Bridging the gap

Securing access to essential TB medicines in the EU and EEA

MEDECINS SANS FRONTIERES

Médecins Sans Frontières/Doctors Without Borders (MSF) is an international, independent medical humanitarian organisation that delivers medical care to people affected by conflict, disease outbreaks, natural and human-made disasters, and exclusion from health care. MSF is the largest non-governmental provider of TB treatment worldwide and has been involved in TB care for 30 years, often working alongside national health authorities to treat people in a wide variety of settings, including conflict zones, urban slums, prisons, refugee camps and rural areas.

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CONTENTS

Executive summary

Tuberculosis (TB) remains one of the world's deadliest infectious diseases, despite being both preventable and curable. To save lives and achieve global TB elimination targets, access to newer and better tests and treatments is urgently required everywhere. While many low and middle-income countries with high TB burdens are taking steps to improve testing and treatment access, inadequate access to new TB medicines and the slow adoption of regimens recommended by the World Health Organization (WHO) in the European Union/European Economic Area (EU/EEA) threaten to fuel the emergence of drug-susceptible TB (DS-TB) and drug-resistant TB (DR-TB) in the region and beyond. People with TB in the EU/EEA region continue to face delayed, interrupted, suboptimal or outdated treatment due to the unavailability, high costs and fragmented supply of TB medicines.

In 2022, as Médecins Sans Frontières (MSF) began a response in Poland to assist Ukrainian refugees and other migrants in accessing TB treatment, systemic gaps in access to WHO-recommended TB treatments became evident – not only in Poland but across the EU/EEA. These gaps included limited availability of newer all-oral regimens for DR-TB, child-friendly formulations, and shorter preventive treatments for DS-TB.

Although the Polish Ministry of Health has taken positive steps over the past three years to improve treatment access, particularly by aligning its national policies with WHO recommendations, many similar access barriers continue to persist across most EU/EEA countries. Critical TB medicines such as bedaquiline, delamanid and pretomanid remain exorbitantly priced – sometimes up to over 100 times higher than in low and middle-income countries. In addition, essential fixed-dose combinations, paediatric formulations, and rifapentine-based preventive therapies remain unregistered and therefore unavailable in many parts of the region.

These access constraints reflect broader systemic challenges, including a lack of political prioritisation, regulatory hurdles, fragmented procurement systems and monopolistic pricing practices – all of which continue to undermine TB care across the EU/EEA.

This policy brief outlines access barriers, highlights regulatory and procurement pathways and flexibilities enshrined in EU legislation, and provides some practical, urgent recommendations for the EU/EEA region in the following areas:

1 AWARENESS AND POLITICAL WILL

Countries should align their national TB policies in line with WHO recommendations, promote a multidisciplinary approach, and engage civil society to raise awareness. At the EU level, countries should collaborate through WHO/Europe platforms and workshops, advocate for TB as a public health priority, and integrate TB into the antimicrobial resistance agenda.

2 COORDINATION AND MARKET RATIONALISATION

Countries should establish centralised procurement and distribution systems that can boost negotiating power and prevent treatment interruptions. Collaborating with the Stop TB Partnership-led Global Drug Facility (GDF) for pooled procurement and participating in joint procurement and stockpiling initiatives through the Director General of Health Emergency Preparedness and Response Authority (HERA) can improve supply and affordability of key TB medicines.

3 REGULATORY ADAPTATIONS

Countries should use flexibility mechanisms to import unregistered TB medicines and work with the European Medicines Agency (EMA) on faster regulatory pathways, including recognition of WHO prequalification and the WHO Collaborative Registration Procedure. Broader pharmaceutical legislative changes at the EU/EEA level could support access to medicines for people affected with TB, antibiotic resistance and other diseases with low incidence.

4 PRICE TRANSPARENCY AND AFFORDABILITY

Countries should negotiate better prices, share pricing information and promote EU/EEA-wide price transparency – including the compilation, publication and dissemination of net prices without rebates and discounts, and the disclosure of research and development (R&D) costs, including public contributions.

Advocate for the removal of secondary patents to make TB medicines more affordable and accessible, especially given that certain TB medicines – such as pretomanid and bedaquiline – were developed with public funding, and others – including bedaquiline and delamanid – remain under extended patent protection in the EU/EEA.

With coordinated actions, the EU/EEA can bridge the access gap, safeguard public health and set a global precedent in ending this preventable and curable deadly infectious disease.

Counsellor from MSF speaking with a person with DR-TB at TB hospital in Bydgoszcz, Poland. © Aleksander Binek/WHO

Introduction

Tuberculosis (TB) remains a significant global public health threat, representing the most deadly infectious disease in the world, causing the deaths of more than 1.2 million[1] people annually.

Despite decades of socioeconomic progress and advancements in research and development that contributed to the past decline in TB incidence, the European Union and European Economic Area (EU/EEA) are now experiencing a resurgence of TB – including drug-resistant forms. There were 38,993 people with TB reported in 30 EU/EEA countries in 2023[2], which represents a continuation of the slight increase observed in most countries for 2022. This resurgence threatens progress toward TB elimination, underscoring the need for renewed focus on prevention, timely diagnosis and effective treatment strategies.

Furthermore, treatment outcomes in the EU/EEA fall short of international standards. Treatment success rates for drug-sensitive TB (DS-TB) reported by EU/EEA countries have seen a gradual worsening lately, while outcomes for drug-resistant TB (DR-TB) remain extremely unsatisfactory, with some countries reporting success rates as low as 40 per cent[3] – worryingly below World Health Organization (WHO) targets.

MSF has been working in the EU/EEA region since 2022, when it launched a TB project in Poland in response to the full-scale invasion of Ukraine, which led to millions of refugees crossing the border into Poland. While striving to ensure the continuation of TB treatment for these refugees, MSF also encountered a lack of availability of necessary medicines in Poland, reflecting a similar situation in other EU countries.

