



Recommendations of the TuBerculosis Vaccine Initiative (TBVI) for the European Commission call for evidence on: Antimicrobial resistance – Recommendation for greater action

Background:

Tuberculosis (TB) remains the deadliest infectious disease in the world, with the exception of COVID-19 in 2020 and 2021, killing 1.5 million each year (*WHO 2021*). Around 10 million people develop TB disease annually and 4,000 die of TB every day. The COVID-19 pandemic has reversed recent advances to combat the TB pandemic estimated to lead to an additional 6.3 million people falling ill with TB and 1.4 million TB deaths over the next five years (*Stop TB Partnership 2021*). Since TB is an airborne disease, it is spread through the air by coughing, sneezing, and even singing.

Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) are both on the rise. MDR-TB entails resistance to at least two of the most effective TB drugs, isoniazid and rifampicin. XDR-TB includes additional resistance to any fluoroquinolone, and to any of the second-line injectable TB drugs (amikacin, capreomycin and kanamycin). Treatments can have exceptionally harsh side effects and need to be taken from six months to two years or more. In European Union/European Economic Area countries, the average treatment success rate is just 47% for MDR-TB, and 28% for XDR-TB. (*ECDC 2020*) Costs of treatment for MDR-TB and XDR-TB are much higher than costs of treatment for drug-susceptible TB.

Drug-resistant tuberculosis is the leading contributor to deaths from AMR, accounting for one fourth of all AMR-related deaths.

Globally MDR-TB could cause 2.59 million deaths each year by 2050 and cost the global economy as much as US\$ 16.7 trillion. (*O'Neil 2016*)

The role of TB vaccines in reducing AMR:

Vaccines are one of the main pillars in the strategy to reduce dependence on antimicrobials (*O'Neill 2016*). The existing TB vaccine (BCG), more than 100 years old, given to newborns, does not adequately protect adolescents and adults, who are most at risk for developing and spreading TB. To interrupt transmission, new and more effective vaccines that also target adolescents and adults are therefore urgently needed.

New, safe and effective TB vaccines are an essential component of the global strategy to address the deadly threat of antimicrobial resistance.

New TB vaccines will be effective in preventing drug-resistant and drug-susceptible TB, reduce the need for lengthy or ineffective treatment. They would reduce the need for antibiotics, which in turn would help curb the rise of antimicrobial resistance.

The TB vaccine field has recently seen exciting scientific breakthroughs, with candidates generating positive results in clinical trials. It is therefore necessary to invest in all phases of TB vaccine research and development.

We strongly recommend that existing and new financing mechanisms at national, European and global level should foresee substantial resources which can be allocated to critical TB vaccine research and development.



About TBVI: The TuBerculosis Vaccine Initiative (TBVI) is a nonprofit Research and Innovation partnership that enables the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people. TBVI has been supporting more than 50 R&D partners to innovate and diversify the pipeline for TB vaccines. It accelerates the most promising vaccine and biomarker candidates through the pipeline, applying portfolio management to support decision-making in an objective and transparent manner and using the available financial resources effectively.