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Editorial

The Empty Medicine Cabinet: Urgent Action Needed to Resolve TB Drug Shortages in Europe

Dear Editor,

Tuberculosis (TB) is one of the most widespread infectious diseases globally, with an estimated 10.8 million new cases in 2023 [1,2]. The treatment typically involves an initial regimen of at least four different antibiotics for two months, followed by four additional months of continuation therapy with two of the four antibiotics [3]. Adherence to therapy is essential for cure and to prevent the development of drug resistance, for which, until very recently, the treatment is more complicated, often longer, and associated with significant side effects [3–5].

With this letter, we highlight the challenges related to the availability and access to World Health Organization (WHO) essential medicines for TB preventive treatment (TPT) and for the treatment of drug-susceptible (DS) and drug-resistant (DR) TB in the WHO European Region. During the last 5 years, several communications about the lack of access to first- and second-line TB drugs have been reported (Table 1). These challenges arise from a range of factors, including the absence of regulatory approval from the European Medical Association, high costs, the lack of registration for use in TB treatment, and drug shortages resulting from limited production or inefficient procurement processes[6].

The WHO European Region comprises 53 countries with highly heterogeneous epidemiological profiles, from some with the highest global rates of multidrug-resistant and rifampicin-resistant TB (MDR/RR-TB) to others with a low TB incidence. Conflicts and regional inequalities have worsened the situation. In 2022/2023, population displacement in Europe due military action of the Russian Federation against Ukraine caused increased MDR/RR-TB notifications across many countries in western and central Europe [7]. This highlighted challenges in maintaining treatment continuity and revealed disparities in access to TB medications [8]. Furthermore, implementing effective treatment regimens, as per the latest WHO tuberculosis treatment guidelines [3], can be hindered by drug availability issues [9].

Challenges in TB treatments, such as delays, interruptions, and poor compliance, can lead to drug rationing, increased resistance, and worse health outcomes. Also, regulatory challenges, like in the case of pretomanid, contribute to the limited supply [10]. Addressing these issues requires a multifaceted approach, including strengthening supply chains, supporting drug production, optimizing procurement, promoting local manufacturing, and continuously monitoring drug availability.

In 2024, a meeting organized by WHO/Europe and the Federal Ministry of Health of Germany brought together representatives from 22 countries to discuss improving access to medicines for DS- and MDR/RR-TB in Europe [11]. The meeting emphasized the urgent need for secure and rapid access and availability of quality TB medicines, particularly for DR-TB and TPT. Despite the significant challenge posed by MDR/RR-TB, the relatively low patient numbers have not generated sufficient demand to sustain a robust market for TB medicines, thereby creating ongoing issues related to supply and accessibility. Therefore, increasing the commercial appeal of TB medicines and consolidating the market are key priorities [11]. In January 2025, another WHO regional meeting with participation from 26 member states and stakeholders addressed issues related to medicine access, costs, and the implementation pace of new WHO-recommended treatment regimens, reaffirming existing commitments [8]. National and European advocacy plans have been developed, with WHO playing a central role in facilitating progress and integrating TB into health policy agendas. WHO/Europe coordinates member state collaboration and uses survey data to inform targeted interventions, highlighting the value of regional cooperation.

For DS TB, shortages of essential first-line medications, in particular rifampicin (both oral and intravenous formulations) and various fixed-dose combinations, have been documented. These shortages disrupt continuity of care and may force clinicians to prioritize the use of rifampicin for TB disease treatment over TB infection (TBI), or other mycobacterial diseases. The lack of pediatric formulations and specific fixed-dose combinations further compromises treatment for children, a population often overlooked in TB care [12].

Access to rifapentine, a key drug for treating both TB disease and TBI, remains limited outside certain low- and middle-income countries, with most of the WHO European Region excluded [13]. A multicenter randomized clinical trial demonstrated that a 4-month regimen including daily rifapentine and moxifloxacin is as effective as the standard 6-month treatment for rifampicin-susceptible TB, a regimen endorsed by WHO. For TBI preventive treatment, rifapentine enables shorter, more manageable regimens: once weekly for three months or daily for one month, both in association with isoniazid.

Altogether, this is far from being just a supply chain issue. It means a significant failure of political prioritization. Despite longstanding global and national commitments to eradicate TB, the lack

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Table 1
Drug shortage reported in Europe, 2020-2025.

Drug or drug formulation	Drug shortage reported in Europe between 2020-2025
Rifampicin, IV formulation	Italy [14]
Rifampicin and isoniazid fixed doses combination	Italy [15]
Rifapentine	Europe [6,13,16]
Bedaquiline, pretomanid and other second-line drugs	Europe [5,6,8,9,17]
Pediatric formulations	Europe [6,12]

Abbreviations. IV: intravenous.

of a coordinated, Europe-wide mechanism to ensure an uninterrupted drug supply highlights systemic neglect. TB medicines, often generic and affordable, offer low profit margins and are therefore deprioritized in production planning. When market forces govern availability, access becomes precarious, and those most in need face the consequences. Access to TB treatment is part of the right to health. Ensuring the continuous availability of medicines should not rely solely on commercial viability. National and regional systems must be equipped with tools to detect, prioritize, and respond to shortages based on clinical relevance. Furthermore, regulatory flexibility should be fully utilized. Some EU Member States have effectively employed emergency import authorizations, labelling exemptions, and shelf-life extensions to address supply disruptions, measures that could be systematically applied to essential TB drugs.

TB drug shortages continue to pose a serious threat to public health across Europe. Although the EU mandates early notification of expected shortages, enforcement varies widely among member states. Harmonization of monitoring systems and the creation of a centralized, transparent EU platform are critical to ensure real-time oversight of essential drug availability.

As representatives of the European Respiratory Society, Study Group of Mycobacterial Infections of the European Society of Clinical Microbiology and Infectious Diseases, International Union Against Tuberculosis and Lung Disease, and TBnet, we urge drug manufacturers, policymakers, and public health authorities to undertake urgent and coordinated action. A joint initiative led by the European Commission, WHO/Europe, and national TB programs should: i) include TB medicines in national and regional critical medicines lists; ii) establish strategic stockpiles and joint procurement mechanisms; iii) strengthen transparency and accountability across supply chains; iv) expand regional manufacturing capabilities for rifampicin, rifapentine and other essential TB drugs, such as rifampicin and rifapentine; v) support regulatory reforms and public education campaigns to accelerate adoption of WHO-recommended treatment regimens; vi) implement mandatory, real-time early warning systems to monitor supply disruptions.

We must also prioritize the voices of clinicians and those affected by TB. Their testimonies emphasize not only the clinical outcomes but also the harm caused by preventable gaps in care. This is not a call for more declarations. It is a call to act decisively, collaboratively, and urgently.

Only through decisive, multidisciplinary cooperation can we guarantee equitable and sustained access to essential TB medicines throughout the WHO European Region.

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