

TO: Ms. Nela Charade G. Puno, RPh, FDA Director General  
Republic of the Philippines Food and Drug Administration  
Civic Drive, Filinvest Corporate City  
Alabang, Muntinlupa City

CC: Dr. Paulyn Ubial, Secretary of Health, the Philippines  
Office of the Secretary  
Dept of Health, San Lazaro Cmpd  
Sta Cruz Manila  
632651-7800

Ms. Melody M. Zamudio, RPh, MGM-ESP, OIC, Center for Drugs Regulation and  
Research, Philippines Food and Drug Administration  
Dr. Mario Raviglione, Director of the Global TB Programme, World Health  
Organization  
Dr. Lucica Ditiu, Executive Secretary, Stop TB Partnership  
Dr. Brenda Waning, Chief of the Global Drug Facility

19 December 2016

**RE: Urgent need to approve delamanid for multi-drug resistant tuberculosis in the Philippines**

Dear Ms. Puno,

As Filipino and global organizations, associations, and individuals concerned about the health and wellbeing of people affected by tuberculosis (TB), we are writing today to congratulate you for your striving to find a balance between innovation and strong regulation, and to respectfully request your rapid approval of delamanid (Delyba), an important treatment option for people with multidrug-resistant tuberculosis (MDR-TB) in the Philippines.

The Philippines has one of the highest burdens in the world of TB and MDR-TB. MDR-TB sickened 15,000 Filipinos in 2015 alone. Treatment reaches only a handful of people with extensively drug-resistant (XDR) forms of the disease. And treatment is only successful in about half of those treated for MDR-TB or XDR-TB.<sup>1</sup> New treatment options are urgently needed.

Fortunately, two new treatment options for MDR-TB exist, delamanid (Delyba) and bedaquiline (Sirturo). The Philippines has been at the forefront of research into these new drugs, hosting the clinical trials that led to their approval by stringent regulatory authorities several years ago. We applaud the Philippines Food and Drug Administration for approving bedaquiline in February 2014, enabling the Philippines to also be at the forefront of implementing this potentially life-saving

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<sup>1</sup> World Health Organization. 2016 Tuberculosis Country Profiles: Philippines. Available from: [https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO\\_HQ\\_Reports%2FG2%2FPROD%2FEFT%2FTBCountryProfile&ISO2=PH&LAN=EN&outtype=html](https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEFT%2FTBCountryProfile&ISO2=PH&LAN=EN&outtype=html)

intervention. We encourage the Philippines Food and Drug Administration to act similarly, and approve delamanid without further delay.

Delamanid is an extremely important drug to register in the Philippines. Recommended by the World Health Organization since 2014 for the treatment of some forms of MDR-TB, delamanid has been used around the world, and appears to be safe and useful in treating otherwise intractable forms of TB.<sup>2</sup> Moreover, the WHO recently issued guidance on the use of delamanid in children down to six years of age, providing an important treatment option in children with MDR-TB.<sup>3</sup>

Given the urgent need to address the MDR-TB epidemic in the Philippines, we commend your actions to date, and look forward to delamanid's registration in the Philippines. For further communication, or for any more information, please contact [erica.lessem@treatmentactiongroup.org](mailto:erica.lessem@treatmentactiongroup.org) and [actasia-pacific@apcaso.org](mailto:actasia-pacific@apcaso.org).

Signed,

APCASO (Asia-Pacific Region)

Asia-Pacific Activists' Coalition on TB – ACT-AP (Asia-Pacific Region)

Association Of people Living With HIV-Pakistan (Pakistan)

Jacqueline Bodibe (South Africa), World Health Organization Civil Society Task Force on TB member

Center for Supporting Community Development Initiatives (SCDI), Viet Nam

Choub Sok Chamreun, KHANA (Cambodia) and ACT-AP Co-Chair

Congress of South African Trade Unions (South Africa)

Maura Elaripe (Papua New Guinea), ACT-AP Member

Global Coalition of TB Activists (Global)

Global TB Community Advisory Board (Global)

James Malar, APCASO (Asia-Pacific Region) and World Health Organization Civil Society Task Force on TB member

Daniel Marguari, Spiritia (Indonesia) and ACT-AP Steering Committee Member

National Coalition of PLHIV in India – NCPI plus (India)

Network of Maharashtra by people living with HIV/AIDS – NMPPLUS (India)

Jintana Ngamvithayapong-Yanai, TB/HIV Research Foundation (THRF) (Thailand)

Nigeria Network of NGOs (Nigeria)

Oluseyi Babatunde Oyebisi, Nigeria Network of NGOs (Nigeria) and World Health Organization Civil Society Task Force on TB member

Gracia Violeta Ross, Bolivian Network of People Living with HIV (Bolivia) and World Health Organization Civil Society Task Force on TB member

Elvi Solita Siahaan, MAP Internasional (Indonesia) and ACT-AP Co-Chair

Treatment Action Group (USA)

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<sup>2</sup> World Health Organization. WHO interim guidance on the use of delamanid in the treatment of MDR-TB. Available from: [http://www.who.int/tb/features\\_archive/delamanid/en/](http://www.who.int/tb/features_archive/delamanid/en/)

<sup>3</sup>World Health Organization. The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents. Available from: <http://apps.who.int/iris/bitstream/10665/250614/1/9789241549899-eng.pdf?ua=1>.