Multi-drug resistant tuberculosis (MDR-TB):
A European cross-border health threat requiring a regional response

While TB rates have been steadily decreasing in the European region,¹ multi-drug resistant TB (MDR-TB) remains a major public health concern in several countries,² including in the European Union. MDR-TB is a form of TB that does not respond to the standard treatment of first-line drugs. It emerges as a result of poor adherence to accepted TB control practices, including inadequate treatment of tuberculosis, patients interrupting their treatment and drug stock-outs.

MDR-TB is much more costly and difficult to treat than TB. Currently, the treatment of MDR-TB takes up to 24 months with the use of second-line drugs, which cause major side effects, from vomiting and headaches to blindness, deafness, and psychological depression. The cost of these drugs is on average 50 to 200 times higher than the cost of drugs used to treat standard TB.³ The overall cost for MDR-TB care has been found to be 10 times higher than treating standard TB.⁴ Furthermore, treatment is not always effective. In the European region, the average success rate for MDR-TB patients in 2013 is as low as 48.5%, compared to 67.2% for new standard TB cases.⁵

Rates of MDR-TB in many countries of the European region are alarming. The World Health Organisation reported an estimated 74,000 cases of multi-drug resistant TB in the European Region in 2012, which accounts for almost a quarter of the global burden.⁶ Fifteen of the 27 MDR-TB high-burden countries worldwide are located in the WHO European region and include five EU Member States: Romania, Bulgaria, Estonia, Lithuania and Latvia. Eastern Europe and Central Asia (EECA) have the world’s highest rates of new TB patients with MDR-TB, with 20% of new cases having MDR-TB.⁷ This

¹ WHO European Region countries: Albania; Andorra; Armenia; Austria; Azerbaijan; Belarus; Belgium; Bosnia and Herzegovina; Bulgaria; Croatia; Cyprus; Czech Republic; Denmark; Estonia; Finland; France; Georgia; Germany; Greece; Hungary; Iceland; Ireland; Israel; Italy; Kazakhstan; Kyrgyzstan; Latvia; Lithuania; Luxembourg; Malta; Monaco; Montenegro; Netherlands; Norway; Poland; Portugal; Republic of Moldova; Romania; Russian Federation; San Marino; Serbia; Slovakia; Slovenia; Spain; Sweden; Switzerland; Tajikistan; The former Yugoslav Republic of Macedonia; Turkey; Turkmenistan; Ukraine; United Kingdom of Great Britain and Northern Ireland; Uzbekistan.
⁴ In the UK, for instance, treating standard TB costs in average 6.234 euro per patient, while the average cost of treating TB reaches 62.343 euro. Data from Costs of tuberculosis disease in the EU – a systematic analysis and cost calculation, Roland Diel, J Vandeputte, G de Vries, J Stillo, M Wanlin and A Nienhaus, European Respiratory Journal, 15 August 2013.
⁵ European Centre for Disease Prevention and Control/WHO Regional Office for Europe. Tuberculosis surveillance and monitoring in Europe 2013.
⁷ Ibidem.
signals that MDR-TB is not anymore only a degeneration of TB but has become a bacterial epidemic in itself.  

Governments in the EECA region often do not have the resources or the political will to adequately fight TB and are often largely dependent on external support to finance their TB programmes. The phasing out of international donors, such as the Global Fund to Fight AIDS, TB and Malaria and USAID from the European region means there is now an increased risk of MDR-TB spreading throughout the European Union on an even greater scale.

This paper aims to demonstrate that political efforts at the EU level are not only crucial in combating the spread of MDR-TB in the region but are also compatible with EU legislation. According to the Treaty on the Functioning of the European Union (TFEU), the main responsibility for health policy and provision of healthcare to European citizens lays with national governments, which are in charge of the management of health services and medical care and related allocation of resources. However, as recognised by the European Commission’s (EC) White Paper “Together for Health: A Strategic Approach for the EU 2008-2013”, there are areas where Member States cannot act effectively alone and where cooperative action at the community level is essential. Therefore the EC’s role is not to mirror or duplicate Member States’ work but to provide an added value to it, as would be the case with major health threats and issues with a cross-border or international impact, such as pandemics or issues relating to free movement of goods, services and people. All together, the EU institutions can drive the creation of a stronger regional engagement to fight the epidemic.

**Tuberculosis: a European cross-border health threat**

The rates of MDR-TB in the WHO Europe Region signal that MDR-TB has developed from being a degeneration of TB into a new bacterial epidemic that can be transmitted from an infected individual to a healthy one through the air with a simple cough or sneeze. In an increasingly globalised world and in an EU without internal boundaries, epidemics could easily spread from one country to another. In such a context, uncoordinated measures taken by individual Member States risk not only being ineffective but could also easily run counter to the fundamental principles of the EU.

