

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

CC: Dr. Valentina Alarcón, Coordinator of the National Strategy for Tuberculosis Prevention and Control  
Luz Estrada Gonzáles, Representative of people affected by tuberculosis, CONAMUSA

17 October 2016

**OPEN LETTER RE: Urgent need for guidance and registration of delamanid to address MDR-TB epidemic in Peru**

Dear Dr. García,

On behalf of TB CAB, we write to acknowledge the good work that the Ministry of Health in Peru (MINSA) and partners have done to respond to the epidemic of multidrug-resistant TB (MDR-TB) in Peru, and we applaud Peru for implementing the provision of bedaquiline, as new tools are urgently needed to improve treatment outcome. However, another equally important new MDR-TB drug, delamanid, is yet not available in Peru.

Peru is a World Health Organization (WHO)-identified high MDR-TB burden country,<sup>1</sup> with 1,317 cases of MDR-TB and 104 cases of extensively drug resistant TB (XDR-TB) in 2015, so needs all tools possible to fight drug-resistant TB.<sup>2</sup> In addition, to our knowledge, Peru has hosted clinical trials which led to delamanid's registration in Europe and Japan,<sup>3</sup> and supported WHO recommendations for delamanid use,<sup>4</sup> yet Peruvians with MDR-TB still cannot obtain this drug. We eagerly anticipate the potential for use of delamanid in Peru in accordance with WHO guidelines.

We are inquiring similarly in other countries where the drug is needed, and encouraging them to provide access to delamanid. Other countries are developing guidelines for and registering delamanid: delamanid has already been approved by the European Medicines Agency, and in Japan, South Korea, and Hong Kong, with additional registrations under review in Turkey, the Philippines, and Indonesia.

---

<sup>1</sup> World Health Organization. Use of high burden country lists for TB by WHO in the post-2015 era. Geneva: World Health Organization; 2015. Available from:

[http://www.who.int/tb/publications/global\\_report/high\\_tb\\_burden\\_country\\_lists\\_2016-2020.pdf](http://www.who.int/tb/publications/global_report/high_tb_burden_country_lists_2016-2020.pdf).

<sup>2</sup> Preliminar Report ESNPCT /DGSP /MINSA /PERU. Date 31-Mar-2016

<sup>3</sup> 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>.

<sup>4</sup> 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/>.

We are simultaneously advocating for delamanid's sponsor, Otsuka, to register delamanid in Peru. However, we understand a first step in facilitating such access is for your TB Strategy program at MINSA to work with an expert group to create normative guidance indicating the use of delamanid under programmatic conditions. Only once that guidance is developed, could MINSA request the General Direction of Medicines, Supplies and Drugs (DIGEMID) to register delamanid for use in Peru.

Could you please update us on the current situation in regards to development of national guidance for the use of delamanid under programmatic conditions, and any other information relevant to the registration and use of delamanid in Peru?

We look forward to your response, which we request by 24 October 2016, and which can be directed to Wim Vandavelde at [wim@eatg.org](mailto:wim@eatg.org).

Thank you in advance,  
The Global TB Community Advisory Board (TB CAB)