

To the Secretary of the Expert Committee on the Selection and Use of Essential Medicines Medicines Selection, IP and Affordability
Department of Health Products Policy and Standards
World Health Organization

Subject: Letter of Support – Changes to Section 6.2.5 Antituberculosis Medicines

Dear Expert Committee,

TB Europe Coalition (TBEC) is pleased to submit this letter of support for key amendments to the WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc) regarding antituberculosis medicines.

As a regional advocacy network uniting approximately 500 civil society organizations and activists across 57 countries in the WHO Europe region, TBEC fully supports the WHO Global Tuberculosis Programme's efforts to review and update the EML to reflect the latest WHO recommendations and procurement practices.

1. Support for the Removal of the Rifabutin Footnote

TBEC strongly endorses the removal of the footnote restricting rifabutin use to "patients with HIV receiving protease inhibitors."

According to WHO's 2024 Operational Handbook on TB (Module 6: TB and Comorbidities), rifampicin-based regimens can pose significant drug interactions with certain ART regimens, leading to reduced drug concentrations. Although rifampicin remains the cornerstone of TB treatment, WHO's 2022 guidelines on drug-susceptible TB treatment (Module 4) recognize rifabutin as a suitable alternative for patients on ART regimens containing nevirapine or protease inhibitors.

Additionally, WHO's 2016 guidelines on TB-HIV integration for people who inject drugs identify rifabutin as the preferred rifamycin for individuals receiving opioid agonist maintenance therapy (OAMT). The current footnote does not account for these expanded indications, and removing it will ensure alignment with WHO's most up-to-date clinical guidance.

2. Support for Alphabetical Listing of All Antituberculosis Medicines in Section 6.2.5

TBEC also strongly supports the proposal to list all TB medicines under the Core List of section 6.2.5 in alphabetical order rather than maintaining a separate Complementary List for multidrug-resistant TB (MDR-TB) medicines.

Historically, MDR-TB treatment was provided exclusively in specialized facilities, creating logistical, financial, and accessibility barriers for patients. However, WHO's 2022 consolidated guidelines (Module 4: Treatment – TB Care and Support) highlight the benefits of decentralized, community-based care, which improves access and reduces the economic burden on people affected by TB.

Additionally, several TB medicines now play dual roles in treating both drug-susceptible and drug-resistant TB, reinforcing the need for an integrated listing under a unified Core List:

- Moxifloxacin included in both the 4-month drug-susceptible TB regimen (WHO's 2022
 Guidelines, Module 4) and MDR-TB regimens such as BPaLM (WHO's 2022 Update on DrugResistant TB Treatment).
- Ethionamide used for MDR-TB but also included in pediatric TB meningitis treatment regimens (WHO's 2022 Guidelines, Module 5).

Given WHO's promotion of decentralized MDR-TB care and the evolving use of certain TB medicines for both drug-susceptible and drug-resistant TB, organizing section 6.2.5 alphabetically under the Core List would improve clarity, accessibility, and alignment with global TB treatment practices.

TBEC respectfully urges the 25th Expert Committee on the Selection and Use of Essential Medicines to:

- 1. Remove the footnote on rifabutin in section 6.2.5 of the EML to ensure its use is guided by the most recent WHO clinical recommendations.
- 2. Reorganize section 6.2.5 so that all TB medicines are listed under the Core List and arranged alphabetically, reflecting their broader clinical application and the shift toward decentralized MDR-TB care.

We greatly appreciate your time and consideration of this letter of support and remain committed to supporting WHO's efforts to optimize TB treatment access globally.

Sincerely,

Yuliia Kalancha

Executive Director TB Europe Coalition