

## 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 26 (Q1 2023)

### 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 for both longer regimens and shorter regimens and is recommended for use in children of all ages. <sup>1</sup> There is one SRA approved supplier.	
Clofazimine 50mg tablet or dispersible tablet	Remain in EOI Add to Priority List	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	Delamanid is a Group C medicine in the WHO DRTB recommendations for longer regimens and is recommended for use in children of all ages. <sup>1</sup> There is one SRA approved supplier. The product remains under patent and there are no other known products in development.	
Linezolid 150mg dispersible tablet	Remain in EOI	Linezolid is a Group A medicine in the WHO DRTB Recommendations in the longer regimen. <sup>1</sup> There is one WHO PQ supplier and one supplier recommended for procurement by the ERP. The product will be removed when two suppliers receive WHO PQ.	
Rifapentine 150mg dispersible tablet (preferably functionally scored)	Remain in EOI Add to Priority List	Recommended in children down to 2 years of age for 3HP for TB Preventive Therapy. <sup>1,2</sup> There are no quality-assured suppliers of this product. One supplier has indicated development submission in Q2 2023.	

## 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 the BPaLM and BPaL regimens, longer regimens, and shorter regimens. <sup>3</sup> There is one SRA approved supplier and two suppliers recommended for procurement by the ERP. The product will be removed when two suppliers receive WHO PQ.	
Clofazimine 100mg tablet, (must be scored)	Remain in EOI	Clofazimine is a Group B medicine in the WHO DRTB Recommendations and is included in the longer regimens and shorter regimens. <sup>3</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.	
Pretomanid 200mg tablet	Remain in EOI	WHO recommended for DRTB as part of the BPaLM and BPaL regimens. <sup>3</sup> There is one SRA approved supplier and one supplier recommended for procurement by the ERP. The product will be removed when two suppliers receive 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.	
Rifapentine 300mg tablet (scored)	Remain in EOI	Rifapentine is WHO recommended for both 3HP and 1HP regimens for TB Preventive Therapy and for treatment of DS-TB. <sup>2,4</sup> There is one supplier recommended for procurement by the ERP and another supplier is in the WHO PQ pipeline. The product will be removed when two suppliers receive WHO PQ.	

## Fixed-Dose Combinations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Isoniazid / Rifapentine 300mg / 300mg, capsule or tablet or scored tablet	Remain in EOI	WHO recommended for the 3HP regimen for TB Preventive Therapy. <sup>2</sup> There is one WHO PQ supplier and one supplier recommended for procurement by the ERP. The product will be removed when two suppliers receive WHO PQ.	
Rifampicin / Isoniazid / Pyrazinamide 75mg / 50mg / 150mg, dispersible tablet	Remain in EOI Remove from Priority List	WHO recommended for DSTB in children (intensive phase). <sup>1</sup> There is one WHO PQ supplier and one supplier under review by WHO PQ. This product will be removed when two suppliers receive WHO PQ.	
Rifapentine / Isoniazid / Moxifloxacin 300 mg / 75 mg / 100mg, tablet	Add to EOI	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). <sup>4</sup>	
Rifapentine / Isoniazid / Moxifloxacin / Pyrazinamide 300 mg / 75 mg / 100mg / 375 mg, tablet	Add to EOI	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). <sup>4</sup>	

## In-vivo Diagnostics Tests

Diagnostics Test	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
TB antigen skin tests	Add to EOI	Three antigen-based skin tests were recommended by WHO in 2022. <sup>5</sup>	

## 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 26 ERP EOI

The final ERP EOIs are available here:

- GF/ERP/Round 26/02-2023: [https://www.theglobalfund.org/media/12773/psm\\_2023-02-13-invitation-to-manufacturers-round-26\\_invitation\\_en.pdf](https://www.theglobalfund.org/media/12773/psm_2023-02-13-invitation-to-manufacturers-round-26_invitation_en.pdf)
- GF/ERP/Ad-Hoc/06-2022: [https://www.theglobalfund.org/media/12774/psm\\_2023-02-13-invitation-to-manufacturers-adhoc\\_invitation\\_en.pdf](https://www.theglobalfund.org/media/12774/psm_2023-02-13-invitation-to-manufacturers-adhoc_invitation_en.pdf)

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

<sup>2</sup> WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment. Geneva: World Health Organization; 2020.

<sup>3</sup> WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-resistant tuberculosis treatment, 2022 update. Geneva: World Health Organization; 2022.

<sup>4</sup> WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-susceptible tuberculosis treatment. Geneva: World Health Organization; 2022.

<sup>5</sup> WHO consolidated guidelines on tuberculosis. Module 3: diagnosis. Tests for tuberculosis infection. Geneva: World Health Organization; 2022.