To: **Mark Dybul**, Global Fund to Fight AIDS, Tuberculosis and Malaria
Mario Raviglione, Global TB Programme, World Health Organization
Jacques van den Broek, Western Pacific Regional Green Light Committee
Cheri Vincent, U.S. Agency for International Development

CC: **Lucica Ditiu**, Stop TB Partnership
Karin Wyer, Fuad Mirzayev, Ernesto Jaramillo, World Health Organization
Eliud Wandwalo, **Mohammed Yassin**, Global Fund
Mukadi YaDiul, Alex Golubkov, U.S. Agency for International Development
Nobuyuki Nishikiori, Shalala Ahmadova, World Health Organization
Regional Office for the Western Pacific, Manila, Philippines
Tauhid Islam, Peter van Maren, World Health Organization Papua New Guinea
Charles Daley, Global Drug-Resistant TB Initiative
Salmaan Keshavjee, Zero TB Cities Project Steering Committee

23 March 2016

Open letter re: Urgent need for improvement of global response to MDR-TB in Papua New Guinea, and for transparency and reform of rGLCs

Dear Mr. Dybul, Dr. Raviglione, Dr. van den Broek, and Ms. Vincent,

We are writing to express our alarm at the global response to the ongoing multidrug-resistant TB (MDR-TB) outbreak in Papua New Guinea, and appeal to you for rapid and effective intervention.

As you may know, MDR-TB is infecting over 170 people in Papua New Guinea every week; only one-third of notified cases are receiving treatment, and far more cases go undetected.[i,ii,iii] In November 2015, the government of Papua New Guinea and their technical partners issued a public joint statement calling for support to ensure successful implementation of the government plan to address MDR-TB in the epidemic hotspot of Daru, where more than 1% of the general population has MDR-TB.[iv,v] Especially in light of the gravity of the epidemic and this appeal for help, we were extremely troubled by the recent public presentation from the regional Green Light Committee (rGLC) of the Western Pacific Region (WPR), which cited recommendations in blatant contradiction to World Health Organization (WHO) guidance for diagnosing and treating MDR-TB.[vi] This raises deep concerns regarding the quality of technical assistance being provided through the WPR GLC (and potentially other rGLCs), as well as their transparency and meaningful engagement of affected communities.

Concern 1: WPR GLC recommendation against the roll out of GeneXpert
Though it does not have an up-to-date website we could find, the WPR GLC, according to publications by the members, "was established in 2011 to promote the rational scale-up of programmatic management of drug-resistant tuberculosis."[vii] Promptly and accurately diagnosing TB and drug resistance is an essential

component of this scale-up. As such, we were appalled to read in the public WPR GLC presentation that they concluded that "further roll out of GeneXpert (and the use of Xpert as an initial test) is not recommended" and they were continuing to prioritize smear microscopy.[viii] This is in direct violation of WHO ethical guidance from 2010, which notes how WHO has urged member states "to achieve universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis as part of the transition to universal health coverage, thereby saving lives and protecting communities," and elaborates how it is not only an ethical requirement but important for public health purposes to offer drug susceptibility testing even when treatment for drug resistant strains is not yet available locally.[ix] Without knowing how many people in Papua New Guinea have MDR-TB, the National TB Program cannot plan, the Global Fund will not know how much funding to allocate, and most importantly, patients in need will not receive treatment. This head-in-the sand approach is unethical and unjustifiable.

We were also disappointed that the WPR GLC commended that GeneXpert MTB/RIF is "increasingly utilized" region-wide, as 5 out of 13 countries have at least one GeneXpert machine. This is a very poor level of uptake for a tool that received WHO endorsement in 2010, and we should not be congratulating such unconscionably slow progress.[x]

Concern 2: WPR GLC focus on drug-susceptible TB at the expense of MDR-TB

Furthermore, it was troubling to see the statement "preventing active, drug-sensitive tuberculosis, or treating it properly, should be everybody's priority: it is the only way to prevent MDR-TB and XDR-TB".[xi] While preventing and treating active drug-susceptible TB is certainly essential, it should not come at the expense of addressing MDR-TB, especially as we know that ongoing transmission of drug-resistant strains is driving many epidemics. The tunnel vision exhibited in the overly narrow focus on drug-susceptible TB is reminiscent of the long-abandoned 1994 WHO DOTS Strategy, rather than the current WHO END TB Strategy, which calls for the "treatment of all people with tuberculosis including drug-resistant tuberculosis."[xii]