The principle of subsidiarity as set out in art. 5 TEU suggests that, when the objectives of a policy action cannot be sufficiently achieved by Member States alone, the Union could intervene in an area of shared competence compatibly with the three following criteria:

- Does the action have transnational aspects that cannot be resolved by Member States?
- Would national action or an absence of action be contrary to the requirements of the Treaty?
- Does action at European level have clear advantages?

In the case at stake, we have seen that MDR-TB clearly has a transnational dimension and that member states alone have not yet managed to effectively control the spread of MDR TB across borders. Secondly, the failure to act of some member states could be considered a violation of the right of access to preventive health care and the right to benefit from medical treatment that is envisaged in art. 35 of the Charter of Fundamental Rights of the European Union. Finally, as we will explore in the

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10 Art. 35 of the Charter of Fundamental Rights of the European Union: Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.
rest of the paper, action at European level has tangible advantages considering the regional dimension of the problem.

In order to minimise the consequences of urgent cross-border health threats, such as MDR-TB, national public health measures need to be consistent with each other and a coordinated political response should be crafted at EU level. Accordingly, art. 168 (1) TFEU gives the EU the power to adopt actions to complement those of the member states with regard to combating serious cross-border threats to health, including but not limited to the promotion of research into their causes, their transmission and their prevention, as well as health information and education, monitoring and early warning.11

A coordinated European approach for TB care and control

People who move from one country to another, for work or other reasons, could carry with them not only potential diseases but also the need to be cured. However, accessing healthcare can be a special challenge for migrants. A recent study identified several issues that limit cross-border TB control and care,12 varying from the limited access to early TB diagnosis to the lack of continuity of care and information during migration and the availability of, and access to, health services in the new country. Moreover, the fear of discrimination and of deportation because of TB may result in hiding symptoms and delay in diagnosis, commencement of self-treatment or even the interruption or discontinuation of treatment, which can eventually lead to development of (multi)drug-resistant TB.13

At the same time, individuals affected with TB are increasingly moving from one country to another to access healthcare. There are a variety of reasons to explain this phenomenon, including the need to access treatments that are not available in the country of origin, better quality of treatment in a foreign country, lower cost of healthcare and/or long waiting times to access certain services in the country of origin. Medical tourism is also an important factor when it comes to MDR-TB. Romania, for instance, has one of the lowest rates of MDR-TB treatment success in the world: 20%.14 This is due to a number of different reasons, including that certain second-line drugs are not available in the country. A growing number of MDR-TB patients from the region, who cannot access MDR-TB treatment in their countries of origin, therefore search for treatment in other countries of the EU. This is also the case of several dozens of individuals affected with resistant forms of TB from Georgia who cannot be cured according to their country’s standards and are coming illegally to France to get treatment.15

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11 Art. 168(1) TFEU: Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and abating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.


From Romania to Italy: in search of MDR-TB treatment

“All of my problems started with tuberculosis. I can say that tuberculosis destroyed my family since my father became ill. He was sick in the hospital a lot; my mom was by herself with no money. My family struggled, got in a lot of debt, which in a few years, led to their not having a home. They were left on the street because of tuberculosis.” – Mariana, 30 years old, Bucharest.  

Mariana, first caught MDR-TB by caring for her dying father. Even though she was lucky enough to be included in a Global Fund cohort (guaranteeing her access to international standard of MDR-TB treatment), she could not deal with the demands of the treatment, crippling side-effects and her responsibilities as a mother and a worker. She grew so weak that her six-year-old had to help her get out of bed. In 2010, she had almost lost all hope. Knowing that to stay in Romania meant certain death, Mariana did something desperate: she took an extra dose of cough medicine, got on an airplane for the first time in her life, and sought treatment in an Italian hospital, where a friend had also been treated for MDR-TB.

By the time Mariana arrived in Italy, her MDR-TB had developed to Extensively-Drug Resistant TB (XDR-TB) and became virtually untreatable. Both of her lungs were severely damaged and she was resistant to nearly all of the standard first and second-line treatments, a consequence of interrupted and inadequate previous treatment. Today, Mariana is completely cured of XDR-TB. Sadly, her treatments over the past seven years have left her completely deaf making it difficult for her to work and to communicate with her loved ones.

One of the worst cases of XDR-TB Romania had been cured in Italy, but at great economic cost. Treating Mariana correctly in Romania early in her illness (even providing the social and economic support she desperately needed) would have been far cheaper than the heroic and costly treatment she received in Italy which ultimately saved her life. What’s more, Mariana’s daring journey from Bucharest to Italy exposed dozens of people to a highly resistant strain of TB placing their lives at risk.

Mariana’s story is far from unique. In Romania alone, there are hundreds of patients who lack access to lifesaving treatment. A small number seek care in other countries, others buy their second-line drugs out of pocket at pharmacies when state supplies are unavailable, and recently patients have begun buying medications for M/XDR-TB through online pharmacies and other questionable sources, and even bringing them by hand from places as far away as Spain and France.

