TBCAB
GLOBAL TB COMMUNITY ADVISORY BOARD

To: **Dr. Patricia Garcia**, Minister of Health of Peru
Ministry of Health of Peru
Av. Salaverry 801 Jesús María
Lima, Peru

CC: **Dr. Julia Rosa Maria Rios Vidal,** Coordinator of the National Strategy for Tuberculosis Prevention and Control
Vicky Roxana Flores Valenzuela, Director General, Directorate General of Medicines, Supplies and Drugs
César Henry Vásquez Sánchez, President of the Health and Population Commission of the Congress of the Republic

10 February 2017

OPEN LETTER RE: Urgent need for delamanid to address multidrug-resistant tuberculosis in Peru

Dear Dr. García,

On behalf of the Global TB Community Advisory Board (TB CAB), we write to follow up on the letter sent 18 October 2016 and to reiterate the important role the Ministry of Health (MINSA) must play in facilitating access to delamanid for Peruvians with multidrug-resistant tuberculosis (MDR-TB).

As a group of activists committed to improving the global response to tuberculosis (TB), **we urge MINSA (1) to support the registration of delamanid in Peru; (2) to ensure the inclusion of delamanid in the country's forthcoming guidelines on the management of drug-resistant TB (DR-TB); and (3) to urgently establish a mechanism for access to delamanid while registration is pending.**

(1) Support the registration of delamanid in Peru
We continue to petition drug sponsor, Otsuka to uphold its obligation to ensure access to delamanid by filing for registration with the Directorate General of Medicines, Supplies and Drugs (DIGEMID). Registration in Peru is necessary to meet the standards outlined by *The Good Participatory Practice Guidelines for TB Drug Trials*.[1] Access in Peru should be prioritized given the contributions of Peruvian patients to the clinical trials that led to delamanid's registration in Europe, Japan, and elsewhere,[2] and that supported World Health Organization (WHO) recommendations for delamanid's use.[3] Toward the common goal of facilitating access to delamanid in Peru, we encourage MINSA to take any steps necessary to hold Otsuka accountable to its obligation to ensure post-trial access and to help expedite the DIGEMID's review of the dossier for delamanid.

(2) Ensure the inclusion of delamanid in forthcoming guidelines on the management of drug-resistant TB (DR-TB)

It is important to ensure that once available, delamanid is used appropriately. In parallel to helping expedite delamanid's registration with DIGEMID, we urge MINSA to ensure the inclusion of delamanid in the guidance on the management of DR-TB that is currently under development and the successful publication of this guidance in 2017. Since we last corresponded, the WHO issued guidelines recommending the use of delamanid in children down to six years old.[4] We hope the forthcoming guidelines will reflect the latest available evidence and WHO guidelines, expanding the potential benefits of access to this important drug to adolescents and children.

(3) Establish a mechanism for access to delamanid while registration is pending
Finally, we appeal to MINSA to work with DIGEMID to rapidly establish an import waiver or other mechanism that allows patients access to delamanid while registration is pending. This is critical for patients in Peru with urgent need for delamanid. We are already aware of ten patients in whom treatment with linezolid-containing regimens has failed. These patients require urgent access to delamanid to enable re-treatment with a bedaquiline-containing regimen and to prevent the development of resistance. Without access to delamanid, a viable treatment regimen cannot be constructed and these patients will likely die, in the meantime putting their families and communities at risk of infection with this difficult to treat and highly resistant strain of TB.

We are happy to further discuss the essentiality of access to delamanid in Peru and, before February 28, require your response regarding your commitment to meeting the above three requests. Please direct your response to the chair of the TB CAB, Wim Vandevelde at wim@eatg.org.

Respectfully submitted,

Lindsay McKenna
Senior TB/HIV Project Officer
Treatment Action Group
On behalf of the Global TB Community Advisory Board (TB CAB)

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[1] Critical Path to TB Drug Regimens. Good Participatory Practice Guidelines for TB Drug Trials. 2012. Available from: http://www.cptrinitiative.org/downloads/resources/GPP-TB%20Oct1%202012%20FINAL.pdf.
[2] Clinicaltrials.gov [Internet] Bethesda (MD): National Library of Medicine (U.S.). 2000. Identifier NCT02573350, A phase 2, multi-center, uncontrolled, open-label trial to evaluate safety, tolerability, and efficacy of orally administered OPC-67683; 2015 October 13 (cited 14 October 2016). Available from: https://clinicaltrials.gov/ct2/show/NCT02573350.
[3] World Health Organization. The use of delamanid in the treatment of multidrug-resistant tuberculosis. Geneva: World Health Organization; 2014. Available from: http://www.who.int/tb/publications/delamanid-in-mdr-tb-treatment/en/.
[4] World Health Organization. The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents: Interim policy guidance. Geneva, Switzerland: World Health Organization, 2016. Available from: http://apps.who.int/iris/bitstream/10665/250614/1/9789241549899-eng.pdf.