Briefing from the workshop on tuberculosis financing

Washington DC

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To: Giving Pledge Donors, CEOs, Celebrities, Finance Ministers, Middle East Countries (Saudi Arabia), Emerging Markets – BRICS, Amazon

RE: Geneva World Bank Meeting, Japan G20 (June), African Countries (July), Commonwealth – Alan Donnelly, Francophonie – Alan Donnelly, African Union – Elizabeth Ivanovich, IMF – Finance Ministers on Sustainable Development – Jeff Sachs, Vatican – Finance Ministers – Jeff Sachs, Health Minister Meeting (ahead of Heads of States) – Willo Brock, Global Health Security Agenda – Wilmot James, US Congress – Wilmot James

What is TB

Tuberculosis (TB), an airborne infection, is the world's top killer among infectious diseases, above HIV or malaria, and is currently among the top 10 most common causes of death, accounting for 1.6 million deaths annually. It is the leading cause of death among people diagnosed with HIV. Today, nearly 2 billion people carry the latent infection, 10 million around the world develop active disease each year, and of those, 1 million are children. While TB is mostly curable with a specific drug regimen of antibiotics, treatment can take six to nine months.

Misuse of these antibiotics, due to inadequate health systems and/or poor adherence has led to drug resistance. Each year over half a million individuals develop the multi-drug-resistant form of TB, MDR-TB, which is defined as resistance to the two most potent TB antibiotics. Out of the 500 thousand new cases of MDR-TB appearing every year only 150 thousand of them receive appropriate treatment. Out of the 10 million people developing active TB disease each year, only 6.4 million are being diagnosed and treated. The remaining, undiagnosed, 3.6 million can contribute to the cycle of transmission and mortality. Current resources and funding permit only 52% of individuals to be diagnosed and treated successfully. In the case of MDR-TB, only 1 in 7 are diagnosed and treated successfully.

2018 marked a turning point in TB history. For the first time since its creation, the UN had a high-level meeting (HLM) focused on the TB global crisis. Resulting from the meeting, participating countries committed to a set of 10 key targets for 2022: increase detection, improve treatment, reduce stigma, shorten funding gaps, among others. Resolving the funding gap for countries around the globe, especially in Africa and Southeast Asia where the burden of TB is the greatest, will have a ripple effect on every other target. It will also greatly assist in reaching the goal of Universal Health Coverage (UHC), the focus of the UN HLM in September 2019. With appropriate funding, the SDG goal of ending the TB epidemic can be achieved and eventually TB can be eliminated.

Current Funding Deficits

Despite the anticipation leading up to the UN high-level meeting, more effective actions need to be taken to effectively identify and reduce funding gaps. TB continues to be concerningly underfunded (for example, for current treatment of patients, health systems supporting patients, health awareness, data of current epidemiology, and R&D for new treatments and diagnostics). StopTB Partnership has calculated that at least 65 billion USD (an average of \$13 billion per year, starting 2018) are required to meet targets by 2022. Current funding reaches roughly half that need, approximately \$7 billion annually. Additional funding sources are urgently needed as deficits accumulate year after year, increasing the risk of not meeting the set targets.

External funding for TB accounts for 20% worldwide, however, low-income nations disproportionately rely on external funding sources for procurement of current treatments and support for health systems delivering care. A number of low-income countries are dependent on external support that represents on average 90% of their TB budget.

In addition to the 13 billion USD per annum resource need for implementing TB services, another 2 billion USD per annum is needed for research and development (R&D) of new treatments, diagnostics and vaccines. Currently available funding for R&D is \$770 thousand, which leaves behind a gap of 1.3 million USD per annum.

Why Invest in TB

TB represents an existential threat in society. In a global world, where TB is a disease easily treated and prevented, should we allow millions to die? Currently, where you are born decides your living conditions and quality of your health system, increasing your risk for becoming infected with TB. Patients in high burden countries are often not diagnosed on their first visit to a clinic and receive low-cost, poor-quality drugs, reducing their chance for being cured.

TB represents a unique opportunity to elimination one of the world's deadliest diseases because it is both treatable and preventable. In developed nations, through improvements of public health and infrastructure, the rates of TB are low and elimination is possible. To meet the goal of ending TB worldwide, the World Health Organization has proposed an End TB Strategy. The UN HLM Political Declaration has set out treatment targets for 2022. Between 2018 to 2022 40 million people with TB need to be treated, including 3.5 million children and 1.5 million with MDR-TB. This means raising treatment coverage to above 90% globally for TB and MDR-TB in adults and children. Since TB most often affects people at ages that most contribute to the workforce, and therefore the economy, investing in TB also contributes to preserve a country's national economy. TB represents economic issues globally. Epidemics of infectious diseases can cause billions of dollars in economic impact further fracturing over-leveraged nations. It is estimated the current rate of TB accounts for \$12 billion a year loss from the global economy due to wage-earners production decrease and the income loss of those prematurely dying due to TB. The burden of diseases like TB has held down the economy of nations, specifically in South America, Africa, and Southeast Asia. The economic fragility of these nations has led to unstable governments and terrorist activity.

Common belief is that TB is not a threat for developed nations that have controlled the disease through effective antibiotics and vaccinations. However, as antibiotic resistances continue to expand globally, vaccination rates begin to decline and air travel becomes more affordable and wide-reaching, the global health risk continues to grow. We have seen with other infectious diseases how transmission is able to occur farther and faster than ever before. MDR-TB raises the greatest threat to global security given the difficulty to treat it with current drugs available.

Lack of funding for TB has caused a reliance on antiquated science (and resulting treatment strategies) from the 1800s. A relatively small financial investment could allow for leaps and bounds in TB treatment and prevention with better access to currently available tools and advancements in R&D for better tools in future. For the first time in 40 years, there are new

treatments and vaccines in the pipeline; 20 drugs in trials and 11 new compounds, new diagnostics and new vaccines. However, they will need funding for completing the research and gathering evidence, including phase III trials and support for implementation.

