

TB Procurement and Market-Shaping Action Team (TPMAT) Recommendations on Updates to the WHO Essential Medicines List and Essential Medicines List for Children 2023

Introduction

The World Health Organization's (WHO) Model Essential Medicines List (EML) and Model Essential Medicines List for Children (EMLc) are updated every two years. Applications to add, delete or modify a medicine are submitted during an open application period. The applications are posted on the WHO's website and interested parties can submit letters of support (or against) a change. The applications and letters are then reviewed by an Expert Committee to determine if the application is accepted.

TPMAT, led by GDF, did a complete analysis of the 22nd EML and the 8th EMLc at the end of 2022. Using the [TB Medicines Dashboard](#) and other resources, TPMAT partners identified missing medicines and formulations that needed to be added and medicines and formulations that were no longer recommended that needed to be removed. TPMAT partners coordinated developing applications for the identified medicines and formulations and letters of support these applications.

TPMAT partners also monitored the applications once they were made public in case any additional applications for TB medicines were submitted. No additional applications for TB medicines were made by other partners in this review of the EML and EMLc.

The table below shows the TPMAT-led recommendations and applications for changes to the EML and EMLc.

TPMAT-Led Recommendations to Update the EML and EMLc

| Medicine and formulation | TPMAT Recommendation | TPMAT Partner that Submitted the Application | Recommendation Rationale | Accepted by WHO Expert Committee |
|--|--------------------------------------|--|--|---|
| Amikacin 100mg / 2mL (as sulfate) in 2 mL vial | Remove from the EML | WHO Global TB Programme (WHO GTB) | Amikacin is recommended by WHO as a Group C medicine in longer regimens for DRTB. ¹ This formulation has a low efficiency for dose delivery (e.g., large volume for intramuscular injection to reach therapeutic doses in most adults). |  |
| | Remove from the EMLc | | |  |
| Bedaquiline 20mg tablet | Remove age restriction from the EML | WHO GTB | WHO recommends the use of bedaquiline in all ages for both the shorter 9 to 12-month bedaquiline-based regimens and in all-oral longer regimens. ² |  |
| | Remove age restriction from the EMLc | | |  |
| Bedaquiline 100mg tablet | Remove age restriction from the EML | WHO GTB | WHO recommends the use of bedaquiline in all ages for both the shorter 9 to 12-month bedaquiline-based regimens and in all-oral longer regimens. ² |  |
| | Remove age restriction from the EMLc | | |  |
| Delamanid 25mg dispersible tablet | Remove age restriction from the EML | WHO GTB | WHO recommends the use of delamanid in children of all ages as part of longer regimens. ² |  |
| | Remove age restriction from the EMLc | | |  |
| Delamanid 50mg tablet | Remove age restriction from the EML | WHO GTB | WHO recommends the use of delamanid in children of all ages as part of longer regimens. ² |  |
| | Remove age restriction from the EMLc | | |  |

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| Medicine and formulation | TPMAT Recommendation | TPMAT Partner that Submitted the Application | Recommendation Rationale | Accepted by WHO Expert Committee |
|--------------------------------------|------------------------------|--|--|---|
| Ethambutol 25mg/mL oral liquid | Remove from the EML | Carryover from 2021 submissions | Ethambutol is recommended by WHO for the treatment of DSTB and in the 9 to 12-month bedaquiline-based shorter regimen and as a Group C medicine in longer regimens for DRTB. ^{1,3} There are multiple quality-assured, dispersible tablet formulations that are commercially available and preferable to a liquid formulation. |  |
| | Remove from the EMLc | | |  |
| Ethionamide 125mg tablet | Remove from the EML | Carryover from 2021 submissions | Ethionamide is recommended by WHO for use in tuberculosis meningitis and in the 9 to 12-month bedaquiline-based shorter regimen and as a Group C medicine in longer regimens for DRTB. ^{1,2} There are multiple quality-assured, dispersible tablet formulations that are commercially available and preferable to a non-dispersible formulation. |  |
| | Remove from the EMLc | | |  |
| Ethionamide 125mg dispersible tablet | Add to core list of the EML | WHO GTB | Ethionamide is recommended by WHO for use in drug-susceptible tuberculosis meningitis. ² There are multiple quality-assured, dispersible tablet formulations that are commercially available and preferable to a non-dispersible formulation. Medicines for the treatment of drug-susceptible TB are included in the core list. |  |
| | Add to core list of the EMLc | | |  |
| Ethionamide 250mg tablet | Add to core list of the EML | WHO GTB | Ethionamide is recommended by WHO for use in drug-susceptible tuberculosis meningitis. ² Medicines for the treatment of drug-susceptible TB are included in the core list. |  |
| | Add to core list of the EMLc | | |  |
| Isoniazid 50mg/5mL oral liquid | Remove from the EML | Carryover from 2021 submissions | Isoniazid is recommended by WHO for use in the treatment of DSTB, in the shorter regimen for DRTB and in TB Preventative Therapy. ^{1,3,4} There are multiple quality-assured, dispersible tablet formulations that are commercially available and preferable to a liquid formulation. |  |
| | Remove from the EMLc | | |  |

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| Medicine and formulation | TPMAT Recommendation | TPMAT Partner that Submitted the Application | Recommendation Rationale | Accepted by WHO Expert Committee |
|--|----------------------|--|--|---|
| Linezolid powder for oral liquid 100mg/ 5mLs | Remove from the EML | WHO GTB | Linezolid is recommended by WHO as a Group A medicine in the longer regimen for DRTB and in some 9 to 12-month shorter regimens for DRTB. ¹ There are multiple quality-assured, dispersible tablet formulations that are commercially available and preferable to a liquid formulation. |  |
| | Remove from the EMLc | | |  |
| P-aminosalicylic acid 4g sachet | Remove from the EML | WHO GTB | PAS is recommended by WHO as a Group C medicine in the longer regimen for DRTB. ¹ There is no quality-assured formulation of PAS acid that is commercially available. There are other suitable oral formulations for both adults and children. |  |
| | Remove from the EMLc | | |  |
| P-aminosalicylate sodium 5.52 g in sachet (equivalent to 4g p-aminosalicylic acid) | Add to the EML | WHO GTB | PAS is recommended by WHO as a Group C medicine in the longer regimen for DRTB. ¹ This is the quality-assured formulation of PAS sodium that is commercially available. |  |
| | Add to the EMLc | | |  |
| Pretomanid 200mg tablet | Add to the EML | Supplier | Pretomanid is recommended by WHO for the treatment of DRTB in the BPaLM and BPaL regimens in adults. ¹ There are multiple quality-assured suppliers of pretomanid. |  |
| Pyrazinamide 30mg/mL oral liquid | Remove from the EML | Carryover from 2021 submissions | Pyrazinamide is recommended by WHO for the treatment of DSTB and in the shorter regimen and as a Group C medicine in longer regimens for DRTB. ^{1,3} There is a quality-assured, dispersible tablet formulation that is commercially available and preferable to a liquid formulation. |  |
| | Remove from the EMLc | | |  |

Final WHO EML and EMLc released in July 2023

The final 23rd EML and 9th EMLc are available here: <https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>

¹ WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-resistant tuberculosis treatment, 2022 update. Geneva: World Health Organization; 2022.

² WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022.

³ WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-susceptible tuberculosis treatment. Geneva: World Health Organization; 2022.

⁴ WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment. Geneva: World Health Organization; 2020.