
















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 23 (Q4 2020)



Paediatric Friendly Formulations


| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by GF |
|---|--|--|---|
| Bedaquiline 20mg tablet | Add to EOI | Bedaquiline is a Group A medicine in the WHO DRTB recommendations and is included in both longer regimens and shorter regimens. ¹ One SRA approved supplier. |  |
| Clofazimine 50mg dispersible tablets | 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 One SRA approved supplier of a capsule formulation, 1 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 One WHO PQ supplier. |  |
| Delamanid 25mg tablet or dispersible tablet | Remain in EOI Add to Priority List | Delamanid is a Group C medicine in the WHO DRTB Recommendations for longer regimens and has an indication for children less than 5 years of age. 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. ² It is also a Group C medicine in the WHO DRTB Recommendations for longer regimens and is used in shorter regimens. ¹ One WHO PQ supplier. |  |
| Isoniazid 100mg dispersible tablet | Remain in EOI | Isoniazid is WHO recommended in different LTBI regimens and in DRTB in the shorter regimen. ^{1,3} 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 in the longer regimen. ¹ No quality-assured supplier. |  |
| Rifapentine 150mg dispersible tablet | Remain in EOI | Recommended in children down to 2 years of age for 3HP for LTBI. ³ |  |

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 One SRA approved supplier. |  |
| Clofazimine 100mg scored 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 One SRA approved supplier of a capsule formulation, 1 WHO Prequalified (PQ) supplier of a tablet formulation (not scored) and 1 WHO PQ supplier of a capsule |  |
| Delamanid 50mg tablet | Remain in EOI | Delamanid is a Group C medicine in the WHO DRTB Recommendations for longer regimens. ¹ One SRA approved supplier. |  |
| Pretomanid 200mg tablet | Remain in EOI | WHO recommended for specific DRTB indication under operational research conditions. ¹ 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. ³ Can also be used for treatment of isoniazid-induced peripheral neuropathy. ³ |  |
| Rifabutin 150mg capsule or tablet | Remain in EOI | For use when rifampicin can not be used due to drug-drug interactions. One WHO PQ supplier. |  |
| Rifapentine 300mg tablet | Remain in EOI Remain in Priority List | Rifapentine is WHO recommended for both 3HP and 1HP regimens for LTBI. ³ It is also being studied to shorten DS-TB 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). ² One WHO PQ supplier. Priority rationale - |  |
| Rifampicin / Isoniazid 75mg / 50mg, dispersible tablet | Remain in EOI | WHO recommended for DSTB in children (continuation phase). ² One WHO PQ supplier and 1 ERP-recommended supplier. |  |

| | | | |
|---|---|--|---|
| Isoniazid / Rifapentine 300mg / 300mg, capsule or tablet or scored tablet | Remain in EOI Removed from Priority List | WHO recommended for 3HP regimen for LTBI. ³ One ERP-recommended supplier. No SRA or WHO PQ 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 23 ERP EOI

The final ERP Round 23 EOI is available here: https://www.theglobalfund.org/media/10377/psm_2020-11-20_invitation-to-manufacturers_en.pdf

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

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

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