This technical brief attempts to outline key barriers faced in accessing lifesaving TB medicines for adults and children in the EU/EEA and to provide policy recommendations for addressing these barriers in collaboration with all stakeholders, including policymakers, procurement bodies and regulatory authorities.

Context

TB epidemiology negative trends in EU/EEA

Historically, TB incidence has been declining in many EU/EEA countries; however, recent trends show a reversal, with increases reported in several EU member states and more broadly across the EEA.

As per the joint surveillance and monitoring report by WHO/Europe and the European Centre for Disease Prevention and Control (ECDC), the majority of EU/EEA countries experienced a rise in TB notifications, from an average notification rate of 8.1 per 100 000 population in 2022 to 8.6 in 2023[4]. This increase also reflects the growing number of drug-resistant TB cases. While EU/EEA countries have committed to reach the Sustainable Development Goal of reducing the TB notifications rate to 2.4 per 100,000 population by 2030, current trends demonstrate that most of them are not on track to achieve an 80 per cent reduction by 2030[5], or the broader goal of TB elimination target by 2050[6].

Access to TB medicines remains a critical issue in the EU/EEA

While effective medicines to treat and prevent TB have been available globally for years, many remain inaccessible across the EU/EEA. WHO/Europe surveys from 2023 and 2024[7] and the Global TB Report (2023) highlighted critical access gaps and called for coordinated action. Among 30 EU/EEA counties, only Estonia, Norway and the Netherlands have reported full availability of all components of the WHO-recommended DR-TB regimen BPaLM (bedaquiline, pretomanid, linezolid and moxifloxacin). Of the estimated 85,000 household contacts in the EU/EEA countries who need TB preventive treatment (TPT), only one-third are currently receiving it.

Lack of access to TB medicines has severe consequences for both people with TB and TB control efforts. For people with TB, delayed, inadequate or interrupted treatment increases

the risk of disease progression, complications and ultimately death. At the community level, inadequate access to effective treatment leads to continued transmission, as starting effective treatment promptly is the most important infection control measure in stopping the spread of TB from individuals with active TB.

From a public health perspective, these gaps undermine elimination efforts, contributing to ongoing morbidity and mortality for the affected populations, placing an additional burden on healthcare systems, and escalating treatment costs.

Notably, TB is not confined by borders. High-income countries are not immune to outbreaks, as plenty of evidence shows[8].

CASE STUDY – POLAND

MSF launched a TB project in Poland in 2022 to support Ukrainian refugees and other migrants, in close collaboration with the Polish Ministry of Health (MoH), focusing on linking people with TB to treatment and providing them with psychosocial support. By the end of 2024, MSF had assisted 281 TB patients, including 171 with DR-TB.

As MSF began its response in 2022, Poland's national TB policies did not reflect the current WHO guidelines for DR-TB. Patients had to endure prolonged hospitalisation and older, toxic regimens, with no access to newer, WHO-recommended oral treatments. Child-friendly formulations were not available and only one fixed dose combination (FDC) for adults was available.

Poland addressed the challenges related to the refugee crisis by launching a pilot project for outpatient DR-TB treatment, successfully reducing hospital stays from several months to a few weeks. This marked an important step forward in bringing national policies close to WHO recommendations.

Further, Poland's existing flexibility mechanisms enabled donations of essential TB medicines—previously unavailable in the country—by MSF and WHO. This enabled the introduction of the all-oral, shorter regimen for treatment of DR-TB. It helped ensure that all people with TB, including refugees, could continue their treatment and access the latest WHO-recommended regimens.

In parallel, Poland also successfully negotiated significant price reductions for new-generation medicines. To overcome financial barriers and support broader implementation, the government introduced a reimbursement system for DR-TB treatment at the hospital level.

While these positive steps have already helped in ensuring quality treatment for people with TB, a comprehensive and systematic approach to TB management in Poland is still needed. This includes adapted strategies for case-finding, diagnosis and patient-centred care.

Juri, a person living with DR-TB and supported by MSF, was started on the all-oral, shorter BPaLM regimen. He spent the first three months of his six-month treatment in hospital, before transitioning to ambulatory care to complete the remainder of his treatment at home.

“I spent the last three months of the treatment at home. The medications that I was taking were very good. Everything was okay. I felt uplifted and started believing in myself. I can say that I was walking towards a brighter future, even with such a deadly disease as tuberculosis.”

Juri, TB survivor who received all-oral DR-TB treatment in Poland. ©Jakub Jasiukiewicz/MSF

Key TB medicines, their clinical use and current access challenges in the EU/EEA

Access to essential TB medicines in the EU/EEA is hindered by regulatory and pricing barriers, particularly for newer treatments and paediatric formulations. As a consequence, clinicians in the EU are not able to implement the latest WHO recommendations to follow best standards of care. Most of these medicines are available outside the EU/EEA market in affordable and quality-assured generic versions.

1 LACK OF ACCESSIBILITY OF CERTAIN TB MEDICINES:

Generic FDCs for DS-TB, including for children, and rifapentine-based combinations for TB preventive treatment are not registered (except two FDCs for adults mentioned in the Annex) at either national or EU/EEA level, making them largely unavailable across the region.

FDCs simplify TB treatment for adults by combining multiple first-line TB medicines into a single tablet, improving adherence and reducing pill burden. In their absence, patients are forced to follow complex dosing regimens with multiple single tablets, increasing the risk of non-adherence and delivery of incomplete regimens if one of the medicines is missing.

The lack of paediatric formulations – designed to be dissolvable and easily palatable – means that children are often given adult medicines crushed into pieces, without appropriate weight-based dosages.

Rifapentine is a key component of the 3-month isoniazid/ rifapentine (3HP) regimen, a short-course treatment consisting of once-weekly rifapentine and isoniazid for three months, which has been proven to be as effective as the traditional six to nine months of isoniazid monotherapy. Its absence from the EU market prevents the use of the latest, WHO-recommended short-course preventive therapy.

