
























TB Procurement and Market-Shaping Action Team (TPMAT) Recommendations on Products to Include on the World Health Organization's (WHO) Prequalification Programme's (PQ) Expression of Interest (EOI)















TB Medicines for Adults

| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by WHO PQ |
|--|-------------------------------------|---|---|
| Amikacin solution for injection 500mg/2ml vial | Remove from EOI | Amikacin is recommended by WHO for the treatment of DRTB. ¹ There are numerous quality-assured suppliers of this formulation. Additional suppliers are not required. |  |
| Bedaquiline 100mg tablet | Remain in EOI | Bedaquiline is recommended by WHO for the treatment of DRTB. ¹ |  |
| Clofazimine 100mg tablet (preferably scored) | Remain in EOI Change Formulation | Clofazimine is recommended by WHO for the treatment of DRTB. ¹ Removed the request for "capsule" formulation. Footnote request to develop a dispersible formulation if possible. |  |
| Cycloserine 250mg capsule | Remain in EOI | Cycloserine is recommended by WHO for the treatment of DRTB. ¹ |  |
| Delamanid 50mg tablet | Remain in EOI | Delamanid is recommended by WHO for the treatment of DRTB. ¹ |  |
| Delamanid 50mg dispersible tablet | Remove from EOI | There are alternative formulation strengths developed for children. |  |
| Ethambutol tablet 400mg (scored) | Remain in EOI Change Formulation | Ethambutol is recommended by WHO for the treatment of DRTB and DSTB. ^{1,2} Removed the request for "capsule" formulation. |  |
| Ethambutol/Isoniazid/Pyrazinamide/Rifampicin 275mg/75mg/400mg/150mg tablet | Remain in EOI | This formulation is recommended by WHO for the treatment of DSTB. ² |  |
| Ethambutol/Isoniazid/ Rifampicin 275mg/75mg/150mg tablet | Remain in EOI | This formulation is recommended by WHO for the treatment of DSTB. ² |  |
| Ethionamide 250mg tablet (scored) | Remain in EOI | Ethionamide is recommended by WHO for the treatment of DRTB. ¹ |  |
| Gatifloxacin 200mg tablet | Remove from EOI | Gatifloxacin is not recommended by WHO for the treatment of any form of TB. |  |



**TPMAT recommendations to World Health Organization's
Prequalification Programme's 22nd EOI**

| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by WHO PQ |
|--|-------------------------------------|--|---|
| Gatifloxacin 400mg tablet (scored) | Remove from EOI | Gatifloxacin is not recommended by WHO for the treatment of any form of TB. |  |
| Imipenem/Cilastatin 500mg/500mg vial | Remove from EOI | Imipenem/Cilastatin is recommended by WHO for the treatment of DRTB. ¹ There are numerous quality-assured suppliers of this formulation. Additional suppliers are not required. |  |
| Imipenem/Cilastatin/Clavulanate 500mg/500mg/125mg vial | Remove from EOI | Imipenem/Cilastatin/Clavulanate has not been developed. Other formulations are available. Broad spectrum antibiotic development requests should be aligned with antimicrobial resistance approaches. |  |
| Isoniazid 300mg tablet (scored) | Remain in EOI Change Formulation | Isoniazid is recommended by WHO for the treatment of DRTB, DSTB and TPT. ^{1,2,3} Removed the request for “capsule” formulation. |  |
| Isoniazid/Rifampicin 75mg/150mg tablet | Remain in EOI Change Formulation | This formulation is recommended by WHO for the treatment of DSTB. ² Removed the request for “capsule” formulation. |  |
| Isoniazid/Rifampicin 150mg/300mg tablet | Remove from EOI | This formulation is recommended by WHO for the treatment of DSTB. ² Programmes generally do not order this product and additional suppliers are not required. |  |
| Meropenem 100mg vial | Remove from EOI | Meropenem is recommended by WHO for the treatment of DRTB. ¹ There are numerous quality-assured suppliers of this formulation. Additional suppliers are not required. |  |
| Meropenem/Clavulanate 1000mg/125mg vial | Remove from EOI | Meropenem/Clavulanate has not been developed. Other formulations are available. Broad spectrum antibiotic development requests should be aligned with antimicrobial resistance approaches. |  |
| Levofloxacin 250mg tablet (scored) | Remain in EOI Change Formulation | Levofloxacin is recommended by WHO for the treatment of DRTB. ¹ Removed the request for “capsule” formulation. |  |
| Levofloxacin 500mg tablet (scored) | Remain in EOI | Levofloxacin is recommended by WHO for the treatment of DRTB. ¹ |  |
| Levofloxacin 750mg tablet (scored) | Remain in EOI | Levofloxacin is recommended by WHO for the treatment of DRTB. ¹ |  |
| Linezolid 600mg tablet (scored) | Remain in EOI | Linezolid is recommended by WHO for the treatment of DRTB. ¹ |  |











