TO:
Dr. Janette Loreto-Garin, Secretary of Health
Dr. Lilibeth C. David, Undersecretary of Health, Office for Policy and Health Systems
Dr. Nestor Santiago, Assistant Secretary of Health Designate, Office for Health Operations
Dr. Celina Garfine, National Tuberculosis Control Program Manager
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CC:
Mario Raviglione, Director of the Global TB Programme, World Health Organization
Lucica Ditiu, Executive Secretary, Stop TB Partnership
Brenda Waning, Chief of the Global Drug Facility (GDF)

24 September 2015

Open Letter RE: Urgent need to scale up access to new treatment options for multi-drug resistant tuberculosis in the Philippines

Dear Dr. Loreto-Garin and colleagues,

As organizations, associations, and individuals concerned about the health and well-being of people affected by tuberculosis (TB), we are writing today to congratulate you for moving forward with introducing new treatment options for multi-drug resistant tuberculosis (MDR-TB) in the Philippines, and urge you to ensure their rapid delivery to people with MDR-TB.

MDR-TB is both preventable and curable. But as an infectious and potentially deadly disease, it is highly destructive to patients, the broader public, and national economies if unaddressed. While the Philippines has made progress in fighting TB, it has one of the highest burdens in the world of MDR-TB.[1] In 2013, there were an estimated 8,500 cases of MDR-TB—but only one in four of those were started on MDR-TB treatment.[2] Of those started on MDR-TB treatment, less than half (41%) had successful treatment outcomes.[3] In the whole country, fewer than 10 patients with an even more difficult to treat form of the disease, called extensively drug resistant TB (XDR-TB), were started on treatment in 2013.[4] The need to scale up

[1] World Health Organization (available from: http://www.who.int/tb/challenges/mdr/MDR_TB_2014.pdf?ua=1)
[2] World Health Organization (available from: https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/EXT/TBCountryProfile&ISO2=PH&outtype=html)
[3] Ibid.
[4] World Health Organization (available from: http://www.who.int/tb/challenges/mdr/MDR_TB_2014.pdf?ua=1)

effective treatment options for people with MDR-TB and XDR-TB in the Philippines is urgent.

Fortunately, new treatment options for MDR-TB exist. Two new drugs, bedaquiline and delamanid, have been approved by stringent regulatory authorities after over five decades without new drugs for MDR-TB. Each drug, when added individually to a background regimen of other MDR-TB drugs, showing evidence of improving efficacy in treating MDR-TB over the background regimen alone. The World Health Organization now recommends the use of bedaquiline or delamanid for MDR-TB when an effective regimen cannot otherwise be constructed due to issues such as resistance and tolerability.[5,6] Several countries such as South Africa, Armenia, Belarus, Georgia, and Swaziland have rolled out bedaquiline in programmatic settings, have reported excellent outcomes to date, and have plans further scale up the use of the drug. Given the current poor cure rates for MDR-TB in the Philippines (and around the world), use of these new drugs is critically important. An estimated 2,000 to 3,000 Filipinos with MDR-TB need these drugs.

We applaud the Philippines for approving bedaquiline in February 2014, finalizing an implementation plan for its use in June 2015, and placing an order for 75 treatment courses in August 2015 (to arrive by November 1st, 2015). **We encourage you to continue this positive momentum and ensure that bedaquiline arrives in country and patients are started on it as soon as possible.**

Multiple clinical trials of new drug delamanid have been conducted in the Philippines, leading to its approval in other countries—but the drug is not available on the Filipino market. As such, **we urge you to secure the availability of delamanid in the Philippines** by 1) requesting the drug from developer Otsuka for eligible patients under existing access mechanisms (compassionate use), and 2) by asking that Otsuka honor principles of Good Participatory Practice[7] and provide post-trial access by registering delamanid in the Philippines.

Simultaneously, the Philippines has committed to making available a nine-month MDR-TB treatment regimen composed of older drugs. Rolled out in a range of countries under operational research, this regimen has been highly appealing to patients as it offers those who consent to try it the chance at cutting time on their grueling treatment by over half. The Philippines began a program to implement this regimen in July 2015. **We further ask you to ensure that consenting patients are rapidly enrolled into the shortened treatment program.**

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[5] http://www.who.int/tb/challenges/mdr/Report_EGM_BDQ_2013.pdf?ua=1
[6] ttp://apps.who.int/iris/bitstream/10665/137334/1/WHO_HTM_TB_2014.23_eng.pdf?ua=1&ua=1
[7] http://www.cptrinitiative.org/downloads/resources/GPP-TB%20Oct1%202012%20FINAL.pdf

Finally, we ask that the Philippines monitors, documents, and shares safety, and interim and final patient cohort outcomes on new drugs and the nine-month regimen.

Given the urgent need to address the MDR-TB epidemic in the Philippines, we commend your actions to date, and look forward to your commitment to the above. Multiple stakeholders are enthusiastically available to support your program with any technical needs that would help facilitate the Philippines in these important efforts if needed.

For further communication and to provide information on progress on the above, or to be connected to any technical assistance providers, please contact Erica Lessem at erica.lessem@treatmentactiongroup.org. We kindly request your response by October 23, 2015.

Signed by:
Global TB Community Advisory Board (Global)
SWIFT (Global)
Treatment Action Group (USA)