2 HIGH COSTS OF NEWER TB MEDICINES:

Newer TB medicines – such as bedaquiline, delamanid and pretomanid – are often not easily accessible due to high prices or a lack of commercialisation in certain countries. These medicines have significantly improved DR-TB treatment outcomes by enabling shorter, all-oral regimens to replace older, longer and more toxic injectable-based regimens.

Bedaquiline and pretomanid are essential components of the WHO-recommended six-month BPaLM regimen (bedaquiline, pretomanid, linezolid, and moxifloxacin), which has demonstrated higher efficacy and a reduced treatment duration compared to traditional DR-TB regimens.

3 REPURPOSED MEDICINES WITH NO INITIAL TB INDICATIONS:

Some older TB medicines, although not centrally authorised, were registered at the national level during the 20th century. While there are no regulatory barriers to access, these medicines either remain expensive (eg linezolid) or don't have a TB indication (eg clofazimine). This is largely because they were initially developed for broader antibiotic use or other use rather than specifically for TB .

The table in the Annex summarises the key TB medicines used for TPT, DS-TB and DR-TB, with their clinical use and identified barriers.

Barriers to accessing TB medicines in the EU/EEA

As outlined earlier, many essential TB medicines remain unregistered, unaffordable or unavailable, despite their inclusion in the WHO Essential Medicines List[9] and WHO treatment guidelines[10].

LIMITED AWARENESS AND POLITICAL WILL

- Awareness of the TB burden and response to this disease is often limited among policymakers across EU/EEA countries, with many not having a standardized approach towards TB.
- TB is viewed as disease of the past due to comparatively low prevalence in the region, thereby missing the public health perspective.
- Many EU/EEA countries lack a national TB strategy, an established programme or national guidelines; where they do exist, they are often outdated.
- Coordination across different national stakeholders – such as ministries of health, regulatory agencies and procurement bodies – is often lacking, hindering the process of finding solutions to ensure access to medicines.

SMALL QUANTITIES DETER MARKET ENTRY

- A wide range of TB medicines is necessary to build regimens for both the prevention and treatment of all forms of TB according to current WHO recommendations. The absence of national guidelines fully aligned with the latest WHO recommendations impede EU/EEA countries from having a consolidated market; instead, fragmentation and poor forecasting are predominant.
- Considering the low demand and the complexity of regulatory/labelling rules in EU/EEA countries, there are limited market incentives for companies manufacturing generic medicines to make all these medicines available.
- The lack of centralised procurement mechanisms at the national level limits the visibility into overall demand and prevents proper forecasting at the country level, which is required for ensuring access for a small market.
- Engagement with pooled procurement mechanisms, such as the Stop TB-led Global Drug Facility (GDF) and the Health Emergency Preparedness and Response Authority (HERA), remains limited despite their potential to offer lower-cost, quality-assured TB medicines and to stockpile identified key medicines.
- The current 'profit-driven' market framework often fails to meet demand for medicines needed in small quantities, as they are typically unprofitable for manufacturers to register or supply. As a result, people affected by TB, antibiotic resistance, and other diseases that are rare in Europe, are frequently left without access to essential treatments.

THE EU AND NATIONAL REGULATORY SYSTEMS ARE NOT WELL ADAPTED

- Manufacturers are frequently discouraged from applying for EU-level market authorisation due to the significant costs associated with collecting the required clinical and other data needed to meet European Medicines Agency (EMA) approval standards. As a result, the EMA registration system is not

adequately equipped to ensure access to TB medicines, particularly in the absence of market-driven incentives for manufacturers to pursue registration.

- While many TB medicines available outside the EU/EEA are WHO-prequalified, this programme is not recognised by EMA, as the WHO is not considered a regulatory authority.
- Mechanisms such as the WHO Collaborative Registration Procedure (CRP) for accelerated registration, which allows for expedited registration of WHO-prequalified TB medicines through confidential data-sharing, are not currently used at the national or EU level.
- Many countries struggle to identify flexible mechanisms available within EU legislation for importing non-registered medicines, or lack similar national legislation sufficiently adapted to meet these needs.

MONOPOLIES AND LACK OF TRANSPARENCY LEADING TO UNAFFORDABLE TB MEDICINE PRICES

- Newer and repurposed TB medicines such as bedaquiline, delamanid, pretomanid and linezolid are priced significantly higher in the EU/EEA compared to in low and middle-income countries (LMICs). For example, the cost of a full-course BPaLM regimen can exceed €45,000 per patient in the EU/EEA, while the same regimen is 150 times cheaper in LMICs where it is available for €275.
- Existing procurement practices and price negotiations prevent countries from securing cost reductions for key TB medicines.
- The lack of transparency in pricing negotiations results in wide variations in the cost of the same medicine across different countries and even in different regions within a country, reducing opportunities for fair and equitable pricing.
- In some countries, not all the treatments are entirely provided free of charge, thereby excluding patients who are not able to afford them.
- Health insurance and reimbursements are not always adequate, which prevents certain TB physicians from prescribing newer, more expensive medicines, leading to continued reliance on older regimens that include painful and toxic injections.
- Secondary patents on medicines such as bedaquiline and delamanid remain in effect in the EU/EEA, potentially delaying the introduction of more affordable generic versions.

