To: Dr. Tereza Kasaeva, Global TB Program Director
Cc: Dr. Tedros Adhanom Ghebreyesus, Director-General
Dr. Soumya Swaminathan, Deputy Director-General
Dr. Gottfried Hirnschall, Global HIV and Hepatitis Program Director
World Health Organization
Avenue Appia 20
CH-1211 Geneva 27, Switzerland

8 May 2018

Open Letter RE: Urgent reforms required for World Health Organization guidelines for the diagnosis and treatment of tuberculosis

Dear Dr. Kasaeva,

We write to you as advocates, implementers, clinicians, members and representatives of affected communities, and members of civil society, to thank you for prioritizing meaningful engagement and partnership with communities, and to share our concerns regarding what we consider to be a crisis in normative guidance for the diagnosis and treatment of tuberculosis (TB).

During this pivotal moment in the global fight against TB, a transparent and consistent normative guidance setting process with regular feedback mechanisms is urgently needed to remedy the current situation where country programs, implementing partners, and donors have differing interpretations of existing guidance, resulting in unnecessary suffering and death from TB.

Given that the World Health Organization's (WHO) core function is to set normative guidance, we call on you as leaders of the WHO and the Global TB Program, to ensure the rapid development of clear, consolidated guidelines for the diagnosis and treatment of TB, and to commit to reforming the processes through which TB guidelines are developed in accordance with the following recommendations:

(a) The fragmented approach to issuing guidance

Within the WHO Global TB Program, interventions are looked at in isolation rather than in the context of how care is delivered, as part of an interlinked system. As a result, guidance is fragmented across multiple documents and issued in a variety of forms from traditional guidelines documents, including meeting reports, best practice statements, and position statements. WHO guidance on the treatment of drug-resistant TB is currently split across eight documents. The differences between these forms of guidance and how each should be weighed and interpreted by country TB programs, donors, and implementing partners is unclear and generates confusion.

To remedy the current untenable situation where WHO recommendations are fragmented across documents; and to advance our collective goal to establish clear, consolidated, and consistent guidelines that better serve the needs of TB programs,

providers, and patients, and better respond to emerging evidence, we recommend the WHO establish a living document for all guidelines relating to TB that can be updated every 6 months and independently evaluated by end-user surveys on a similarly regular basis.

(b) The Guideline Development Group (GDG) selection process

The process through which the WHO selects members to serve on GDGs is unclear. GDGs are responsible for formulating recommendations based on available evidence and experience, yet the WHO's conflict of interest policy often rules out experts best placed to provide input into a drug's value and optimal role. The conflict of interest policy also provides convenient cover for the WHO to unfairly exclude certain experts in the field and to invite people with little expertise or who are superficially engaged in the process to serve on GDGs instead. The lack of involvement from the affected patient side is especially poignant.

The WHO's policies for selecting GDG members often result in wildly disparate treatment of evidence of the same quality. Based on the same data, a more progressive GDG might recommend a regimen or intervention with low quality evidence, while a more conservative GDG might reject it entirely or drastically weaken the strength of the recommendation.

We recommend that the WHO establish a transparent process for GDG member selection that ensures inclusion of people with experience in addressing various types of TB in diverse populations, and survivors of different kinds of TB. WHO should place more emphasis on providing meaningful disclosures than on excluding people who are well qualified to inform how data should be analyzed and interpret relevant findings, especially as certain conflicts of interest identified by WHO may be perceived differently by end-users of the guidelines.

For consistency, and to improve the WHO's ability to rapidly respond to emerging data, the same GDGs should be maintained for a fixed term and convened whenever new evidence is available in their field of expertise, whether that be diagnosis, prevention or treatment. We also recommend the selection of civil society representation to the GDG be left up to civil society to determine.

(c) The PICO question selection process

The WHO develops PICO questions with little room for negotiation or input by other stakeholders. Yet, PICO questions should be informed by what TB programs and providers need to know. The way a PICO question is phrased and its relevance to clinical care is crucial in that it influences how evidence is evaluated, the strength of the resulting recommendation(s), and how guidance is ultimately interpreted and implemented.

In line with reforming the process through which GDGs are selected, we recommend the WHO establish a transparent process for developing PICO questions and soliciting input from the public, and that questions be formulated taking into

account available evidence to maximize the possibility of producing strong recommendations.

