

Dear Honourable Ministers,

It is our honour to write to you on behalf of the TB Vaccines Advocacy Roadmap, an international advocacy coalition of tuberculosis (TB) survivors, researchers, affected communities, and civil society organisations working to accelerate the development of new, effective, and globally accessible TB vaccines. With this note, we urge you to uphold your global commitments to end TB by 2030 by placing TB vaccines at the forefront of the EU, G20, and G7 agendas on global health research, pandemic preparedness, and antimicrobial resistance (AMR).

The disruptions caused by COVID-19 have, for the first time in over a decade, reversed progress in TB control; 1.5 million people died from TB, including 214,000 people living with HIV, for whom TB remains the leading cause of death, and almost 10 million people fell ill with TB disease in 2020. Amid already constrained financial support for essential TB services, our hard-won gains of the last thirty years risk unravelling further without immediate action.

COVID-19 has shown us the impact that a deadly respiratory disease can have on people's lives, their families, and society at large. We cannot allow the COVID-19 health crisis to further divert our attention away from the urgent need to address TB. Therefore, we call upon you to increase and sustain European investments for TB research, both at the central and member state levels, through robust resourcing mechanisms by at least \leq 320 million annually, with \leq 90 million dedicated for vaccine development. This would not only help to ensure a fully resourced TB vaccine pipeline by 2023 but make it possible for new TB vaccines to be available as early as 2025.

It was in Europe that the only approved TB vaccine to date, the Bacille Calmette-Guérin (BCG) vaccine, was developed—over 100 years ago. While this ground-breaking innovation provides some important protection against the most severe forms of TB in infants and young children, it is ineffective in adolescents and adults, who are most at risk for developing and spreading the disease. New TB vaccines are urgently needed to ensure the End of TB.

However, TB research continues to be chronically impeded by an annual shortfall of nearly €1 billion, and funding for TB vaccines has never exceeded more than €107 million per year. The EU gives less than 40% of its Fair Share of TB research funding needs¹, and only one MS, Ireland, reaches over 50% of its Fair Share². Collectively, less than 16% of all investments from the EU and MS is dedicated to vaccine research. At the 2018 United Nations High-Level Meeting to End TB, European leaders pledged their support to increase global investments to €1.7 billion annually for TB research, of which €488 million was earmarked for development of new TB vaccines. Substantially more funding is needed to mitigate the cumulative annual shortfalls and additional impact of COVID-19 to ensure that TB research is sustainably funded.

As part of the EU's Horizon 2020 Programme, mechanisms like the European & Developing Countries Clinical Trials Partnership (EDCTP) have meaningfully contributed to advances in TB vaccine research. European researchers have developed dozens of promising candidate TB vaccines in clinical and preclinical studies, with three of these currently undergoing late-stage trials supported by the EDCTP. These mechanisms demonstrate an important commitment to TB as part of the European health agenda and must be further strengthened. Today, new TB vaccines are within reach and while the inclusion of poverty-related and neglected diseases in the new Horizon Europe Programme is promising, we need to ensure that TB vaccine R&D receives the sustained and proportionate funding that it desperately needs. Otherwise, their development will be further delayed, and the world is likely to lose up to 20 years of progress. Without new TB vaccines, the needless suffering will continue, and the increasing threat of drug-resistant TB will grow.



This is particularly relevant in Europe where TB is affecting already discriminated populations in EU Member States (MS), as well as vulnerable populations of many of our close neighbours and economic partners. Growing numbers of people affected by TB in Europe are suffering from drug-resistant TB, for which existing treatments often prove ineffective. More than two thirds of the 500,000 people estimated to fall sick with drug-resistant TB each year go undiagnosed. Also, treatment adherence is a huge challenge, with available treatments taking months or years, and with many debilitating side effects Together this accelerates the global public health and security threat of AMR. New TB vaccines will be effective in preventing drug-resistant and drug-susceptible TB, reduce the need for lengthy or ineffective treatment, and offer vital protection to adolescents and adults to stop further transmission.