IMPACT ON INDIVIDUALS

People affected with TB —including children—endure longer, harsher treatments that are not adapted to their needs

IMPACT ON EFFECTIVENESS OF TREATMENT REGIMENS

Clinicians cannot offer WHO recommended, evidence based regimens, with higher risk of unfavourable outcomes

INCREASED BURDEN ON HEALTHCARE SYSTEMS

Longer, more complex treatments and higher failure rates place additional pressure on health systems

PRICE COMPARISON OF KEY DR-TB MEDICINES IN THE EU/EEA VS. GDF (APRIL 2025)

MEDICINE	Prices in EU for six-month course	GDF prices for six-month course
Bedaquiline	€20,000 - €25,000	~€86
Pretomanid	€15,000 - €35,000	~€151
Delamanid	€30,000 - €35,000	~€764
Linezolid	€5,000 - €10,000	~€23

TB MEDICINES EXORBITANTLY PRICED AND OUT OF REACH DESPITE PUBLIC INVESTMENT IN R&D

In 2022, global spending on TB research and development (R&D) exceeded US$1 billion, with only 11 per cent covered by the private sector; the rest was spread between 66 per cent from the public sector, 19 per cent from philanthropic entities and 4 per cent from multilateral donors[11].

A stark example is the TB medicine pretomanid, developed by the TB Alliance (TBA) – a not-for-profit entity exclusively funded by governments – including the US, UK, Ireland, Germany and Australia – and philanthropic entities. Further, the TBA was awarded a lucrative Tropical Disease Priority Review Voucher (PRV), estimated to be worth US$67-350 million, by the US Food and Drug Administration (FDA) in 2019[12]. Despite being so heavily publicly funded, pretomanid is currently procured in EU/EEA countries at a price 100 times higher than that procured by the StopTB-led GDF.

This is not an isolated case. In 2024, the Health and Digital Executive Agency (HaDEA)[13] issued a tender to carry out clinical and non-clinical services for finalising the development and submission of the market authorisation application for DS-TB paediatric formulations (see Annex for more details) to ensure their commercialisation in the EU. In January 2025, pharmaceutical company Macleods was awarded the tender and will receive €5 million funding to gather additional data to obtain EMA regulatory approval of these paediatric TB formulations by 2027/28.

The same paediatric DS-TB formulations already received substantial funding from UNITAID in the past for their development and are already WHO-prequalified. They have been supplied in LMICs by Macleods and Lupin, funded by the Global Fund, for the past 10 years. Collectively, this reflects a considerable amount of EU funding in development of those formulations.

Further, the EC has invested more than €90 million to support the UNITE4TB platform[14] through the Innovative Health Initiative (IHI), which aims to develop new TB compounds for both DS-TB and DR-TB regimens. To ensure that the resulting innovations are accessible and affordable in the EU, access and pricing conditions must be embedded in public funding agreements and negotiated with pharmaceutical corporations involved in UNITE4TB.

Global and regional initiatives that could support access to TB medicines

Global initiatives

WHO Prequalification

The WHO Prequalification (WHO PQ) programme[15] aims to ensure that key health products meet global standards of quality, safety and efficacy, in order to optimise the use of health resources and improve health outcomes. Under this prequalification process, each product undergoes a transparent and scientifically rigorous assessment, which may include dossier review, product testing, performance evaluation and inspection of the manufacturing sites. Prequalification outputs – including the list of prequalified[16] products, and WHO Public Assessment and Inspection Reports – are used by UN agencies and other procurement bodies to inform their purchasing decisions regarding health products.

WHO Collaborative Registration Procedure (CRP) for medical products

This collaborative procedure was created to facilitate the assessment and accelerate the national registration of WHO prequalified finished pharmaceutical products (FPPs)[17]. It also allows accelerated registration of FPPs that have already received approval from a Stringent Regulatory Authority.

Global Drug Facility

As part of the Stop TB Partnership, the Global Drug Facility (GDF)[18] serves as a one-stop bundled procurement and supply mechanism providing a unique package of services that combine strategic procurement of TB medicines and medical tools, coordination of market activities, technical assistance and capacity-building for TB programmes. This unique approach has made GDF the largest global provider of quality-assured TB products to the public sector.

GDF has a quality assurance system for procurement and supply management of TB medical products which is compliant with WHO and International Council for Harmonisation (ICH) quality standards[19]. The GDF routinely publishes a catalogue of quality-assured TB medicines along with their specifications and prices[20].

EU initiatives

The Critical Medicines Alliance (CMA)

Under the Health Emergency Preparedness and Response Authority (DG HERA) coordination, CMA was set up in January 2024 as a consultative mechanism bringing together relevant stakeholders from EU member states, key industries, civil society, and the scientific community. The Alliance aims to identify priority actions and propose solutions to strengthen the supply of critical medicines within the EU and prevent shortages. The EU's Union List of Critical Medicines[21] contains several TB medicines: rifampicin, rifabutin, isoniazid, ethambutol, bedaquiline and isoniazid/rifampicin FDC. However, this list does not represent the full range of existing TB medicines.

Joint Procurement and stockpiling

DG HERA is currently exploring joint procurement of TB medicines at the EU level. While an EU-level market authorisation is not a pre-condition to launch a joint procurement, countries must ensure that they have regulatory pathways in place to receive medicines. Joint procurement could also serve as an incentive for Market Authorisation Holders (MAH) to apply for EU level authorisation if there is substantial demand.

The EU Pharmaceutical Legislation Reform

In 2023, the Directorate-General for Health and Food Safety (DG SANTE) led the European Commission (EC) to adopt a proposal for a new Directive and a new Regulation, which would revise and replace the existing general pharmaceutical legislation. The reform provides the legal basis for the Union List of Critical Medicines, last updated in December 2024. It is being developed in parallel with the consideration of the proposal for the Critical Medicines Act and both legal instruments are intended to be complementary. This reform is expected to be adopted by the Council of the European Union before the end of 2025.

Together, these initiatives can provide an opportunity to address the barriers to accessing TB treatments in the EU. They include proposals to strengthen manufacturing capability, promote innovative public and collaborative procurement practices, and advance regulatory reform, both at the national level and through the centralised procedure within the EU.