(d) Undue consideration of cost

WHO recommendations should be based on the efficacy, safety, and public health and clinical merits of the product or intervention under review. The WHO or the GDG's perception of the affordability of an intervention, for example a new drug's cost, must not preclude a strong recommendation if the safety and efficacy data support broad use. Instead, if there are concerns about cost and feasibility, WHO and partners should work to identify solutions, and keep in mind that cost reductions are highly unlikely in the absence of guidance to support broad uptake that can lead to the increased demand and volumes, and competition that can bring prices down.

We strongly urge the WHO to implement these suggested changes as its plans to consolidate its guidance for treating drug-resistant TB (DR-TB) move forward.

Before 23 May 2018, we look forward to a response detailing how the WHO plans to address each of the concerns raised in this correspondence. Please direct your reply to Lindsay McKenna at Lindsay.McKenna@treatmentactiongroup.org.

Finally, we would like to remind the WHO that a prior correspondence regarding the urgent need for WHO to address the unjustified subjection of MDR-TB patients to the risk of, and the actual, severe side effects associated with the injectable agents, endorsed by 39 organizations, remains unanswered.

Respectfully submitted,
On behalf of the undersigned organizations and individuals

Organizations

Advance Access and Delivery, USA
AIDS and Rights Alliance for Southern Africa (ARASA), Southern and East Africa
Drug Resistant TB Scale Up Treatment Action Team (DR-TB STAT), USA
Fundacion Damian, Guatemala
Global Coalition of TB Activists (GCTA), Global
Global TB Community Advisory Board (TB CAB), Global
Harvard Medical School Center for Global Health Delivery– Dubai, North America and the Middle East
Health and Development Alliance (HEAD), Cambodia
International Treatment Preparedness Coalition (ITPC), Eastern Europe and Central Asia
Kenya AIDS NGOs Consortium (KANCO), Kenya
KHANA, Cambodia
NEPHAK, Kenya
Noncommercial Partnership Medical Social Programs, Moldova
Pamoja TB Group, Kenya
Parceria Brasileira Contra a Tuberculose, Brazil
Partners In Health, USA

Peruvian Group of Respiratory Health (GRUPSAR), Peru
TB Proof, South Africa
The Sentinel Project on Pediatric Drug-Resistant Tuberculosis, USA
Treatment Action Group (TAG), USA

Individuals
Alberto Colorado, Americas TB Coalition, USA
Ana Millones, Socios En Salud (SES), Peru
Arne von Delft, TB Proof & University of Cape Town School of Public Health and Family Medicine, South Africa
Arlette Bekker, Tygerberg Hospital, South Africa
Carolina Moran Jara, Socios En Salud (SES), Peru
Carole Mitnick, Harvard Medical School & Partners in Health, USA
Chris Dell, TB people, United Kingdom
Cynthia Lee, Community Research Advisors Group (CRAG), USA
Edwardo Patac, TB People, Philippines
Esther Sonamzi, TB Proof, South Africa
Eva Limachi Salgueiro, Bolivia
Francisco Olivares Antezana, Periodista, Chile
Helene-Mari van der Westhuizen, TB Proof, South Africa
Ingrid Schoeman, TB Proof, South Africa
Jared J. Eddy, Boston Medical Center, USA
Jennifer Furin, Harvard Medical School, USA
Karen Kuria, Stop TB Partnership Kenya, Kenya
Khairunisa Suleiman, Global TB Community Advisory Board (TB CAB)
Marcia de Avila Berni Leão, Fórum Ong aids RS, Brazil
Marcia Leão, Parceria Brasileira Contra Tuberculose, Brazil
Marion Heap, University of Cape Town, South Africa
Mark Harrington, Treatment Action Group (TAG), USA
Mercedes Becerra, Harvard Medical School, USA
Michael L. Rich, Partners In Health (PIH), USA
Michael Wilson, Advance Access & Delivery, USA
Michelle Galloway, TB Proof, South Africa
Naomi Wanjiru, Vision Makers, Kenya
Nelson Otwoma, NEPHAK, Kenya
Paul E. Farmer, Harvard University, USA
Philip Lederer, Boston University, USA
Phumeza Tisile, TB Proof, South Africa
Rahab Mwaniki, KANCO, Kenya
Salmaan Keshavjee, Harvard Medical School, USA
Stellah Bosire, Kenya Medical Association, Kenya
Su Myat Han, Médecins Sans Frontières Access Campaign (MSF AC), Japan
Uzma Khan, Interactive Research and Development (IRD), Pakistan
Wieda Human, TB Proof, South Africa
Wubshet Jote Tolossa, TB Proof, Ethiopia
Zara Trafford, University of Cape Town, South Africa