23rd Invitation
to Manufacturers of Antituberculosis Medicines
to Submit an Expression of Interest (EOI) for Product Evaluation to the WHO Prequalification Unit

To support national and global efforts to increase access to and the affordability of care and treatment of tuberculosis, WHO, together with UNICEF, UNAIDS, UNITAID and the Stop TB Partnership Global Drug Facility invites manufacturers of selected pharmaceutical products to submit Expressions of Interest (EOIs) for product evaluation.

ARTICLE 1. PROCEDURE FOR THIS EOI

The current Invitation is published in accordance with the *Procedure for Prequalification of Pharmaceutical Products*, adopted in 2001 by the 37th WHO Expert Committee on Specifications for Pharmaceutical Preparations, and amended subsequently as part of the 45th report of the Committee, published as No. 961 of the WHO Technical Report Series in 2011.

Assessment of product(s) submitted under this Invitation for EOI includes evaluation of:

- product dossiers, which must include product data and information as specified in the guidelines for submission (see Procedures & Fees)
- manufacturing sites, which must adhere to good manufacturing practices (GMP)
- clinical sites (if applicable), which must adhere to good clinical practices (GCP).

If evaluation demonstrates that a product and its corresponding manufacturing (and clinical) site(s) meet WHO recommended standards, it will be included in the list of medicinal products that are considered to be acceptable for procurement by UN organizations and others.

ARTICLE 2. MEDICINAL PRODUCTS INCLUDED IN THE 22nd INVITATION

The ultimate aim of this 22nd EOI is to increase the range of selected products and sources available in relation to treatment and prevention of tuberculosis (TB). These formulations are included either in the WHO Model List of Essential Medicines and/or in the WHO guidelines for treatment and prevention of TB.

Products included in the WHO Model List of Essential Medicines are those which satisfy the priority health care needs of a population. They are selected on the basis of disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.

Products included in WHO treatment guidelines are selected on the basis of an assessment of the quality of evidence for benefits, harms, costs, and appropriateness for use in a variety of situations, taking into account the needs of special populations, and the values and preferences of the groups (health care providers and patient) using them. Interested manufacturers are encouraged to submit documentation for recommended dosage forms and strengths, as specified below, of medicinal products in the following categories.

TB and HIV programmes are fully supportive of the corresponding EOIs. While the product Sulfamethoxazole/Trimethoprim/Isoniazid/Pyridoxine (scored tablet 800 mg/ 160 mg/ 300 mg/25 mg; scored tablet 400 mg/80 mg/150 mg/12.5 mg) is included in the HIV EOI under Section 5.2. Antibacterial, antiprotozoal and antifungal agents,[1] we want to emphasize the importance of this product for prevention of TB, the leading cause of death among people with HIV.

WHO encourages manufacturers to develop paediatric formulations of TB medicines that are acceptable for children, considering aspects such as palatability upfront in the development process.

The list below includes TB medicines for adults (section 1), TB medicines for children (section 2) and medicines to support TB treatment (section 3). More information on the use of each medicine and formulation across weight bands and indications (i.e., for drug-susceptible TB, drug-resistant TB, TB preventive treatment) can be found in the latest WHO guidelines and operational handbook. (https://tbksp.org/en)

1. TB medicines for adults

- Bedaquiline, tablet 100 mg
- Clofazimine, film-coated tablet 100 mg (preferably scored)[1]
- Cycloserine, capsule 250 mg
- Delamanid, film-coated tablet 50 mg
- Ethambutol hydrochloride, film-coated tablet 400 mg (scored)
- Ethambutol hydrochloride/Isoniazid/Pyrazinamide/Rifampicin, film-coated tablet 275 mg/75 mg/400 mg/150 mg
- Ethambutol hydrochloride/Isoniazid/Rifampicin, film-coated tablet 275 mg/75 mg/150 mg
- Ethionamide, film-coated tablet 250 mg
- Isoniazid, tablet 300 mg (scored)
- Isoniazid/Rifampicin, film-coated tablet 75 mg/150 mg
- Isoniazid /Rifapentine, tablet 300/300 mg (scored)

[1] If a dispersible formulation of either 50 mg or 100 mg can be developed (even considering the highly hydrophobic nature of clofazimine), that should be considered.

