

TB Procurement and Market-Shaping Action Team (TPMAT) Recommendations on Updates to the WHO Essential Medicines List and Essential Medicines List for Children 2019

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 20th EML and the 6th EMLc at the end of 2018. 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. TPMAT partners reviewed all additional applications to determine if they were in alignment with best practices and contributed to access goals for TB medicines. Letters of support or opposition were then submitted by TPMAT partners based on this assessment.

The first table below shows the TPMAT-led recommendations and applications for changes to the EML and EMLc. The second table shows the TPMAT response and recommendations to applications submitted by other partners.

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
Amoxicillin/clavulanic acid oral powder for suspension 125mg/31.25mg/5 mL	Add to the EML (restricted to children)	WHO Global TB Programme (WHO GTB)	Clavulanic acid formulations are recommended by WHO to be used in conjunction with a carbapenem (e.g., meropenem or imipenem-cilastatin) in the treatment of DRTB. ¹	
	Add to the EMLc			
Amoxicillin/clavulanic acid oral powder for suspension 250mg/62.5mg/5 mL	Add to the EML (restricted to children)	WHO GTB	Clavulanic acid formulations are recommended by WHO to be used in conjunction with a carbapenem (e.g., meropenem or imipenem-cilastatin) in the treatment of DRTB. ¹	
	Add to the EMLc			
Amoxicillin/clavulanic acid tablet 500mg/125mg	Add to the EML	WHO GTB	Clavulanic acid formulations are recommended by WHO to be used in conjunction with a carbapenem (e.g., meropenem or imipenem-cilastatin) in the treatment of DRTB. ¹	
	Add to the EMLc			
Bedaquiline 100mg tablet	Add to the EMLc	WHO GTB	Bedaquiline is a Group A medicine in the WHO DRTB recommendations. It is recommended for use in adults and in children 6-17 years of age. ¹	
Capreomycin powder for injection 1gm vial	Remove from the EML	WHO GTB	Capreomycin formulations are no longer WHO recommended in the treatment of DRTB. ¹	
	Remove from the EMLc			
Clofazimine 50mg, 100mg solid oral dosage form	Change in the EML	Stop TB Global Drug Facility (GDF)	Clofazimine had previously been listed as a “capsule” formulation. The formulation was changed to “solid oral dosage form” to account for the possibility for different formulations to be developed.	
	Change in the EMLc			
Cycloserine 125mg solid oral dosage form	Add to the EML (restricted to children)	GDF	Cycloserine is a Group B medicine in the WHO DRTB recommendations. A cycloserine 125mg mini-capsule formulation was recently quality-assured. This formulation should aligns better with dosing recommendations for children. ¹	
	Add to the EMLc			


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Medicine and formulation	TPMAT Recommendation	TPMAT Partner that Submitted the Application	Recommendation Rationale	Accepted by WHO Expert Committee
Delamanid 50mg tablet	Remove age restriction in EML	WHO GTB	Delamanid is a Group C medicine in the WHO DRTB recommendations. It is recommended for use in adults and in children > 3 years of age. Delamanid is currently restricted to use in ≥ 6 years of age. ¹	
	Remove age restriction in EMLc			
Ethambutol 100mg dispersible tablet	Add to the EML (restricted to children)	GDF	Ethambutol is a Group C medicine in the WHO DRTB recommendations, recommended in the Shorter Regimen for DRTB and used for the treatment of DSTB. A child-friendly ethambutol 100mg dispersible tablet has recently been quality-assured. ^{1,2}	
	Add to the EMLc			
Ethambutol/Isoniazid 400mg/150mg tablet	Remove from the EML	WHO GTB	Ethambutol/isoniazid is no longer recommended in the continuation phase of treatment for DSTB. ²	
Ethionamide 125mg dispersible tablet	Add to the EML (restricted to children)	GDF	Ethionamide is a Group C medicine in the WHO DRTB recommendations and recommended in the Shorter Regimen for DRTB. A child-friendly ethionamide 125mg dispersible tablet has recently been quality-assured. ¹	
	Add to the EMLc			
Imipenem 250mg/250mg vial for intravenous infusion	Add to the EML	WHO GTB	Imipenem/cilastatin is a Group C medicine in the WHO DRTB recommendations. ¹	
Imipenem 500mg/500mg vial for intravenous infusion	Add to the EML	WHO GTB	Imipenem/cilastatin is a Group C medicine in the WHO DRTB recommendations. ¹	
Isoniazid 100mg dispersible tablet	Add to the EML (restricted to children)	GDF	Isoniazid is recommended in the Shorter Regimen for DRTB and in the treatment of LTBI. A child-friendly isoniazid 100mg dispersible tablet has recently been quality-assured. ^{1,3}	
	Add to the EMLc			
Isoniazid/pyrazinamide/rifampicin 150mg/500mg/150mg tablet	Remove from the EML	WHO GTB	The use of three times weekly dosing in the intensive phase of treatment of DSTB is no longer recommended. ²	
Isoniazid/rifampicin 60mg/60mg dispersible tablet	Remove from the EML	WHO GTB	The use of three times weekly dosing in the continuation phase of treatment of DSTB is no longer recommended. The doses in this fixed-dose combination (FDC) are no longer recommended by WHO. ²	