However, MSF raised its concerns to the EU Parliamentarians that the current proposal for the EU pharmaceutical legislation (Directive and Regulation) would fail to propose concrete steps to improve access to safe, effective, and affordable TB medicines in line with the WHO guidelines. Unless explicit encouragement is made to use the flexibilities enshrined in the pharmaceutical legislation, these life-saving medicines will remain out of reach for most patients needing them.

Existing EU Regulatory procedures and flexibilities for medical products

At national level

There are several regulatory pathways for companies to register medicines in the EU, each designed to accommodate different types of medical products and market strategies.

- **National procedure[22]:** Used for obtaining marketing authorisation in a single EU member state. This is typically chosen for medicines intended for markets in one specific country.
- **Decentralised procedure[23]:** Allows a company to apply for marketing authorisation in multiple EU countries simultaneously, provided the medicine has not yet been authorised in any EU country.
- **Mutual Recognition Procedure[24]:** Used when a medicine has already been authorised in one EU member state (the 'reference member state') and the company seeks to obtain marketing authorisations in other EU countries (the 'concerned member states').
    - Under article 126a Directive 2001/83/EC[25], also known as Cyprus Clause, marketing authorisation can be granted even without the consent of an authorisation holder for justified public health reasons for a product registered in one of the EU countries.

When registration for certain medicines is not achievable at the national level, EU countries can use flexibilities existing in the EU pharmaceutical legislation to allow the use of non-authorised medicines.

Exceptional Use Authorisation under article 5 Directive 2001/83/EC[26] of the EC enables temporary or patient-basis access for unregistered medicines:

- Article 5(1) allows access on 'named-patient basis,' sometimes referred to as 'compassionate use,' in cases of special needs for individual patients.
- Article 5(2) allows temporary authorisation for supply and use of medicalproducts at the national level in response to emergencies.

At the national level, similar flexibilities may exist under different articles translating the above-mentioned flexibilities enshrined in European legislation to allow the importation and use of non-registered medical products.

At the European Medicines Agency level

- **Centralised procedure** – This pathway is coordinated by the **European Medicines Agency (EMA)** and results in a single marketing authorisation which is valid across all EU member states as well as the EEA countries (Iceland, Liechtenstein and Norway). The EMA evaluates the product and provides

a recommendation, which is then approved by the EC.

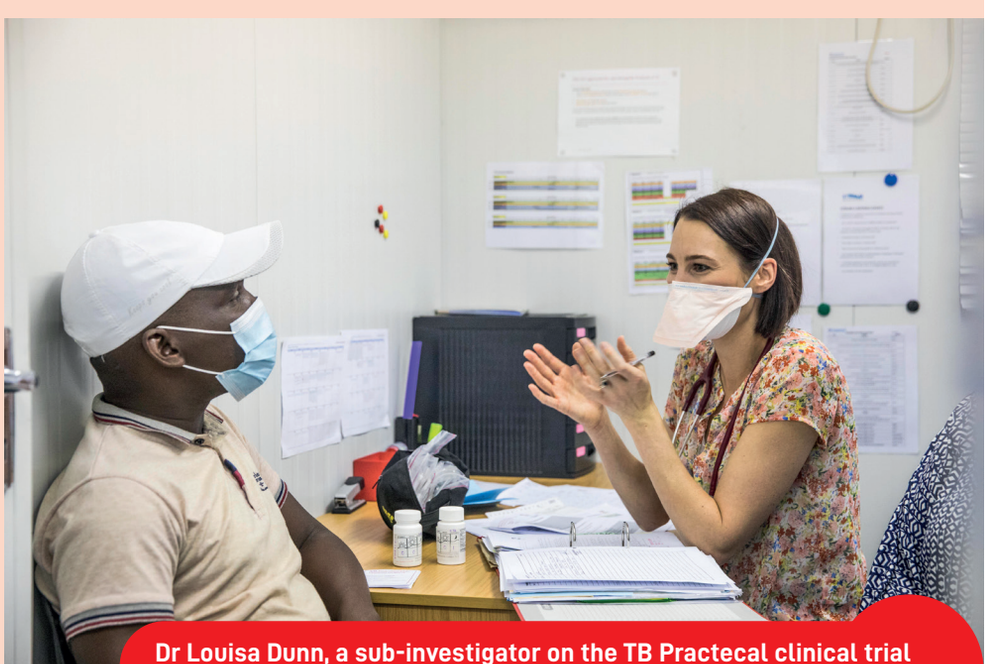
Within the centralised procedure, there are four expedited authorisation pathways for medicines available through the EMA, particularly relevant for products with 'orphan designation', which are more likely to meet the programme criteria:

- **PRIME scheme for priority medicines[27]:** Designed for medicines that address unmet medical needs, where no treatment option exists, or where a new therapy offers a major benefit over existing therapies.
- **Accelerated assessment[28]:** Intended for medical products expected to be 'of major public health interest,' particularly those that demonstrate significant therapeutic innovation. This pathway shortens evaluation timeframes.
- **Approval under 'exceptional circumstances'[29]:** Applied for medicinal products where comprehensive data on efficacy and safety cannot be provided (eg for extremely rare medical conditions).
- **Conditional market approval[30]:** Available for products where comprehensive clinical data is unavailable, or those needed for a public health emergency. The applicant is required to provide comprehensive data post-authorisation.

Products with 'orphan designation' are mandated to use the centralised marketing approval process conducted by the EMA. Sponsors applying for 'orphan designation' benefit from reduced regulatory fees and receive other incentives to undergo the entire registration process.

