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Shri Narendra Modi Prime Minister of India 152, South Block, Raisina Hill, New Delhi-110011	Shri Jagat Prakash Nadda Health Minister, Government of India Nirman Bhawan, Maulana Azad Road, New Delhi- 110001	Dr. Sunil Khaparde DDG (TB) 522-C, Nirman Bhawan, Maulana Azad Road, New Delhi-110001
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To: Shri Narendra Modi, Prime Minister of India

CC: Shri Jagat Prakash Nadda
Union Minister of Health and Family Welfare, Govt of India
Dr. Sunil Khaparde, Deputy Director General, RNTCP

Date: 14/0917

Open letter re: Urgent need to introduce Delamanid into India, and include affected communities in planning for rollout

Dear,

Mr. Narendra Modi, Hon'ble Prime Minister of India, Dr. J.P. Nadda and colleagues,

As members of civil society organisations and representatives of people affected by tuberculosis in India, we write in alarm about the slow progression of Delamanid rollout, a medicine for the treatment of otherwise very difficult to treat drug-resistant TB, in India. Delamanid has been available in the EU and Japan for over three years, and India is one of the few high burden developing countries to have received a registration dossier and granted approval by the Drugs Controller General of India (DCGI) for its use in RNTCP's DR TB programme. WHO also recommends Delamanid's use in children six years and older, filling an important gap as there are few medicines for drug-resistant TB that have been tested in children.

Yet, to our knowledge there is still no concrete plan or timeline made available by the RNTCP for the introduction and scale up of this potentially life-saving medicine. The delayed and restricted criteria for accessing new TB medicines in India have already led to a landmark court case on access to Bedaquiline and Delamanid. To avoid further loss of life, violation of the human rights to health, spread of drug-resistant TB, **we urge you to**

i) Immediately develop a concrete plan for the introduction of Delamanid in India, which should include:

- the timeline for the phased introduction of Delamanid;
- Selection for the first stage of rollout, and considerations of whether the same or different sites involved in the Bedaquiline rollout will be included;
- Plans and timeline for training the sites;
- Inclusion of children of 6 years and above;

- Considerations for use in pregnant women, in select cases where potential benefits outweigh harm;
- Use of Delamanid beyond six months, in select cases where potential benefits outweigh harm;
- Consider the needs of DR TB patients who need co-administration with Bedaquiline;
- Develop criteria of access by private sector institutions and clinicians who have been treating DR TB ethically, including but not limited to those who have already accessed Delamanid under compassionate use;

Plans and timeline for scale up for country-wide access;

- No restrictions based on domicile of patients;
- Ensure domestic production of Delamanid and Bedaquiline to ensure sustainable supply and affordable access, transparent tendering of these new TB drugs.

ii) Include civil society organization/affected communities in the development of such plans

Given the important role the Civil Society Organizations (CSO) and Affected Communities (AC) can play in informing, aiding, and monitoring the introduction of new tools such as Delamanid, it is essential to include representatives from CSO and AC in the planning process, including on the expert committee that will develop the concrete plans for Delamanid's introduction in India. We therefore request that you include us in all meetings and discussions around the introduction of Delamanid.

iii) Launch this plan by 11 October, 2017

Given the already unconscionable delay in introducing Delamanid in India, we expect this plan to be finalized and launched by 11 October 2017, and the details of this plan be made public, in advance of the Union World Conference on Lung Health 2017.

iv) Ensure scale-up so that Delamanid is accessible to all Indians who need it by 2017.

While we understand Delamanid's introduction may need to begin in a phased manner, we have been disheartened by the extremely slow scale up of Bedaquiline throughout India, and urge you to ensure that Bedaquiline be made available nationally urgently, and that Delamanid be made available nationally by 2017.

We look forward to your kind response, which can be directed to kethoa@gmail.com by 25th September 2017.