**TPMAT recommendations to World Health Organization's
Prequalification Programme's 22nd EOI**

| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by WHO PQ |
|--|-------------------------------------|---|---|
| Moxifloxacin 400mg tablet (scored) | Remain in EOI | Moxifloxacin is recommended by WHO for the treatment of DRTB. ¹ Removed the request for “capsule” formulation. |  |
| Para-aminosalicylic Acid (PAS) 4g granules sachet | Remove from EOI | PAS is recommended by WHO for the treatment of DRTB. ¹ PAS is no longer commercially available. Alternative formulations and suppliers are available. |  |
| Para-aminosalicylate sodium 5.52g in sachet (equivalent to 4g p-aminosalicylic acid) | Remain in EOI | PAS Sodium is recommended by WHO for the treatment of DRTB. ¹ |  |
| Pretomanid 200mg tablet | Remain in EOI | Pretomanid is recommended by WHO for the treatment of DRTB. ¹ |  |
| Protionamide 250mg tablet (scored) | Remain in EOI Change Formulation | Protionamide is recommended by WHO for the treatment of DRTB. ¹ Removed the request for “capsule” formulation. |  |
| Pyrazinamide 400mg tablet (scored) | Remain in EOI | Pyrazinamide is recommended by WHO for the treatment of DRTB and DSTB. ^{1,2} |  |
| Pyrazinamide 500mg tablet (scored) | Remain in EOI | Pyrazinamide is recommended by WHO for the treatment of DRTB and DSTB. ^{1,2} |  |
| Rifabutin 150mg capsule/tablet | Remain in EOI | For use when rifampicin cannot be used due to drug-drug interactions. |  |
| Rifampicin 150mg capsule/tablet | Remain in EOI | Rifampicin is recommended by WHO for the treatment of DSTB and TPT. ^{2,3} |  |
| Rifampicin 300mg capsule/tablet | Remain in EOI | Rifampicin is recommended by WHO for the treatment of DSTB and TPT. ^{2,3} |  |
| Rifapentine 300mg tablet (scored) | Remain in EOI | Rifapentine is recommended by WHO for the treatment of DSTB and TPT. ^{2,3} |  |
| Rifapentine/Isoniazid/Moxifloxacin 300mg/75mg/100mg tablet | Add to EOI | This formulation is recommended by WHO for the treatment of DSTB. ² |  |
| Rifapentine/Isoniazid/Moxifloxacin/Pyrazinamide 300mg/75 mg/100mg/375mg tablet | Add to EOI | This formulation is recommended by WHO for the treatment of DSTB. ² |  |
| Streptomycin powder for injection 1000mg vial | Remove from EOI | Streptomycin is recommended by WHO for the treatment of DRTB. ¹ There are numerous quality-assured suppliers of this formulation. Additional suppliers are not required. |  |







**TPMAT recommendations to World Health Organization's
Prequalification Programme's 22nd EOI**

| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by WHO PQ |
|---------------------------|-------------------------------------|---|---|
| Terizidone 250 mg capsule | Remain in EOI Change Formulation | Terizidone is recommended by WHO for the treatment of DRTB. ¹ Removed the request for a "tablet" formulation. |  |
| Terizidone 500 mg tablet | Remove from EOI | Terizidone is recommended by WHO for the treatment of DRTB. ¹ The 500mg strength creates dosing complexity across weight bands. |  |