- Isoniazid/ Rifapentine/ Moxifloxacin,
  tablet 75 mg/ 300 mg/100 mg
- Isoniazid / Rifapentine / Moxifloxacin / Pyrazinamide,
  tablet 75 mg/300 mg/100 mg/ 375 mg
- Levofloxacin, film-coated tablet 250 mg (scored); tablet 500 mg (scored); tablet 750 mg (scored)
- Linezolid, film-coated tablet 600 mg (scored)
- Moxifloxacin film-coated tablet 400 mg (scored)
- Para-aminosalicylate sodium: 5.52 g powder (for oral solution) in sachet (equivalent to 4 g p-aminosalicylic acid)
- Prothionamide, film-coated tablet 250 mg (scored)
- Pyrazinamide, tablet 400 mg (scored); 500 mg (scored)
- Rifampicin, capsule/tablet 150 mg; 300 mg
- Rifabutin, capsule/tablet 150 mg
- Rifapentine, film-coated tablet 300 mg (scored)
- Terizidone, capsule 250 mg
- Pretomanid, tablet 200 mg[2]

2. TB medicines for children[3]

- Bedaquiline, dispersible tablet 20 mg (scored)
- Clofazimine, film-coated tablet 50 mg[1]
- Cycloserine, minicapsule 125 mg
- Delamanid, dispersible tablet 25 mg
- Ethambutol hydrochloride, dispersible tablet 100 mg (scored)
- Ethionamide, dispersible tablet 125 mg (scored)
- Isoniazid, dispersible tablet 100 mg (scored)
- Levofloxacin, dispersible tablet 100 mg (scored)
- Linezolid, dispersible tablet 150 mg (scored)
- Moxifloxacin, dispersible tablet 100 mg (scored)
- Pyrazinamide, dispersible tablet 150 mg
- Rifampicin/Isoniazid,
  dispersible tablet 75 mg/ 50 mg
- Rifampicin/Isoniazid/Pyrazinamide,
  Dispersible tablet 75 mg/ 50 mg/ 150 mg
- Rifampicin, dispersible tablet 100 mg (scored)[4]
- Rifapentine, dispersible tablet 150 mg (scored)

[2] For use only as part of the BPaLM/BPaL regimen.
[3] All paediatric formulations should ideally be palatable (ie,formulations that easily disperse in small volumes of water and have a pleasant taste to facilitate administration in young children).
[4] For use to top up rifampicin dose in the combination with pediatric FDC.

- Co-pack[5] of Rifapentine dispersible tablets 150 mg (scored) + Isoniazid dispersible tablets 100 mg (scored)

3. Medicines to support TB treatment and prevention

- Pyridoxine (vitamin B6), tablet 100 mg (scored), 50 mg (scored), tablet 10 mg (scored)

ARTICLE 3. HOW TO SUBMIT AN EOI

In order to submit an expression of interest for product evaluation, the manufacturer must send the required documentation, arranged according to the information provided in Procedures & Fees in the medicines section of the WHO prequalification website at https://extranet.who.int/prequal.

ARTICLE 4. QUALITY ASSESSMENT PROCEDURE FOLLOWING SUBMISSION OF AN EOI BY A MANUFACTURER

The quality assessment is undertaken to assess whether the pharmaceutical product being evaluated meets the requirements recommended by WHO and is manufactured in compliance with good manufacturing practices (GMP).

