















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 19 (Q3 2018)









Pediatric Friendly Formulations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Clofazimine 50mg capsule, dispersible tablet	Remain in EOI Add to Priority List	Clofazimine is a Group B medicine in the WHO DRTB Rapid Communication. ¹ There is one SRA-approved supplier and one ERP-recommended supplier. Priority rationale – Additional suppliers are needed, particularly for tablet formulations for children	
Cycloserine 125mg capsule	Remain in EOI	Cycloserine is a Group B medicine in the WHO DRTB Rapid Communication. 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 Rapid Communication. ¹ There is one WHO PQ supplier.	
Ethionamide 125mg dispersible tablet	Remain in EOI	Ethionamide is a Group C medicine in the WHO DRTB Rapid Communication. ¹ There is one WHO PQ supplier and one ERP-recommended supplier.	
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 Rapid Communication. ¹ It is recommended in the WHO Hr-TB Guidance 2018. ⁴ There is one WHO PQ supplier and one ERP-recommended supplier.	
Linezolid 150mg dispersible tablet	Remain in EOI Add to Priority List	Linezolid is a Group A medicine in the WHO DRTB Rapid Communication. ¹ There are no quality-assured suppliers. Priority rationale - Product is needed to complete pediatric DRTB regimens.	 
Moxifloxacin 100mg dispersible tablet	Remain in EOI	Moxifloxacin is a Group A medicine in the WHO DRTB Rapid Communication. ¹ There are two ERP-recommended suppliers.	






Adult Formulations

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Clofazimine 100mg capsule or tablet	Remain in EOI Add to Priority List	Clofazimine is a Group B medicine in the WHO DRTB Rapid Communication. ¹ There is one SRA-approved supplier of the capsule and one ERP-recommended supplier of the tablet. Priority rationale – Additional suppliers are needed to improve supply security.	
Levofloxacin 750 mg capsule or tablet	Add to EOI	Levofloxacin is a Group A medicine in the WHO DRTB Rapid Communication. ¹ There is one WHO PQ supplier and 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	Remain in EOI	Rifapentine is WHO-recommended for use in LTBI. ³ There is one quality-assured supplier.	
Rifapentine 300mg scored tablet	Add to EOI	Rifapentine is WHO-recommended for use in LTBI. ³ The product is being prioritized by the Unitaid-funded IMPAACT4TB Project on rifapentine-based short course preventative treatment. There are no quality-assured suppliers	
Terizidone 250mg capsule or tablet	Remain in EOI	Terizidone is a Group B medicine in the WHO DRTB Rapid Communication. ¹ There are two quality-assured suppliers.	
Rifampicin 450mg film coated tablet	Remain in EOI	Rifampicin is used in the treatment of DS-TB. ² Currently no quality-assured suppliers of this product and unclear role of this formulation for treatment. Further recommendations to be provided for the next ERP EOI.	
Pyrazinamide 250mg capsule or tablet	Remove from EOI	Pyrazinamide 250mg has never been developed or submitted to WHO PQ or an SRA. There are multiple quality-assured suppliers of multiple other formulations (400mg and 500 mg tablets) that have a lower pill burden.	
Ethambutol 200mg capsule or tablet	Remove from EOI	Ethambutol 200mg has never been developed or submitted to WHO PQ or an SRA. There are multiple quality-assured suppliers of the 400mg tablet formulation that has a lower pill burden.	

**TPMAT recommendations to Global Fund
Expert Review Panel's EOI Round 19**

Medicine formulation	TPMAT Recommendation	Recommendation Rationale	Accepted by GF
Ethambutol 275mg capsule or tablet	Remove from EOI	Ethambutol 275mg has never been developed or submitted to WHO PQ or an SRA. There are multiple quality-assured suppliers of the 400mg tablet formulation that has a lower pill burden.	
Capreomycin 500mg vial	Exclude from EOI	The product is no longer recommended by WHO.	
Kanamycin 1g vial	Remove from EOI	The product is no longer recommended by WHO.	
Gatifloxacin 200mg tablet	Remove from EOI	The product was removed from SRA markets due to adverse events. There are no quality-assured suppliers of this formulation. This product has been rejected for inclusion in the TB section of the WHO Model Essential Medicines List. WHO has not reviewed this product in the most recent TB guidelines or rapid communication.	
Gatifloxacin 400mg tablet	Remove from EOI	The product was removed from SRA markets due to adverse events. There are no quality-assured suppliers of this formulation. This product has been rejected for inclusion in the TB section of the WHO Model Essential Medicines List. WHO has not reviewed this product in the most recent TB guidelines or rapid communication.	
Terizidone 300mg tablet	Remove from EOI	There are no quality-assured suppliers of this formulation. There is a very similar formulation (Terizidone 250mg capsules) that has quality-assured suppliers. The consolidation of demand around one formulation that is already quality-assured and eligible for procurement is preferable to maintain availability.	
Para-Aminosalicylic Acid sachets, 4g granules	Remove from EOI	The role of the product in treatment has been downgraded in the WHO Rapid Communication. ¹ The consolidation of demand around two formulations that are already quality-assured and eligible for procurement is preferable to maintain availability.	
PAS Sodium 100g Jar granules, 4g/9.2g sachets granules, powder for oral solution, sachets	Remove from EOI	The role of the product in treatment has been downgraded in the WHO Rapid Communication. ¹ The consolidation of demand around two formulations that are already quality-assured and eligible for procurement is preferable to maintain availability.	

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. Priority rationale – There is only one supplier of this formulation creating a supply security risk for paediatric DS-TB treatment.	
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	Remain in EOI	Target formulation unclear until more information is available on dosing in children. Further recommendations to be provided for next ERP EOI round. There are no quality-assured suppliers.	
Isoniazid / Rifapentine 300mg / 300mg capsule or tablet	Remain in EOI	WHO-recommended for 3HP regimen for LTBI. ³ There are no quality-assured suppliers.	
Ethambutol hydrochloride / Isoniazid / Rifampicin 275 mg / 75 mg / 150 mg capsule or coated tablet	Remove from EOI	There are three quality-assured suppliers of this formulation. The formulation is no longer eligible for the ERP review process.	

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 19 ERP EOI

The final ERP Round 19 EOI was published on the Global Fund website on 15th August 2018 (Reference Number: GF/ERP/Round 19/08-2018).

¹ Rapid communication: key changes to treatment of multidrug- and rifampicin-resistant tuberculosis (MDR/RR-TB). Geneva: World Health Organization; 2018.

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