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### Pediatric Friendly Formulations

| Medicine formulation                            | TPMAT Recommendation                           | Recommendation Rationale  | Accepted by GF  |
|---|--|---|---|
| Clofazimine 50mg capsule, dispersible tablet    | Remain in EOI<br><br>Remove from Priority List | Clofazimine is a Group B medicine in the WHO DRTB Rapid Communication. <sup>1</sup> There is one SRA-approved supplier and one ERP-recommended supplier.<br>Rationale for removing from Priority List – There is at least one quality-assured tablet formulation. |    |
| Cycloserine 125mg capsule                       | Remain in EOI                                  | Cycloserine is a Group B medicine in the WHO DRTB Rapid Communication. <sup>1</sup> 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. <sup>2</sup> It is a Group C medicine in the WHO DRTB Rapid Communication. <sup>1</sup> 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. <sup>1</sup> 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. <sup>3</sup> 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. <sup>1</sup> It is recommended in the WHO Hr-TB Guidance 2018. <sup>4</sup> There is one WHO PQ supplier and one ERP-recommended supplier.  |  |
| Linezolid 150mg dispersible tablet              | Remain in EOI<br><br>Remain in Priority List   | Linezolid is a Group A medicine in the WHO DRTB Rapid Communication. <sup>1</sup> There are no quality-assured suppliers.<br>Priority rationale - Product is needed to complete pediatric DRTB regimens.  |  |
| Moxifloxacin 100mg dispersible tablet           | Remove from EOI                                | There are two WHO PQ suppliers. The small market is unlikely to support more than two suppliers.  |  |

## Adult Formulations

| Medicine formulation                | TPMAT Recommendation                           | Recommendation Rationale   | Accepted by GF  |
|-------------------------------------|--|--|---|
| Clofazimine 100mg capsule or tablet | Remain in EOI<br><br>Remove from Priority List | Clofazimine is a Group B medicine in the WHO DRTB Rapid Communication. <sup>1</sup> There is one SRA-approved supplier of the capsule, one ERP-recommended supplier of the capsule, and one ERP-recommended supplier of the tablet.<br>Rationale for removing from Priority List – There is at least one quality-assured supplier of each formulation. |    |
| Bedaquiline 100mg tablet            | Add to EOI                                     | Bedaquiline is a Group A medicine in the WHO DRTB Rapid Communication. <sup>1</sup> There is one SRA-approved supplier.  |    |
| Delamanid 50mg tablet               | Add to EOI                                     | Delamanid is a Group C medicine in the WHO DRTB Rapid Communication. <sup>1</sup> 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            | Remain in EOI                                  | Rifapentine is WHO-recommended for use in LTBI. <sup>3</sup> There is one quality-assured supplier.  |    |
| Rifapentine 300mg tablet            | Remain in EOI<br><br>Remain in Priority List   | Rifapentine is WHO-recommended for use in LTBI. <sup>3</sup> It is being studied in different LTBI regimens. There is one quality-assured supplier.<br>Priority rationale – Rifapentine 300mg could be used in multiple short-course LTBI regimens while lowering the pill burden.   |    |
| Terizidone 250mg capsule or tablet  | Remain in EOI                                  | Terizidone is a Group B medicine in the WHO DRTB Rapid Communication. <sup>1</sup> There are two quality-assured suppliers.  |  |
| Rifampicin 450mg tablet             | Remove from EOI                                | There are two quality-assured suppliers for this product. It is not in the WHO PQ EOI, and multiple other formulations of rifampicin (150mg, 300mg, 600mg tablets/capsules) are available. FDCs are preferred by WHO.  |  |

## Fixed-Dose Combinations

| Medicine formulation  | TPMAT Recommendation                     | Recommendation Rationale  | Accepted by GF  |
|---|--|---|---|
| Rifampicin / Isoniazid / Pyrazinamide 75mg / 50mg / 150mg, dispersible tablet | Remain in EOI<br>Remain in Priority List | WHO-recommended for DSTB in children (intensive phase). <sup>2</sup> There is one WHO PQ supplier.<br>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). <sup>2</sup> 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. There are no quality-assured suppliers.   |  |
| Isoniazid / Rifapentine 300mg / 300mg capsule or tablet                       | Remain in EOI<br>Add to Priority List    | WHO-recommended for 3HP regimen for LTBI. <sup>3</sup> There are no quality-assured suppliers.<br>Priority rationale – Ideal formulation for 3HP regimen to minimize pill burden.   |  |

## 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 20 ERP EOI

The final ERP Round 20 EOI was published on the Global Fund website on 14<sup>th</sup> February 2019 (Reference Number: GF/ERP/Round 20/02-2019).

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

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

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

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