TB-PRACTECAL TRIAL AND THE PUSH FOR CLINICAL TRIAL COST TRANSPARENCY: AN INITIATIVE BY MSF TO IMPROVE ACCESS TO MEDICINES

In a bid to challenge the pharmaceutical industry's longstanding claims that high medicines prices are justified by high R&D costs, MSF publicly disclosed the cost of its groundbreaking TB-PRACTECAL clinical trial[31], which led to the WHO-recommended six-month, all-oral regimen for DR-TB treatment, and cost a total of €33.9 million. This marked the first time that detailed clinical trial costs have been made public, setting a new standard for transparency in biomedical research. MSF also launched the *Transparency CORE* toolkit[32], encouraging other public and non-profit actors to publish their trial costs and calling for international policy that mandates standardised cost reporting. This effort is critical to informing fairer pricing policies and ensuring that lifesaving treatments, including for TB, are accessible and affordable for all.



Dr Louisa Dunn, a sub-investigator on the TB Practecal clinical trial consults with a patient in South Africa.2019 © Oliver Petrie/MSF

Recommendations

	National level	EU/EEA level
Awareness and political will	• Promote a multidisciplinary approach to tackling challenges related to access to TB medicines, including the establishment of a national coordinating mechanism. • Align national TB guidelines with WHO recommendations for TPT, DS-TB and DR-TB regimens. • Encourage civil society organisations to raise awareness and mobilise community support.	• Facilitate the identification of access challenges and experience sharing among countries by participating in platforms or workshops organised by WHO/Europe and DG HERA. • Encourage member states to advocate with DG HERA and DG SANTE to identify TB as an important public health problem and facilitate appropriate solutions. • Call on DG HERA & DG SANTE to prioritise the EU's response to TB and consider integrating it into the antimicrobial resistance agenda.
Small quantities deter market entry	• Determine the critical TB medicines needed in alignment with WHO recommendations. • Establish a centralised or coordinated procurement and distribution mechanism to aggregate demands and increase capacity to negotiate better prices and conditions with manufacturers. In addition to improved forecasting of demand, a centralised system would ensure timely treatment initiation and prevent treatment interruptions. • Explore collaboration with StopTB Partnership's Global Drug Facility (GDF), assessing feasibility considering national laws (including flexibilities existing in the EU pharmaceutical legislation) and potential national exclusivity agreements with manufacturers that may restrict access to certain GDF-procured medicines. • Consider collaboration with DG HERA to pool needs at the EU/EEA level, thereby further increasing volumes and visibility for suppliers.	• Leverage the ongoing pharmaceutical legislation reform to promote sustainable procurement practices for all critical medicines, including TB medicines, in line with the latest WHO guidelines. • DG HERA should identify the most needed TB medicines based on national demand. The Union list of critical medicines should be expanded to include all necessary TB medicines. • DG HERA and/or WHO/Europe should raise awareness and encourage countries to participate in joint procurement agreements (JPAs) to procure and stockpile TB treatments

	National level	EU/EEA level
EU/national regulatory system not aligned and adapted	• Encourage the use of existing regulatory flexibility mechanisms to import unregistered or unavailable TB medicines to facilitate their immediate availability until long-term solutions are developed.	• Until long term solutions are found and implemented, collectively work with EMA to explore regulatory and legislative solutions to fast-track access to essential TB medicines not marketed in the EU/EEA by considering: ◦ Recognition of WHO PQ and adherence to the CRP. Clarification of liability aspects. • For sustainable solutions, consider proposing amendments to current pharmaceutical legislation to improve access to TB and other medicines needed for low-prevalence diseases with a significant public health impact. These may include establishing a 'special status' for critical medicines and adaptation of pharmaceutical regulations to better secure rapid, simplified and unified access to and availability of quality TB medicines and medicines for other diseases rare in Europe.
Monopolies and lack of transparencies drive unaffordable prices	• Engage with pharmaceutical companies to negotiate better prices and supply conditions, including the compilation, publication and dissemination of net prices without rebates and discounts, and the disclosure of R&D costs, including public funding contributions. • Share medicine pricing data with other countries through collaborative platforms and workshops to strengthen collective bargaining power and ensure full transparency.	• Actively promote transparency on medicine prices and supply to enhance countries' negotiation capacity. • Keep track of its public investments in R&D and establish a mechanism to make sure that medicines developed using public funding are affordable and accessible for all EU member states. • Civil society organisations should advocate for patent reforms – challenging secondary patents and evergreening practices by manufacturers – and push for updating the EU pharmaceutical legal framework to prevent such barriers to access in the future. • Encourage adoption and implementation of transparency tools such as the Transparency CORE toolkit by all developers to publish their clinical trial costs and ensure access to affordable products.

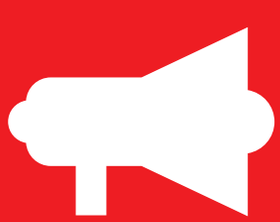
Conclusion

The lack of access to essential TB medicines in the EU and EEA remains a critical challenge, threatening both individual patient care and broader public health objectives. Despite significant advancements in TB treatment and prevention, persistent regulatory barriers, high medicine costs and fragmented procurement mechanisms continue to limit the availability of lifesaving medicines for those who need them most.

Failure to address these systemic challenges not only prolongs people's suffering and increases mortality among TB patients, but also exacerbates the spread of DR-TB strains, posing a growing risk of transmission across the region and beyond. The EU and its member states must take urgent action to streamline medicine approval processes, improve coordinated procurement and distribution mechanisms, and ensure equitable and transparent pricing mechanisms to support sustainable access to TB medicines.

Key stakeholders, including the EC, DG HERA, DG SANTE, EMA, member states and their regulatory and procurement agencies, along with international partners such as the UN and civil society organisations, must work collaboratively to analyse and work on the recommendations outlined in this briefing document to document to ensure access to lifesaving TB medicines for people who need them in the EU/EEA.

Besides all these above, sustained investment in TB research, surveillance and innovation is also essential to drive the development of new treatment strategies and strengthen health system resilience. By placing TB high on the EU health agenda and by fostering multisectoral collaboration, EU policymakers can lead meaningful change – ensuring timely access to quality-assured TB medicines for all and advancing the region's commitment to ending TB.