The procedure established by WHO for quality assessment incorporates:

- general understanding of the production and quality control activities of the manufacturer
- assessment of product data and information on safety, efficacy and quality submitted by the manufacturer, including product formulation, manufacture and test data and results
- assessment of the manufacturing site's adherence to GMP, and its consistency in production and quality control of starting materials, with specific emphasis on active pharmaceutical ingredients, and finished product
- assessment of clinical testing units or organizations (i.e. parties performing one or more clinical trials with the product) for compliance with good clinical practices and good laboratory practices, as appropriate;
- random sampling and testing of medicines supplied.

Previous evaluation conducted by the relevant national medicines regulatory authority (NMRA) may be taken into account during the evaluation conducted by WHO, provided that the NMRA has expertise in the product area. If appropriate, the relevant NMRA may be invited to collaborate with WHO on the quality assessment. Any manufacturer who submits a product for evaluation, is therefore encouraged to authorize its NMRA to discuss relevant product files with WHO representatives, during assessments and inspections, if required (subject to appropriate confidentiality provisions, if necessary).

Once WHO is satisfied that quality assessment has been completed for the manufacturer of the relevant starting materials, the finished pharmaceutical product, and the clinical testing units, and that the product meets WHO recommended standards, the product (as produced at the specified manufacturing site) is added to the WHO List of Prequalified Medicinal Products.

ARTICLE 5. REFERENCES AND FURTHER INFORMATION

For further information on WHO medicines prequalification, please visit the WHO prequalification website at:

[5] Separate blisters in the same box.

https://extranet.who.int/prequal. Should you have any questions relating to the procedure for responding to an EOI, please email: prequal@who.int. Your question(s) will be directed to the prequalification team member who can best advise you.

For further information on WHO treatment guidelines, please consult:

1. WHO consolidated guidelines on tuberculosis. Module 1: prevention – tuberculosis preventive treatment. Geneva:World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/bitstream/handle/10665/331170/9789240001503-eng.pdf?sequence=1, accessed 20 February 2024.

2. WHO operational handbook on tuberculosis. Module 1: prevention - tuberculosis preventive treatment. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0IGO. https://iris.who.int/bitstream/handle/10665/331525/9789240002906-eng.pdf?sequence=1, accessed 14 March 2024.

3. WHO consolidated guidelines on tuberculosis. Module 4: treatment and care. Geneva:World Health Organization; 2025. **ISBN:** 978-92-4-010724-3. https://www.who.int/publications/i/item/9789240107243, accessed 6 February 2026.

4. WHO operational handbook on tuberculosis Module 4: Treatment and care. Geneva: World Health Organization; 2025. **ISBN:** 978-92-4-010814-1. https://www.who.int/publications/i/item/9789240108141, accessed 6 February 2026.

5. WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/bitstream/handle/10665/352522/9789240046764-eng.pdf?sequence=1, accessed 20 February 2024.

6. WHO operational handbook on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0IGO.C. https://iris.who.int/bitstream/handle/10665/352523/9789240046832-eng.pdf?sequence=1, accessed 14 March 2024.

7. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO. https://iris.who.int/bitstream/handle/10665/342899/9789240031593-eng.pdf?sequence=1, accessed 20 February 2020.

All consolidated WHO guidelines and operational handbooks can also be found on: https://tbksp.org/en.

For the latest WHO Model List of Essential Medicines and Model List of Essential Medicines for children, please consult;

1. WHO Model List of Essential Medicines. 23rd edition (2023) https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1

2. WHO Model List of Essential Medicines for Children. 9th edition (2023) https://iris.who.int/bitstream/handle/10665/371091/WHO-MHP-HPS-EML-2023.03-eng.pdf?sequence=1

Other references

Relevant publications and reports on the management of TB in children and adolescents, including latest Paediatric Drug Optimization for TB (PADO-TB) meeting reports can be found at:

World Health Organization. Ending TB in children and adolescents. https://www.who.int/activities/ending-tb-in-children-and-adolescents, accessed 14 March 2024.