TB Medicines for Children

| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by WHO PQ |
|---|-------------------------------------|--|---|
| Bedaquiline 20mg dispersible tablet (scored) | Remain in EOI | Bedaquiline is recommended by WHO for the treatment of DRTB. ⁴ |  |
| Clofazimine 50mg tablet | Remain in EOI Change Formulation | Clofazimine is recommended by WHO for the treatment of DRTB. ⁴ Removed the request for "capsule" formulation. Footnote request to develop a dispersible formulation if possible. |  |
| Cycloserine 125mg mini-capsule | Remain in EOI | Cycloserine is recommended by WHO for the treatment of DRTB. ⁴ |  |
| Delamanid 25mg dispersible tablet | Add to EOI | Delamanid is recommended by WHO for the treatment of DRTB. ⁴ |  |
| Ethambutol 100mg dispersible tablet (scored) | Remain in EOI | Ethambutol is recommended by WHO for the treatment of DRTB and DSTB. ⁴ |  |
| Ethionamide 125mg dispersible tablet (scored) | Remain in EOI | Ethionamide is recommended by WHO for the treatment of DRTB and DSTB meningitis. ⁴ |  |
| Isoniazid 100mg dispersible tablet (scored) | Remain in EOI | Isoniazid is recommended by WHO for the treatment of DRTB, DSTB and TPT. ⁴ |  |
| Levofloxacin 100mg dispersible tablet (scored) | Remain in EOI | Levofloxacin is recommended by WHO for the treatment of DRTB. ⁴ |  |
| Linezolid 150mg dispersible tablet (scored) | Remain in EOI | Linezolid is recommended by WHO for the treatment of DRTB. ⁴ |  |
| Linezolid oral powder for suspension (20 mg/ml) 240 ml bottle | Remove from EOI | Linezolid is recommended by WHO for the treatment of DRTB. ⁴ There are alternative formulations that are more child-friendly. |  |

**TPMAT recommendations to World Health Organization's
Prequalification Programme's 22nd EOI**

| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by WHO PQ |
|---|----------------------|--|---|
| Moxifloxacin 100mg dispersible tablet (scored) | Remain in EOI | Moxifloxacin is recommended by WHO for the treatment of DRTB. ⁴ |  |
| Pyrazinamide 150mg dispersible tablet () | Remain in EOI | Pyrazinamide is recommended by WHO for the treatment of DRTB and DSTB. ⁴ |  |
| Rifampicin/Isoniazid 75mg/50mg dispersible tablet | Remain in EOI | This formulation is recommended by WHO for the treatment of DSTB and TPT. ⁴ |  |
| Rifampicin/Isoniazid/Pyrazinamide 75mg/50mg/150mg dispersible tablet | Remain in EOI | This formulation is recommended by WHO for the treatment of DSTB. ⁴ |  |
| Rifapentine 150mg dispersible tablet (scored) | Remain in EOI | Rifapentine is recommended by WHO for the treatment of TPT. ⁴ |  |
| Rifapentine dispersible tablets 150 mg (scored) + Isoniazid dispersible tablets 100 mg (scored) [Co-pack] | Add to EOI | Rifapentine is recommended by WHO for the treatment of TPT. ⁴ This co-pack was requested by partners to support implementation of rifapentine-based short course TPT regimens in children. |  |

Medicines to Support TB Treatment and Prevention

| Medicine formulation | TPMAT Recommendation | Recommendation Rationale | Accepted by WHO PQ |
|---|----------------------|---|---|
| Pyridoxine (vitamin B6) 100mg tablet (scored) | Add to EOI | Pyridoxine is recommended by WHO for the prevention and treatment of peripheral neuropathy caused by TB therapy. ³ |  |
| Pyridoxine (vitamin B6) 50mg tablet (scored) | Remain in EOI | Pyridoxine is recommended by WHO for the prevention and treatment of peripheral neuropathy caused by TB therapy. ³ |  |
| Pyridoxine (vitamin B6) 10mg tablet (scored) | Remain in EOI | Pyridoxine is recommended by WHO for the prevention and treatment of peripheral neuropathy caused by TB therapy. ³ |  |

WHO PQ 22nd EOI available here:

- https://extranet.who.int/prequal/sites/default/files/document_files/EOI_TB_v21_29June2021_v1_2024Review_v8_final.pdf

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 4: treatment - drug-susceptible tuberculosis treatment. Geneva: World Health Organization; 2022.

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

⁴ WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022.