With coordinated action and political will, Europe has the opportunity to overcome the barriers to accessing TB medicines and to set a global precedent in the fight against this preventable and curable disease.

The time to act is now.

Annex: Key TB medicines and regimens recommended by WHO and their registration status

(Updated as of April 2025: The information provided is accurate to the best of MSF's knowledge).

WHO RECOMMENDED REGIMENS FOR DS-TB[33]:

- **Adults:**
  - 2 months E 275/H 75/Z 400/R 150 mg tablet + 4 months H 75/ R 150 mg tablet
  - 2 months HhPZM+ 2 months HPM (the first WHO prequalified FDCs for adults may come to market by Q2 2025)
- **Children**
  - 2 months H 50/Z 150/R 75 mg dispersible tablet + 4 months H 50/ R 75 mg dispersible tablet

WHO RECOMMENDED REGIMENS FOR DR-TB[34]:

- **Priority to be given to all-oral and shorter treatment regimens**
- **Alternative treatment regimens for DR-TB:**
  - 6-month (standard): BPaLM, BDLLfxC
  - 9-month (standard): BLMZ, BLLfxCZ, BDLLfxZ
  - 18-month (individualised): when 6- and 9-month regimens cannot be used or after treatment failure of 6- and 9-month regimens (may include cycloserin, ethionamide, imipenem/meropenen, amoxicilline/clavulanate)

WHO RECOMMENDED REGIMENS FOR TPT[35]:

- **1HP: one month of rifapentine plus isoniazid given daily**
- **3HP: three months of rifapentine plus isoniazid given weekly**
- **3HR: three months of rifampicin plus isoniazid given daily**
- **4R: four months of rifampicin given daily**
- **6 or 9 and 36H: 6/9 to 36 months of isoniazid given daily (also known as isoniazid preventive therapy)**
- **6 months of levofloxacin for contacts of MDR/RR-TB, in people of all ages**

	PRODUCT DETAILS / CLINICAL USE	EMA/ NATIONALLY APPROVED	KEY ACCESS BARRIER(S)	REMARKS
Rifapentine 150mg tablet (P)	Sanofi innovator For TPT and new DS-TB regimen	NO/NO	Absence of registration in the EU	Orphan drug designation (2010) at the EMA. It is not possible to file the registration dossier as it's an old drug. USFDA approved since 1998 but no recognition by EMA. No WHO prequalified product available.
Rifapentine 150 mg dispersible tablet (P)	Generic product developed by Indian suppliers For TPT In children	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.
Rifapentine 300 mg tablet (P)	Generic product developed by Indian suppliers For TPT and for new DS-TB regimen	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified that could be combined with isoniazid registered in the EU
Rifampicin 150, 300 mg caps (R)	Sanofi innovator For DR-TB and TPT	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory	Existing production in the EU. Old medicines, registered in some individual EU countries before EMA was put in place in 1995. Existing medicine are WHO prequalified.
Isoniazid 300 / Rifapentine 300 / mg tablet (HP)	Generic product developed by Indian manufacturers FDC for adults for TPT and new DS-TB regimen	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified. FDC of isoniazid/rifapentine for children is not yet developed anywhere and so not available even at the global market. Existing medicines are WHO prequalified.

	PRODUCT DETAILS / CLINICAL USE	EMA/ NATIONALLY APPROVED	KEY ACCESS BARRIER(S)	REMARKS
Ethambutol 275/ Isoniazid 75/ Pyrazinamide 400/ Rifampicin 150 mg tablet (EHZR)	Generic product developed by Indian manufacturers FDC for adults for DS-TB	NO/NO	Valid registration in the EU uncertain and production stopped	Existing medicines are WHO prequalified.
Isoniazid 75/Rifampicin 150 mg tablet (HR)	Multiple manufacturers in EU countries FDC for adults for DS-TB	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory	Existing production in the EU. Old medicines, registered in some individual EU countries[36] before EMA was put in place in 1995. Existing medicines are WHO prequalified.
Isoniazid 50/ Pyrazinamide 150/ Rifampicin 75 mg dispersible tablet (HZR)	Generic product developed by Indian manufacturers FDC for children for DS-TB For DR-TB and TPT	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.
Isoniazid 50/ Rifampicin 75 mg dispersible tablet (HR)	Generic product developed by Indian manufacturers FDC for children for TPT and DS-TB	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.
Isoniazid 300 mg, 100 mg tablet (H)	Multiple EU manufacturers For TPT, DS-TB and for DR-TB	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory	Existing production in the EU. Old medicines, registered in some individual EU countries[37] before EMA was put in place in 1995. Existing medicines are WHO prequalified.

	PRODUCT DETAILS / CLINICAL USE	EMA/ NATIONALLY APPROVED	KEY ACCESS BARRIER(S)	REMARKS
Isoniazid 100, 50 mg dispersible tablet (H)	Generic product developed by Indian manufacturers For TPT, DS-TB and DR-TB in children.	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.
Ethambutol 400 mg tablet (E)	Multiple EU manufacturers For DS-TB and DR-TB in adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory	Old medicines, registered before the EMA was set up. (effective commercialisation to be verified) Existing medicines are WHO prequalified.
Ethambutol 100 mg dispersible tablet (E)	Generic product developed by Indian manufacturers For DS-TB and DR-TB in children	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.
Pyrazinamide 400, 500 mg tablet (Z)	Multiple EU manufacturers For DST and DRTB adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory	Old medicines, registered before the EMA was set up- put in place (effective commercialisation to be verified) Existing medicines are WHO prequalified.
Pyrazinamide 150 mg dispersible tablet (Z)	Generic product developed by Indian manufacturers For DS-TB and DR-TB children	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.

