

30 September 2021

| | | |
|---|---|---|
| Mr. Mansukh Mandaviya Union Minister of Health, India & Chair of the Stop TB Partnership Board | Mr. Rajesh Bhushan Secretary Ministry of Health & Family Welfare Union of India | Dr. Sudarsan Mandal DDG (TB) National TB Elimination Programme (NTEP) India |
|---|---|---|

Re: Urgent: Stock out of the drug delamanid, CBNAAT testing kits, & Non-Availability of TB screening tools for children and PLHIV

Dear Mr. Mandaviya, Mr. Bhushan, Dr. Mandal,

We members of TB affected communities, TB survivors, civil society would like to draw your immediate attention to urgent issues of drug stockouts and the lack of screening kits in many parts of India. This, as you know, undermines the national goal of TB elimination in India.

Stockouts of CBNAAT screening kits and delamanid in India

- Delamanid is a drug in the WHO and National Essential Medicines List for the treatment of DR-TB. As you may be aware, the availability of bedaquiline and delamanid are essential to the roll-out of injection-free regimens under the NTEP for adults and children. The drug is in short supply, and civil society from across the country is reporting a stock out of delamanid. As the drug is under patent monopoly, it is expensive, and supply to NTEP is dependent on a sole supplier, Mylan Inc, which is the patentee's distributor in India. There is no tender for the procurement. The file with the proposal from Mylan to supply delamanid in 2021 at 1275 USD per course is pending with the office of the Health Minister, even though it is already Q3 of the year. We also draw your attention to the Order¹ of the Department for Promotion of Industry and Internal Trade on the directions of the High Court of Bombay in *Meera Yadav & Anr. v. Union of India*² in which DPIIT arbitrarily rejected compulsory license for the generic supply of delamanid, citing that "the available stock is sufficient to meet the requirements for the next 9 months." Such false representation and projections have risked the lives of DR-TB patients who urgently need delamanid. Therefore, we request you to take steps to approve the delamanid procurement for 2021 immediately. We also urge you to encourage generic suppliers to register the adult and child formulations of delamanid with the CDSCO so that in 2022 a similar situation of high pricing failed negotiations with the patentee, leading to stock out in NTEP, can be avoided. In the circumstances, a government authorization or a compulsory license must be issued to allow generic companies to supply delamanid to NTEP.
- Procurement of CBNAAT kits and, in particular, GeneXpert kits was decentralized by NTEP this year after state governments had finished their Programme Implementation Plans (PIP), which outlines the budget requirement of the state. As a result, PIPs of states do not reflect the budget needed to procure the kits, and additional approvals by state government cabinets are

¹ Order no. P-24015/41/2018-IPR-III dated 27/04/2021

² PIL no. 495 of 2021 before the High Court of Judicature at Bombay

required for this single source product before procurement can begin. The resulting stockout of kits for the GeneXpert machine is a severe setback to the upfront screening for TB and DR-TB as promised by the PMDT guidelines 2021. Therefore, we request Centre/NTEP to provide financial and technical support to states who have been unable to procure kits and will be unable to do so until 2022 PIPs are revised and approved.

Availability of TB screening tools for children and people living with HIV

- The WHO has recommended that TB programmes adopt the Xpert MTB/ RIF Ultra in gastric aspirate or stool specimens as the initial diagnostic test for TB and detect rifampicin resistance in children under ten years with signs and symptoms of pulmonary TB. [Operation research in India](#) has highlighted that Stool CBNAAT can be used for bacteriological confirmation of paediatric pulmonary TB and found to have a high degree of concordance with the conventionally used gastric aspirate CBNAAT. We request that the same be incorporated into the NTEP diagnostic guidelines immediately.
- Six years ago, in 2015, WHO recommended using the TB lipoarabinomannan (TB LAM) test for diagnosing TB in people living with HIV. The only TB LAM test available globally (Determine TB LAM/Abbott) is a rapid and affordable point-of-care urine test applicable at the point of care. Multiple studies have shown that it allows earlier diagnosis of TB in people with advanced HIV and reduces TB mortality by early diagnosis and prompt treatment. Despite being a life-saving tool for TB testing recommended by WHO, TB LAM is still not available in India at antiretroviral therapy (ART) centres to routinely screen PLHIVs seriously ill or have a CD4 count less than 200. We believe that registration of TB LAM by the CDSCO will strengthen the case for its implementation and scale-up by competent authorities – NACO and NTEP – in the country. We request that the NTEP and CDSCO work together to consider the registration of TB-LAM on a priority basis to ensure timely screening of TB in people living with HIV at risk of dying of AIDS due to advanced HIV disease.

Thank you in advance for your cooperation, and we look forward to your immediate action on these issues, as access to testing and treatment of people are at stake.

Signed by:

*Access to Rights and Knowledge Foundation, Nagaland
Assam Network of Positive People
Bengal Forum of People who Use Drugs
Bichitra Jena, TB Survivor
Bulu Mallick, TB Survivor
Centre for Health and Mental Health, School of Social Work, TISS
Community Network for Empowerment Manipur
Delhi Network of Positive People
Delhi Users Network
Drug Action Forum – Karnataka
Freedom Foundation Trust
Ganesh Acharya, TB Survivor & Activist, Mumbai
Haryana Drug User Forum
Henry Zohmingthanga, Person Living with HIV, Mizoram
Health Care Community of Positive People, Beed (HCCP+)
HOPE, Community Based Organization of PLHIV, Manipur
Indian Drug Users Forum (IDUF)
Indian Network of People Living HIV/AIDS (INP+)
International Treatment Prepared Coalition, South Asia*

Jan Swasthya Abhiyan-Mumbai
Khalid, TB Survivor
Kolkata Rista, Community Based Organisation
Kripa Foundation Nagaland
Lawyers Collective
Manipur Network of Positive People (MNP+)
Manoj Pardesi, Person Living with HIV
Meghalaya State Network of Positive People
Mumbai TB Collective
Mumbai HIV/AIDS Forum
Nandita Venkatesan, TB Survivor and Activist
National Coalition of People Living with HIV in India (NCPI+)
Naz Foundation India
Positive Women's Network (PWN)
Punjab Network of Positive People
PWID, Community Based Organisation Tripura
Sahara Aalhad, Pune
Sahayog, Orissa
Sankalp Rehabilitation Trust
Sikkim Drug Users Forum
Subrat Mohanty, representing Developing Country NGO, Stop TB Partnership Executive Board
Survivors Against TB, India
TB Mukta Vahini
TB Survivors Forum Orissa
The Global Coalition of TB Activists
Touched by TB- the India National Coalition of people affected by TB
Voice of Patients
World Vision India

Cc.

Dr Lucica Ditiu, Executive Director, STOP TB Partnership
Dr Tereza Kasaeva, Director, Global Tuberculosis Programme, World Health Organization
Dr Meg Doherty, Director, Global HIV, Hepatitis, STI Programmes, World Health Organization