Respectfully Submitted,

1. Access to Rights and Knowledge (ARK) Foundation, Kohima, Nagaland
2. All Manipur Positive Women Network (AMPWN+)
3. Andhra Pradesh Positive Women Network (APWN+)
4. Arunachal Pradesh Network of Positive People

- 5.Assam Network of Positive People (APN+)
- 6.Bengal Forum of People Who use Drugs
- 7.Bengal Network of Positive people
- 8.Bihar Network of Positive People
- 9.Bihar State Drug Users' Forum
- 10.Chandigarh Network of Positive people
- 11.Chhattisgarh Network of Positive People
- 12.Community Network for Empowerment (CoNE)
- 13.Council of Kerela people living with HIV/AIDS
- 14.Delhi Network of Positive People (DNP +)
- 15.Delhi Positive Women Network (DPWN+)
- 16.Empower India
- 17.Espoir Society, Nagaland
- 18.Ganesh Acharya, TB survivor and HIV/AIDS Activist, Mumbai, India
- 19.Global Coalition of TB activist
- 20.Gujarat State Network of People Living with HIV/AIDS
- 21.Haryana Network of Positive People
- 22.Haryana State Drug Users' Forum
- 23.HeAT (Hepatitis, AIDS and Tuberculosis) Forum, North-East Region
- 24.Hepatitis Coalition of Meghalay (Hep.CoM)
- 25.Hepatitis Coalition of Sikkim (HepCoS)
- 26.Hepatitis Forum of Manipur (HepFoM)
- 27.Himachal Pradesh Network of Positive people
- 28.Hopers Foundation, Chennai
- 29.Jammu and Kashmir Network of Positive people
- 30.Jharkhand State Network of Positive People
- 31.Kalinga Network for People Living with HIV/AIDS (KNP+), Odisha
- 32.Karnataka Network of Positive People
- 33.Karnataka Positive Women Network (KPWN+)
- 34.Kekhrie Foundation, Kohima, Nagaland
- 35.Kerela Positive Women Network (KPWN+)
- 36.Kohima Users' Network, Nagaland
- 37.Love Life Society
- 38.Madhya Pradesh Network of People Living with HIV/AIDS Society
- 39.Manipur Network of Positive People
- 40.Meghalaya State Network of Positive People (MSNP+)
- 41.Mizoram Drug Users' Forum (MDUF)
- 42.Mizoram Hepatitis Response Team (MiHReT)
- 43.Mizoram State Network of Positive People (MISNOPP)
- 44.Nai Umang (NU+)
- 45.National Coalition of People Living with HIV/AIDS (NCPI+)
- 46.Network of Maharashtra by People Living with HIV/AIDS
- 47.Network of Naga people Living with HIV/AIDS
- 48.Network of Telangana People Living with HIV/AIDS
- 49.Orissa Positive Women Network (OPWN+)
- 50.Pondichery Positive Women Network (PPWN+)
- 51.Positive Women Network (PWN+)
- 52.Positive Women Network of Mizoram (PWNM+)
- 53.Prashant Sharma (TB Survivor), Sikkim
- 54.South Indian Drug Users' Forum, (SIDUF), Chennai

- 55.South Indian Harm Reduction Network (SIHRN)
- 56.Saksham Positive Women Network (SPWN+)
- 57.Sikkim Network of Positive People
- 58.Sutirtha Dutta, Drug User's Activist
- 59.Tamil Nadu Network of Positive People
- 60.Tamil Nadu Positive Women Network (TPWN+)
- 61.Telangana Positive Women Network (TPWN+)
- 62.Telugu Network of Positive People
- 63.Touched by TB, India
- 64.Tripura State Network of Positive People (TSNP+)
- 65.Uttarakhand Association of Positive people living with HIV/AIDS
- 66.Uttar Pradesh Positive Women Network (UPPWN+)
- 67.Uttar Pradesh Welfare for People Living with HIV/AIDS Society
- 68.Western (India) Harm Reduction Network
- 69.Zindagi, Goa