

10 March, 2015

To:

Mr. Donal Brown, Head, Global Funds Department, U.K. DFID
Amb. Deborah Birx, U.S. Global AIDS Coordinator
Dr. Patrizia Carlevaro, Managing Director, Otsuka
Dr. Charles Daley, Chair, Global Drug-Resistant TB Initiative (GDI)
Dr. Lucica Ditiu, Executive Secretary, Stop TB Partnership
Mr. Philippe Douste-Blazy, Chair, UNITAID
Dr. Mark Dybul, Executive Director, Global Fund to Fight AIDS, TB and Malaria
Dr. Eric Goosby, UN Secretary-General's Special Envoy for TB
Dr. Gilla Kaplan, Director, Tuberculosis, Bill and Melinda Gates Foundation
Dr. Petra Keil, Head of Global Public Policy, Novartis
Dr. Joel Keravec, Manager, Global Drug Facility, Stop TB Partnership
Dr. Susan Maloney, Global TB coordinator, U.S. CDC
Mr. Lelio Marmora, Executive Director, UNITAID
Mr. Greg Perry, Executive Director, MPP
Dr. Yogan Pillay, Deputy Director General, National Department of Health, South Africa
Dr. Mario Raviglione, Director, Global TB Program, WHO
Dr. Thomas Shinnick, Chair, Global Laboratory Initiative
Dr. Adrian Thomas, VP of Global Market Access & Commercial Strategy Operations and Head of Global Public Health, Janssen
Ms. Cheri Vincent, Chief, Infectious Diseases Division, USAID
Mr. David Wilson, Global AIDS Program Director, World Bank
Mr. Hiroyuki Yamaya, Director, Global Health Policy Division, International Cooperation Bureau, Ministry of Foreign Affairs

Dear colleagues,

We are deeply concerned by the delay in the introduction of new and repurposed drugs to treat drug-resistant tuberculosis (DR-TB) in high-prevalence settings for people who need better, more effective treatment.

We call upon your agencies and organisations to accelerate and strengthen activities to ensure access to new and repurposed DR-TB drugs in 52 countries. We propose an informal consortium, convened by the World Health Organisation (WHO), which will operate in the spirit of greater coordination and towards agreed-upon responsibilities and time-bound goals.

New drugs to treat DR-TB have finally been developed; yet long after their approval, they are only available to a small number of those who need them. New drugs delamanid (DLM) and bedaquiline

(BDQ) have been granted accelerated or conditional approval by stringent drug regulatory authorities; delamanid in April 2014 by the European Medicines Agency (EMA), and bedaquiline by the US FDA in December 2012.

WHO issued interim guidance recommending the programmatic use of bedaquiline in June 2013 and delamanid in October 2014. However, at the end of 2014, a little more than 600 people have received BDQ through expanded access programmes, and fewer than 10 have received DLM outside clinical trial settings.

Janssen, the manufacturer of bedaquiline, issued a press release in December 2014 announcing a donation of 30,000 courses of bedaquiline through USAID, but nearly three months later, the details are unknown and there is no mechanism established for accessing this programme.

We call upon you to work together with in-country partners to urgently make these drugs available to patients to both save their lives and stop ongoing transmission of highly resistant strains in the community.

Towards this end, we request that you develop a consortium and create a framework for action and provide necessary support to enable national governments to have the information, technical assistance (TA), and resources they need to rapidly make new and repurposed DR-TB drugs available to patients.

This includes supporting governments to develop implementation plans; establish fast-track registration or import waiver processes and compassionate use (CU), or a similar mechanism, as an interim strategy; establish pharmacovigilance (PV) as required; and update guidelines, and procure drugs in order to start providing treatment with these drugs to people in need.

Drug companies also must meet their responsibilities. They must allow broad early access to these drugs through compassionate use-like mechanisms, and rapidly register their products widely (especially in countries where clinical trials have been conducted and in countries with a high TB burden). Companies should have transparent and fair policies for pricing, registration and licensing, particularly for low- and middle-income countries.

We encourage actors in the proposed consortium to address the numerous barriers to accessing BDQ and DLM and other DR-TB drugs, and seize the opportunities that exist to overcome them.

These barriers include a lack of technical assistance and capacity support to countries, regulatory hurdles, and the heavy resource requirements of pharmacovigilance (PV) and cohort event monitoring (CEM). The consortium actors should take advantage of opportunities to implement better treatment for DR-TB, such as reprogramming funding from the Global Fund to Fight AIDS, TB, and Malaria, and establishing compassionate use, or similar pre-approval access programmes, as an interim strategy in advance of regulatory approval.

We urge the consortium to commit to the following goals:

1. **Quickstart:** Ensure 500 patients are started on routine regimens which include BDQ by July 2015, and 500 patients started on routine regimens which include DLM by January 2016.

2. **Optimal DR-TB treatment:** Technical assistance provided for 25 countries by 2016 and 52 countries by 2017 for drafting implementation plans; implementation plans are adopted by 25 countries by 2016 and 52 countries by 2018; and BDQ and DLM are routinely used by 20 countries by end of 2016 and 52 countries by end of 2019. Key repurposed drugs (especially linezolid and clofazimine) should be on the national Essential Medicines List (EML), and countries and national TB programmes (NTPs) should be using these drugs.
3. **Regulatory status:** BDQ and DLM dossiers are submitted for registration in 25 countries by beginning of 2016 and 52 countries by 2017; and drugs are registered, or import waivers are in place, by 2016.
4. **Pharmacovigilance (PV):** The consortium supports a flexible approach for countries implementing BDQ (such as sentinel PV), proposes a set of standardised data for monitoring and reporting on adverse events, and works towards a supranational body to collect and analyse data.
5. **Procurement:** Forecasting of drugs is completed; procurement strategies are developed for 52 countries by 2018; and, the turnaround time between ordering and drug delivery is reduced.