Concern 3: Lack of support for introduction of new drugs and regimens

Another of the WPR GLC's purported priorities is the "provision of technical support […] including assistance with the introduction of new drugs and regimens."[xiii] As such, we are also concerned about the lack of WPR GLC support for widening access to important drugs such as linezolid, bedaquiline, and delamanid. On Daru Island, 11% of patients with XDR-TB are on treatment waiting lists; even those who receive treatment only have a 22% success rate, which is equal to the mortality rate.[xiv] Despite the high rates of transmission and extremely high mortality on existing regimens, just four patients have been able to start regimens containing bedaquiline. All four patients have done quite well, indicating programmatic capacity to utilize this drug. Yet an estimated 150 new MDR-TB patients are in need bedaquiline and are not receiving it.[xv] Many more need delamanid. Meanwhile, eight treatment courses of bedaquiline arrived on in Port Moresby in August 2015 and

cleared customs, but have not been used and are sitting in either the National Treatment Program or WHO offices close to expiring, while patients wait to be treated. Finally, linezolid is only being released to individuals after XDR-TB treatment fails.[xvi]

It appears that WPR GLC has not done enough to support the scale-up of effective regimens in Papua New Guinea, and is now opposing the further scale-up of GeneXpert. The WPR GLC may be in fact doing harm by acting as a "red light committee" in a gatekeeping role that has long ago been deemed inappropriate.

Concern 4: Lack of transparency

We anticipate that there are likely other areas where WPR GLC recommendations contradict WHO guidance and are hindering progress against MDR-TB and perpetuating needless suffering in Papua New Guinea, but since rGLC reports are not made publicly available, we have no way of conducting a full assessment. We find this lack of transparency deeply unsettling: as rGLCs receive public funding to evaluate public programs, we can think of no compelling reason why these reports should not themselves be public.

Concern 5: Lack of meaningful rGLC engagement with affected communities

During the cited WPR GLC presentation, one of the members of the undersigned Global TB Community Advisory Board (TB CAB) inquired why there was not a community representative on the committee. The outgoing head of the WPR GLC flippantly claimed that he himself, as well as the newly elected chair of the WPR GLC, were representatives of TB-affected community, due to positive tuberculin skin tests. This points to a worrisome lack of understanding of appropriate engagement of representatives from communities impacted by TB. Further indicating the lack of respect for community engagement by the rGLCs, another TB CAB member had applied to the GLC Africa in August 2015, and has never received a response.

We urge you to take the following steps without delay to address the WPR GLC's egregious violations of WHO recommendations, and the broader structural issues concerning the transparency and community representation of rGLCs. If unaddressed, these problems will continue to adversely impact the use of Global Fund and U.S. Agency for International Development (USAID) funds and contribute to the persistence of substandard diagnosis and treatment of TB in Papua New Guinea and beyond.

In light of these concerns, we urge you to immediately:

1. **Formally communicate to the Papua New Guinea government that the roll-out of GeneXpert and new and repurposed drugs for MDR-TB in line with WHO guidance is encouraged, and that Global Fund funding is available to do so.**
2. **Conduct trainings and implement quality-assurance measures with any technical assistance providers, including rGLCs, to ensure that**

recommendations are in line with WHO guidance and are not an obstacle to implementation.

3. **Make all rGLC documents available to the public on the Global Drug-Resistant TB Initiative or other webpage.**
4. **Appoint to the WPR GLC an outspoken and knowledgeable member of the affected community.** Ideally, this person would come from Papua New Guinea. This would be consistent with the government's plan to build local capacity and support community engagement in MDR-TB. We would be happy to help identify appropriate candidates and build their capacity if needed.
5. **Arrange for a visit from a member of the global activist community to support the MDR-TB survivors in the region and develop an advocacy plan to combat the spread of TB throughout the country.**
6. **Consider the utility and structure of the WPR GLC and whether it is well-positioned to accomplish its purported tasks, and should continue to be funded by the donor community or other stakeholders.**

These actions should not be delayed until the next election cycle for the WPR GLC, or the next GLC meeting to Papua New Guinea, which we understand is not due till July 2016.

We request an emergency call with you to discuss these issues. We look forward to receiving your response to this letter by 1 April 2016. Kindly direct your replies to Erica Lessem at erica.lessem@treatmentactiongroup.org.

Respectfully submitted,

The Global TB Community Advisory Board
Treatment Action Group

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[xv] Ibid.
[xvi] Ibid.