As Drug-resistant TB accounts for a third of all global antimicrobial resistance (AMR) related deaths each year, addressing the issue of MDR-TB would have a compounding effect on AMR diseases. This could be a turning point not just for TB, but also non-communicable diseases that greatly affect the developing world. That is because investments in diseases like TB put in place the infrastructure and capacities of systems to improve overall public health and preparedness for any future epidemics. It also contributes to reaching the goal of UHC. Fully financing TB has a return on investment of potentially \$344 trillion to the global economy. The benefit for every dollar spent is four times that of other deadly infectious diseases at \$43.

Scientific Needs

Advancement of science is needed in all three categories of tools for fighting TB; (1) better vaccines need to be introduced and made readily available to the highest burdened areas, (2) new combinations of drugs need to be created and tested that can not only treat non-resistant TB, but MDR-TB as well, and (3) easy-to-use, efficient diagnostic tools need to be created to help identify MDR-TB patients sooner in the course of treatment.

Although treatment for TB can be highly effective and the medication is often free for patients, the six-month timeline required for TB treatment drastically alters the financial stability of those infected and their families, due to loss of income and out-of pocket costs. The average out-of-pocket patient treatment cost, related to daily transport to the clinic for treatment or lost wages, can equal up to \$650, or 30% of a patient's annual income. Funding for treatments should be specifically focused on drug regimens that would drastically reduce the amount of time patients would be without income. With MDR-TB representing the largest obstacle in treatment, new drugs need to be produced that can treat these forms of the disease at highly effective rates. Additionally, new medicines need to be tested in a pan-TB drug regimen during phase III trials to increase efficacy and bring best-practices to patients faster.

Service Needs

The Stop TB partnership's Global Drug Facility (GDF) is the largest global procurer and provider of quality assured TB medicines, diagnostics, and laboratory supplies. Any country can buy drugs and diagnostics from GDF. Many middle-income nations, using their domestic budgets, purchase directly through local procurement mechanisms, causing them to pay higher price and sometimes lower standards, increasing their risk of shortages and decreased treatment outcomes for patients. These nations should be able to change national procurement laws and purchase quality assured products through the GDF at a lower price.

High-income countries that help to lead organizations like the Commonwealth or South-South Cooperation, should take a leadership role in controlling TB. These entities could help

nations cooperate to purchase vaccinations and drugs through a pooled procurement mechanism like GDF.

External Funding Needs

External funding for TB accounts for about 20% of the available funding. The remaining comes mostly from domestic budgets of countries affected by TB. External funding for TB care and prevention comes mainly from the The Global Fund, a partnership organization that brings together governments, civil society, and the private sector to support programs run by local experts in countries and communities aimed to end AIDS, TB, and malaria. The Global Fund needs to be funded at the full amount estimated to end the three diseases. The Global Fund has its replenishment in 2018 with an ask of 14 billion USD for the next 3 years for all the three diseases. Besides a fully replenished Global Fund, domestic budgets in high TB burden countries need to go up substantially, and to close the funding gap, additional funding techniques will need to be implemented. There is also a need to finance national networks of civil society advocates to hold governments accountable for keeping promises made at the UNHLM on TB

Public/Private Partnerships for delivery of current TB Treatment

Matching gifts through private entities and the Global Fund could incentivize countries to prioritize TB funding on a national level. All private donors and governments should make contributions through the Global Fund to ensure the best allocation of funds and guarantee efficient priorities. Currently Global Fund allocates only 18% of its resources to TB and in future this proportion must grow.

R&D Funding for Future Treatment, Diagnostics and Vaccines

R&D funding should focus on companies working on TB specific diagnostics, medicines and vaccines. Through Impact Investing, private funding could support initiatives that would otherwise not generate capital. Even large pharmaceutical companies will need partnership and risk sharing and cannot/ will not invest in phase III trials alone, opening a funding opportunity for donors that have a higher risk appetite than early science research. Buyout opportunities for small companies creating new technology could help to eliminate risk and encourage companies to move into the TB market.

Bringing together investors, service providers, and outcome funders could drastically change the landscape for TB through Blended Finance such as Social Impact Bonds. Funding based on social targets would allow for generating capital, but also apply pressure and incentive for achieving goals.

Billions of dollars could be raised with a micro-levy specific to TB. Levies used by organizations have successfully and sustainably raised almost \$3 billion annually for infectious diseases. Advances in technology, such as online shopping, creates an opportunity to generate funds through small taxes on consumers.

Federal Governments

Globally, the federal governments must take responsibility in all areas including health delivery to their citizens, health systems strengthening, funding for new R&D, and investment in

future health systems to be ready for new innovations. In countries where TB has a large incidence rate, the federal government could offer tax breaks to companies who provide TB vaccinations or treatment to their employees or for those who invest in TB specific philanthropy. Countries burdened by the disease should be encouraged to create a line item under their health budget specifically for TB. But they should be offered budget management support by the international community, especially in cases of young nations or nations who have just moved from a low-income to middle-income status. Civil Society and community leaders in this country should hold government accountable for investing in TB and allocating the funds effectively. All nations, whether heavily burdened or not, should allocate at least 0.1% of their R&D budget to TB.

Changing the outlook for the world's deadliest infectious disease will not be possible without a global effort and true partnership. Countries devastated by its effects need to be supported both financially and administratively. Scientists and engineers need to be drawn to the field of TB by its financial incentives in addition to its social benefits. Creating a sustainable, multilateral effort to fund TB medicines, diagnostics, and service delivery will be the answer to eliminating the disease.