WHO PQ supplier.	
Rifampicin / Isoniazid 75mg / 50mg, dispersible tablet	Remain in EOI	WHO-recommended for DSTB in children (continuation phase). ³ One WHO PQ supplier and one ERP-recommended supplier.	

Isoniazid / Rifapentine 300mg / 300mg, capsule or tablet or scored tablet	Remain in EOI Remain in Priority List	WHO-recommended for 3HP regimen for LTBI. ⁴ There is one ERP-recommended supplier. No quality assured suppliers.	
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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 22 ERP EOI

The final ERP Round 22 EOI is available here: https://www.theglobalfund.org/media/9435/psm_2020-03-round22selectedmedicinesmanufacturerseoi_invitation_en.pdf

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

² Rapid Communication: Key changes to the treatment of drug-resistant tuberculosis. Geneva: World Health Organization; 2019.

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

⁴ Latent TB Infection: Updated and consolidated guidelines for programmatic management. Geneva: World Health Organization; 2018.