To: Dr. Tedros Adhanom Ghebreyesus, Director-General, World Health Organization

Cc: Dr. Soumya Swaminathan, Chief Scientist, World Health Organization
Dr. Tereza Kasaeva, Director, Global Tuberculosis Program, World Health Organization
Ms. Susan Norris, Guideline Review Committee Secretariat, World Health Organization
Mr. Nathan Ford, Guideline Review Committee Chair, World Health Organization
Mr. Andreas Mlitzke, Director, Office of Compliance, Risk Management and Ethics, World Health Organization
Dr. Lucica Ditiu, Executive Director, Stop TB Partnership
Ms. Cheri Vincent, Chief, Infectious Diseases Division, U.S. Agency for International Development
Mr. Lelio Marmora, Executive Director, Unitaid
Mr. Peter Sands, Executive Director, the Global Fund
Members of the WHO Civil Society Task Force

Open Letter: Crisis of Confidence in the World Health Organization's Ability to Issue Recommendations for the Treatment of Rifampicin-Resistant and Multidrug-Resistant Tuberculosis (RR-/MDR-TB)

June 5, 2019

Dear Dr. Tedros:

We are writing to follow up the letter[1] sent on April 23, 2019 in which we raised multiple serious concerns about the World Health Organization (WHO) guidelines for the treatment of rifampicin-resistant and multidrug-resistant tuberculosis (RR-/MDR-TB).[2] We acknowledge your response[3] and participated in the webinar held May 22, however, the specific technical issues we raised remain unaddressed. There is a growing crisis of confidence in the WHO's ability to produce normative guidance for the treatment of RR/MDR-TB. This crisis is especially urgent as we expect data to more regularly emerge from programs and clinical trials nearing completion.

During the webinar on May 22, additional concerns were raised by other organizations and we heard worrisome reports regarding how the new consolidated guidelines are being interpreted and implemented. The regional Green Light Committee (rGLC) representatives reported that many countries in the AFRO and SEARO regions are still using capreomycin and kanamycin—drugs associated with worse outcomes and increased mortality in the case of capreomycin. We also heard reports that many countries consider replacing kanamycin with amikacin in the shorter regimen a successful "transition" to the new WHO recommendations for the treatment of RR-/MDR-TB, and that few countries are implementing all-oral short-course regimens under operational research conditions. During the webinar, representatives from the Global Drug Facility (GDF) reported that many countries are not planning for bedaquiline supply beyond June 2020, when stocks from the donation program are expected to run out, and that only 11 countries have requested medications consistent with a more complete adoption of the all-oral regimens recommended as the preferred standard of care by the new WHO guidelines for RR-/MDR-TB (with 21 more expected by quarter 4 of 2019). It is apparent that countries are not prioritizing the implementation of all-oral regimens as intended by the new WHO guidelines for RR-/MDR-TB. These updates are alarming, with clear negative implications for people and communities affected by RR-/MDR-TB, namely the continued unnecessary subjugation of patients to sub-optimal treatment regimens that result in poor treatment outcomes and considerable toxicities, including permanent hearing loss

The undersigned organizations request an urgent in-person meeting with you and the newly appointed Chief Scientific Officer, Dr. Swaminathan. During this meeting, we would like to discuss concrete actions that can be taken to address: (1) the technical and guideline development process-related issues we have raised; (2) apparent

[1] http://www.tbonline.info/media/uploads/documents/final_who_open_letter_drtb_tx_guidelines_4.23.19.pdf.
[2] https://www.who.int/tb/publications/2019/consolidated-guidelines-drug-resistant-TB-treatment/en/.
[3] http://www.tbonline.info/media/uploads/documents/who_dg_response_letter_to_open_letter.pdf.

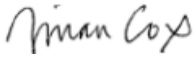
technical assistance and other support deficiencies; and (3) strategies to mitigate the continued subjugation of people with RR-/MDR-TB to unnecessary harms resulting from the lack of clarity in the current WHO guidelines for the treatment of RR-/MDR-TB.

This is an urgent request and our group looks to you to respond accordingly.

Sincerely,

Joanne Liu, MD., International President, Médecins sans Frontières

Mark Harrington, Executive Director, Treatment Action Group

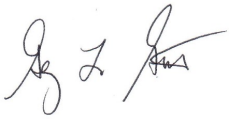


Vivian Cox, MD., MPH, Chair, Drug-Resistant TB Scale-Up Treatment Action Team

Mercedes Becerra, ScD, Director, Sentinel Project on Pediatric Drug-Resistant Tuberculosis

Patrick Agbassi, Co-Chair, Global Tuberculosis Community Advisory Board

Carolina Moran Jara, Co-Chair, Global Tuberculosis Community Advisory Board



Gary L. Gottlieb, MD, MBA, Chief Executive Officer, Partners In Health