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Medicine and formulation	TPMAT Recommendation	TPMAT Partner that Submitted the Application	Recommendation Rationale	Accepted by WHO Expert Committee
Isoniazid/rifampicin 150mg/150mg tablet	Remove from the EML	WHO GTB	The use of three times weekly dosing in the continuation phase of treatment of DSTB is no longer recommended. ²	
Kanamycin powder for injection 1gm vial	Remove from the EML	WHO GTB	Kanamycin formulations are no longer WHO recommended in the treatment of DRTB. ¹	
	Remove from the EMLc			
Levofloxacin 100mg dispersible tablet	Add to the EML (restricted to children)	GDF	Levofloxacin is a Group A medicine in the WHO DRTB recommendations and recommended in the Shorter Regimen for DRTB. A child-friendly levofloxacin 100mg dispersible tablet has recently been quality-assured. ¹	
	Add to the EMLc			
Linezolid 150mg dispersible tablet	Add to the EML (restricted to children)	GDF	Linezolid is a Group A medicine in the WHO DRTB recommendations. A child-friendly linezolid 150mg dispersible tablet is in development. ¹	
	Add to the EMLc			
Meropenem 500mg vials for intravenous infusion	Add to the EML	WHO GTB	Meropenem is a Group C medicine in the WHO DRTB recommendations. ¹	
	Add to the EMLc			
Meropenem 1000mg vials for intravenous infusion	Add to the EML	WHO GTB	Meropenem is a Group C medicine in the WHO DRTB recommendations. ¹	
	Add to the EMLc			
Moxifloxacin 100mg dispersible tablet	Add to the EML (restricted to children)	GDF	Moxifloxacin is a Group A medicine in the WHO DRTB recommendations and recommended in the Shorter Regimen for DRTB. A child-friendly moxifloxacin 100mg dispersible tablet has recently been quality-assured. ¹	
	Add to the EMLc			
Rifabutin 150mg solid oral dosage form	Change in the EML	GDF	Rifabutin had previously been listed as a “capsule” formulation. The formulation was changed to “solid oral dosage form” to account for the possibility for different formulations to be developed.	

Other Applications to the EML and EMLc

Medicine formulation	Recommendation from Submitting Organization	Recommendation from TPMAT	TPMAT Recommendation Rationale	TPMAT Recommendation Accepted by WHO Expert Committee
Ethambutol 1000mg vial for injection	Add to EML and EMLc	Do NOT add to EML or EMLc	WHO does not generally recommend the use of injectable agents for the treatment of TB. A full regimen, WHO-recommended regimen could not be developed with the available agents (neither DS nor DRTB). Quality-assured formulations not available.	
Ethambutol 2000mg vial for injection	Add to EML and EMLc			
Isoniazid 300mg vial for injection	Add to EML and EMLc	Do NOT add to EML or EMLc	WHO does not generally recommend the use of injectable agents for the treatment of TB. A full regimen, WHO-recommended regimen could not be developed with the available agents (neither DS nor DRTB). Quality-assured formulations not available.	
Isoniazid 500mg vial for injection	Add to EML and EMLc			
Isoniazid 900mg vial for injection	Add to EML and EMLc			
PAS 3gm vial for injection	Add to EML and EMLc	Do NOT add to EML or EMLc	WHO does not generally recommend the use of injectable agents for the treatment of TB. A full regimen, WHO-recommended regimen could not be developed with the available agents (neither DS nor DRTB). Quality-assured formulations not available.	
PAS 9gm vial for injection	Add to EML and EMLc			
PAS 12gm vial for injection	Add to EML and EMLc			
Rifampicin 450mg vial for injection	Add to EML and EMLc	Do NOT add to EML or EMLc	WHO does not generally recommend the use of injectable agents for the treatment of TB. A full regimen, WHO-recommended regimen could not be developed with the available agents (neither DS nor DRTB). Quality-assured formulations not available.	
Rifampicin 900mg vial for injection	Add to EML and EMLc			

Final WHO EML and EMLc updated in June 2019

The final 21st EML and 7th 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 drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2019.

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

³ Latent tuberculosis infection: updated and consolidated guidelines for programmatic management. Geneva: World Health Organization; 2018.