While this case is the most striking because Romania is an EU member state, it should be noted that the EU borders with some of the highest MDR-TB burden countries in the world. Moldova, for example, where 40% of the employed population work in other countries, has less than 40% of M/XDR-TB cases on proper treatment due to a lack of funding. As long as there are such wide disparities between the quality of M/XDR-TB care in Europe, it is inevitable that some patients, knowing they cannot access proper treatment in their home countries, will seek treatment elsewhere.

Increased population mobility requires an effective and sustainable mechanism to coordinate interventions, ensuring quality TB prevention and care, including early diagnosis, uninterrupted

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17 In Romania, only about ¼ of M/XDR-TB patients access drugs provided by a Global Fund grant. All the rest are treated by the Romanian national health system with a much lower success rate.

18 According to *Costs of tuberculosis disease in the EU – a systematic analysis and cost calculation*, a fair esteem of the cost of treating a case of XDR-TB in Italy is 170,744 euro, including loss of productivity.
treatment and patient support across borders. On the basis of Art. 168 (2) TFEU, the EU should encourage cooperation between Member States and support their action to improve complementarity of their health services in order to address current gaps in providing TB and MDR-TB control and care across borders. The same article provides for the Commission to take any useful initiative to promote coordination among Member States, in particular initiatives aimed at the establishment of guidelines and indicators, the organisation of exchange of best practices, and the preparation of the necessary elements for periodic monitoring and evaluation.

Furthermore, TB not only causes devastating loss of life and immeasurable suffering but also bears a catastrophic cost for the people affected and their families. According to a study recently published, the direct cost of TB in the EU adds up to about €537 million per year. The cost of treating standard TB cases in the 18 wealthier EU countries is estimated at €7,848 per case, whereas the costs of treating MDR-TB cases and XDR-TB cases are estimated at €54,779 and €168,310 respectively. Figures on lost productivity are also dramatic: the study calculated that a TB patient represents a loss of €2,434 for the national economy. All costs combined, TB costs the European Union about €5.9 billion per year.

This situation is neither acceptable from a moral point of view nor economically bearable if the EU is set to become a smart, sustainable and inclusive economy that delivers high levels of employment, productivity and social cohesion. Good health is a key factor for economic growth and promoting a healthy life is crucial for overcoming the current crisis and entering into a new economy, as rightly stressed in the EC’s Communication Europe 2020.

RECOMMENDATIONS:

TB and MDR-TB epidemics know no administrative border, neither with the EU nor within its territory. The MDR-TB epidemic is already a sad reality in various countries of the European region, but the current situation could be made worse by the absence of international donor resources, the lack of domestic funding to fill this gap and more generally a lack of regional political leadership on the issue.

In order to control the spread of the epidemic, save lives and reduce the costs related to MDR-TB in the European region, the European Institutions and EU member states should:

➔ **Recognise that MDR-TB is a cross-border health threat, and that provisions of the Decision No 2119/98/EC and the EC’s Communication on Serious cross-border threats to health fully apply. In particular, the Health Security Committee, once established, should gather in order to coordinate member states’ responses to the MDR-TB epidemic.**

➔ **Create a high-level political task force on MDR-TB under EU leadership, gathering Ministers of Health of EU high burden countries and ideally Ministers of Health of Eastern Partnership countries to discuss the emergency and agree on common actions. A WHO Action Plan on MDR-TB is already available for technical assistance to countries, but political will is lacking. The EU can help generate this political will to address the epidemic before it is too late.**

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19. Art. 168 (2) TFEU: The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation.

Organise under the leadership of the European Commission a regional summit of the Ministers of Health and Ministers of Finance on domestic financing for TB, in coordination with the Stop TB Partnership and the Global Fund to Fight AIDS, TB and Malaria.

Currently, countries are handling the epidemic on their own with very mixed results and huge disparities in terms of success rates within the EU territory. A growing number of European citizens are forced to migrate to other EU countries to access MDR-TB treatments and drugs that are not available in their countries of origin. At the same time, lack of coordination between health systems is making it very hard to access diagnostics or to follow treatment for European citizens who are voluntarily moving from one EU country to the other to live and work.

We call on high burden EU member states to use funds aimed at reducing disparities among member states, such as the European Social Fund and the European Regional Development Fund, to reduce health inequalities that continue to exist within its territory with regard to the treatment of MDR-TB.

Through the provisions included in art. 168(2) TFEU, the European Commission should foster coordination among national health systems to favour access to MDR-TB diagnosis and treatment for migrants in order to encourage earlier diagnosis and therefore reduce the amount of permanent lung damage and additional infections associated with each patient. Moreover, continuum of TB care between countries should be done through a shared updated list of TB services and national focal points for effective and timely communication regarding transferred TB patients as recommended by the Minimum package for cross-border TB control and care in the WHO European region: a Wolfheze consensus statement.