Given the urgent need to act without further delay, we request that:

1. USAID and Janssen ensure the donation agreement for bedaquiline is finalised and the details made public by World TB Day, 24 March 2015, and that it reflects input from treatment implementers and affected communities;
2. The recipients of this letter express willingness and agreement to participate in such a consortium by World TB Day on 24 March 2015; and
3. WHO convene the consortium and develop a framework for action in April 2015.

Sincerely,

Médecins Sans Frontières (MSF)
 ACTION Global Health Advocacy Partnership
 SWIFT Response Project
 Treatment Action Campaign (TAC)
 Treatment Action Group (TAG)

Action against AIDS, Germany
 AIDES, France
 AIDS & Rights Alliance for Southern Africa (ARASA), South Africa
 AIDS-Free World, USA/Canada
 Alliance Burundaise pour la Lutte Contre la Tuberculose et la lepre, Burundi
 All Ukrainian Charitable Organization All Ukrainian Network of People Living with HIV/AIDS, Ukraine
 ARAS - the Romanian Association Against AIDS, Romania
 Asociatia Centrul de Expertiza si Consultanta Sociala - CECS, Romania
 Association of HIV affected women and their families "Demetra", Lithuania

Australasian Tuberculosis Forum, Australia
Bangladesh Lung Foundation, Bangladesh
Community and Family Aid Foundation, Ghana
Community Research Advisors Group, USA, South Africa, Peru, Vietnam, Spain, Uganda
Development Network, Afghanistan
Dignitas International, Canada
Empower India, India
European AIDS Treatment Group, WHO, Belgium
Federal Teaching Hospital, Nigeria
Forum for Medical Ethics Society (FMES), India
Global Coalition of TB Activists, India
Global Media Foundation, Ghana
Global TB Community Advisory Board (TB CAB), Global
Grandmothers Advocacy Network, Canada
Health GAP (Global Access Project), U.S.
Health Digest Foundation, Ghana
Health Ministry, Sri Lanka
Health Poverty Action, UK
HIV Prevention Justice Alliance, USA
Hospital & Research Institute, India
INSPIRE R8 Alliance to Control Tuberculosis, Philippines
Interagency Coalition on AIDS and Development (ICAD), Canada
International Community of Women Living with HIV Rate Africa Region-Icwea, Uganda
International HIV/AIDS Alliance in Ukraine, Ukraine
International Human Rights Clinic, University of Chicago Law School, United States
International Relief and Development, Pakistan
LGBT Voice Tanzania, Tanzania
Malawi Network of Religious Leaders living with or personally affected by HIV AIDS, Malawi
Ministry of Health/National TB Programme, Fiji
Narcological Hospital, Ukraine
National Administration of Penitentiaries, Ministry of Justice, Romania
National TB Control Program Pakistan, Pakistan
National Tuberculosis control Program, Senegal
NTP Pakistan, Pakistan
Philippine Coalition Against Tuberculosis, Philippines
Philippine College Of Chest Physicians - Council on Tuberculosis, Philippines
Physicians for Human Rights at University of Colorado, USA
Positive People Armenian Network NGO, Armenia
RENIP+, Niger
RESIST-TB (Research Excellence to Stop TB Resistance), USA
Restless Development, UK
Rural Health Advocacy Project (RHAP), South Africa
Rural-Urban Women and Children Development Agency (RUWACDA), Ghana
Salience Consulting Ltd, UK
Social Action and Rehabilitation Centre, India
Standing Committee on Public Health, Nigeria

Stanford University, US
STOPAIDS, UK
Stop TB, USA
Stop-TB Forum, Germany
Swaziland Migrant Mineworkers Association (SWAMMIWA), Swaziland
Swiss Tropical and Public Health Institute, Switzerland
Tanzania Network of Women Living with HIV, Tanzania
TB Proof, South Africa
TB Research Unit, Case Western Reserve University (TBRU)
TB Photovoice, US
The Brea TB and Aids Foundation, Uganda
The Delhi Network of Positive People (DNP+), India
The Swaziland Business Coalition on Health and AIDS (SWABCHA), Swaziland
The Union, India
Tnata PLHIV Network, Namibia
Treatment Action Campaign (TAC)
Treatment Action Group (TAG)
Tuberculosis Center of Research Excellence, Australia
Tuberculosis Consortium , Kenya
Tuberculosis Support Group South Africa, South Africa
Uganda Harm Reduction Network(UHRN), Uganda
UN World Food Programme, Thailand
Universal Health Development Foundation (UHDF), Uganda
University of Calabar Teaching Hospital, Nigeria
USAID-funded Quality Health Care Project, Kyrgyz Republic
WEDNET-AFRICA (Welfare Development Network), Uganda
Women in Action Against Gender Based Violence, Cameroon
Wote Youth Development Projects, Kenya
ZAPHIT Support Program, Zambia