	PRODUCT DETAILS / CLINICAL USE	EMA/ NATIONALLY APPROVED	KEY ACCESS BARRIER(S)	REMARKS
Bedaquiline 100 mg tablet (B) **Bedaquiline 20 mg, tablet (B)**	For DR-TB in adults For DR-TB in children	YES (received full marketing approval in 2024)	High price in the EU	Orphan drug designation expired Marketing Holder: Janssen-Cilag International N.V. Existing WHO prequalified manufacturers for generic 100mg tablets (not for 20 mg) Secondary patents held by the innovator Johnson & Johnson / Janssen Cilag that could be a barrier in the EU for generic versions
Pretomanid 200 mg tablet (Pa)	For DR-TB in adults	YES (received full marketing approval in 2023)	High price in the EU Lack of commercialisation in certain EU countries	Orphan drug designation Marketing Holder - Mylan IRE Healthcare Limited Existing medicines are WHO prequalified. The license signed with Mylan and other generic companies by the innovator TB Alliance may limit competition in the EU between Mylan and other generic companies.
Delamanid 50 mg tablet (D) **Delamanid 25 mg dispersible tablet (D)**	For DR-TB in adults For DR-TB in children	YES (received conditional approval in 2014)	High price in the EU	Orphan drug designation Marketing Holder - Otsuka Novel Medicines GmbH Existing WHO prequalified manufacturers for generic 50 mg tablets (not for 25 mg) Secondary patents held by the innovator Otsuka could be a barrier in the EU for generic versions

	PRODUCT DETAILS / CLINICAL USE	EMA/ NATIONALLY APPROVED	KEY ACCESS BARRIER(S)	REMARKS
Linezolid 600 mg tablet (L)	Multiple EU manufacturers For DR-TB in adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory. High price in the EU	Existing production in the EU. Old medicines, registered in some individual EU countries[38] before EMA was put in place in 1995. Linezolid is off patent since 2014 but in HICs, even generic manufacturers have kept a high price. Used for many infections. It has no indication in TB therefore its price in HICs is not determined for use in TB and need for long duration of treatment compared to other infectious diseases.
Linezolid 150 mg dispersible tablets (L)	Generic product developed by Indian suppliers For DR-TB in children	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.
Levofloxacin 250, 500 mg tablet (Lfx)	Multiple EU manufacturers For DR-TB in adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory. High price in the EU	Existing production in the EU. Old medicines, registered in some individual EU countries[39] before EMA was put in place in 1995. Used for many infections. It has no indication in TB therefore its price in HICs is not determined for use in TB and need for longer duration of treatment compared to other infectious diseases
Levofloxacin 100 mg dispersible tablet (Lfx)	Generic product developed by Indian suppliers For DR-TB in children	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.
Clofazimine 50, 100 mg capsules (C)	For DR-TB in adults and children	NO/NO	Absence of registration for TB indication	Novartis is the license holder in France and Switzerland for leprosy indication. There is no commercialisation of clofazimine in the EU. Existing medicines are WHO prequalified(in tablets).

	PRODUCT DETAILS / CLINICAL USE	EMA/ NATIONALLY APPROVED	KEY ACCESS BARRIER(S)	REMARKS
Cycloserin 250 mg tablet (Cs)	Potential EU manufacturers in the past. For DRTB in adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory.	Existing medicines are WHO prequalified.
Cycloserin 125 mg dispersible tablet (Cs)	Generic product developed by Indian suppliers For DR-TB in children	NO/NO	Absence of registration in the EU	
Ethionamide 250 mg tablet (Et)	Potential EU manufacturers in the past. For DR-TB in adults	NO/?	Valid registration in the EU uncertain and production may have stopped.	Existing medicines are WHO prequalified.
Ethionamide 125 mg dispersible tablet (Et)	Generic product developed by Indian suppliers For DR-TB in children	NO/NO	Absence of registration in the EU	
Moxifloxacin 400 mg tablet (M)	Multiple EU manufacturers For DR-TB in adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory. High price in the EU	Existing production in the EU. Old medicines, registered in some individual EU countries[40] before EMA was put in place in 1995. Used for many infections. It has no indication in TB therefore its price in HICs is not for TB and long duration of treatment
Moxifloxacin 100 mg dispersible tablet (M)	Generic product developed by Indian suppliers For DR-TB in children	NO/NO	Absence of registration in the EU	Existing medicines are WHO prequalified.

	PRODUCT DETAILS / CLINICAL USE	EMA/ NATIONALLY APPROVED	KEY ACCESS BARRIER(S)	REMARKS
Imipenem 500 mg/ Cilastatine 500 mg powder for injection	Multiple EU manufacturers For DR-TB in adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory. High price in the EU	Existing production in the EU. Used for many kinds of bacterial infections mostly with a short treatment duration (e.g., 10 days). It has no indication in TB therefore its price in HICs is not determined for use in TB and need for longer duration of treatment compared to other infectious diseases.
Meropenem 1 gr, powder for injection	Multiple EU manufacturers For DR-TB in adults	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory. High price in the EU	Existing production in the EU. Used for many kinds of bacterial infections mostly with a short treatment duration (e.g., 10 days). It has no indication in TB therefore its price in HICs is not determined for use in TB and need for longer duration of treatment compared to other infectious diseases.
Amoxicilin 500 mg/ Clavulanate 125 mg, tablet	Multiple EU manufacturers For DR-TB in adults, in systematic use with Imipenem or Meropenem	NO/YES	National registrations in certain countries in the EU. Mutual recognition can be used for other countries where it is not registered - No real barrier in theory. High price in the EU	Existing production in the EU. Used for many kinds of bacterial infections mostly with a short treatment duration (e.g., 10 days). It has no indication in TB therefore its price in HICs is not determined for use in TB and need for longer duration of treatment compared to other infectious diseases.

For the detailed list of TB medicines that are WHO prequalified and/or registered in the EU, WHO prequalification program list[41] and European Medicines Agency Database[42] can be consulted.

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