Europe is home to unparalleled research excellence and some of the brightest minds in TB innovation in the world. European science and innovation have been critical to the success of the unprecedented and rapid development of multiple COVID-19 vaccines in the last two years. This unified and dedicated response gives us hope that if TB vaccine research receives the needed attention and investment by the EU and MS, then the next lifesaving, preventive TB vaccine will no longer be a thing of dreams.

We do hope that you as our leaders truly appreciate how new and effective TB vaccines can prevent the needless suffering and catastrophic social and economic losses that burden people living with TB, their families and communities, and countries around the world. We, the European community of TB survivors and advocates, stand in solidarity with the millions of others affected by this disease and urge you to fulfil your funding and political commitments to deliver new TB vaccines.

Yours faithfully,

The TB Vaccine Advocacy Roadmap, On behalf of the undersigned

[1] Fair Share Targets are set in relation to the United Nations High-Level Meeting commitment to invest €1.7 billion in TB research each year. The targets ask that each government invest 0.1% of its annual gross domestic expenditure (GERD) in research and development to TB research. The Fair Share Target for the EU is set against 0.1% of the total EU budget rather than the GERD. MS Fair Shares achieved are calculated as the total of national level investments plus the proportional investments of each MS to EU-level TB R&D using the MS proportional contribution to the EU.

[2] Fair Shares achieved for contributing MS for 2020: Denmark 16,44%; Finland 21,85%; France 30,33%; Germany 26,41%; Ireland 53,15%; Netherlands 30,41%; Spain 39,84%; Sweden 23,79%.

[3] The following vaccine candidates in late stage trials are being developed by European institutions and with European funding mechanisms: MTBVAC is being developed in Spain and is embarking on Phase III trials; VPM1002 is being developed in Germany is also undergoing Phase III trials; and H56:IC31 is being developed in Denmark and has progressed to Phase IIb trials. Many other candidates developed in Europe are in early clinical or preclinical development.



This open letter is endorsed by the following 91 organizations

















































































































(Results Australia &

Results Canada)



(Results UK)

















































Arc en Ciel, Niger

Alliance Burundaise pour la lutte contre la Tuberculose et la Lèpre (ABTL), Burundi

Association des Anciens Patients Tuberculeux du Bénin (ASSAP-TB), Bénin

Association pour le Bien-être des Personnes Infectées et Affectées par le VIH/Sida (ABPIAS), Burkina Faso

Association Mauritanienne de Lutte Contre la Tuberculose et le SIDA (AMALUTS), Mauritius

Association Yientodima de Piéla, Burkina Faso

<u>Association Wendkouni du Namentenga</u>, Burkina Faso

Conseil burkinabè des organisations de développement communautaire (BURCASO), Burkina Faso

ONG Stop Tuberculose Bouaké, Côte d'Ivoire

<u>Plateforme des ONG et Associations de lutte contre le Paludisme, République du Congo</u>

Réseau Association des Femmes Samaritaines, Madagascar

This open letter is endorsed by TB Survivors of the EU States



The family of Sumaya Aguilar Mármol Belgium



Rhea Lobo Denmark



Mauro Guarinieri France



Anna Sutyagina Germany



Frederica Poli Italy



Frouke Procee
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Enrique Delgado Spain

This open letter is endorsed by the following members of the global TB community

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- Amrita Limbu, Touched by TB, India
- Ani Hernasari, Rekat Peduli Indonesia Foundation
- Augustin Dokla, RAS+TOGO, Togo
- · Austin Obiefuna, Afro Global Alliance, Ghana
- Ben Ahmed lamine Bamba, ONG Fraternité, Côte d'Ivoire
- Bertrand Kampoer, DRAF TB, Cameroon
- Cheleka Mpande, Eh!woza, South Africa
- Clotaire Rodonne Siribi, Groupe d'Action de Paix et de Formation pour la Transformation (GAPAFOT), Central African Republic
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