



The Delhi Network of Positive People

Honorable Shri Narendra Modi
Prime Minister of India
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13 January 2017

RE: Urgent need to save a young girl with XDR TB and ensure availability of new TB drugs in India to combat drug resistant tuberculosis

Respected Prime Minister,

Patients in India with drug-resistant tuberculosis (DR TB) are struggling to access effective treatment regimens. It is reflected in the case currently pending in the Delhi High Court¹ over lack of access to new TB drugs - bedaquiline and delamanid - for a young woman who has been slowly dying of extremely drug-resistant TB (XDR TB).

We, therefore, write to you as concerned citizens and organizations working on treatment and public health to express our concern on the bureaucratic delay in the roll out of diagnostics and new anti TB drugs to tackle the growing burden of DR TB in India and respectfully urge your attention and swift action.

Patients with multi- or extremely drug-resistant TB (M/XDR TB) are treated inadequately in India and often die because not enough medications are available to compose a suitable regimen. Current treatment for DR TB can involve people having to take almost 15,000 pills for two years, plus a daily painful injection for eight months. Side effects caused by the drugs are horrendous, ranging from persistent nausea to deafness and psychosis. There is a desperate need for new drugs to improve not just treatment outcomes but also to provide safer alternatives to the most toxic DR TB drugs.

The impact of introducing new drugs to the armamentarium of old TB drugs which are currently available under the RNTCP's Programmatic Management of Drug Resistant TB (PMDT) will enable clinicians in many settings across the country to improve care for their patients. The effect of introductions of two new drugs has substantial public health implications on reduced transmission of M/XDR TB.

Given the great urgency of the TB and DR-TB epidemics, we have been appalled by the slow roll out of life-saving innovations such as new TB drugs - bedaquiline and delamanid, and the necessary second line drug susceptibility testing (DST) - in India. Failure to ensure access to these interventions is a clear violation of the rights to health and to the benefits of scientific progress.

As such, we implore you to rectify this horrifying situation and ensure:

1. **immediate scale up of bedaquiline** — the new medicine has only reached fewer than 200 of the

¹ High Court of Delhi. Status of Cases. India: High Court of Delhi, 2016.
http://delhihighcourt.nic.in/dhc_case_status_list_new.asp

estimated 42,900–85,800 Indians with DR-TB, who are eligible for the drug according to WHO guidance². As reflected in the above-mentioned court case, Lal Ram Sarup TB Hospital, in line with RNTCP guidelines, has denied this young woman access to bedaquiline simply because she is not a domicile of Delhi. We urge you to ensure that bedaquiline is immediately made available nationwide to individuals suffering from M/XDR TB regardless of their domicile. To support the national effort, RNTCP should also accredit treatment providers in the non-governmental or private sector to provide M/XDR treatment with effective DR TB drugs such as bedaquiline.

2. **registration of delamanid** — Delamanid is also a new essential medicine for patients with M/XDR TB disease. It should be available under RNTCP's Programmatic Management of Drug Resistant TB (PMDT) and to other accredited health care providers with experience of treating M/XDR TB patients based on their drug susceptibility testing (DST) reports. Delamanid is also becoming increasingly important for treating children with DR-TB³. Yet, it is still not available in India. The young woman in the above illustrated court case is also struggling to access this drug which together with bedaquiline and other DR TB drugs could form an optimized regimen to save her life. We urge you to ensure that the Ministry of Health and RNTCP make efforts to get delamanid - a patented medicine - registered and available in India so that treatment needs can be met immediately. If necessary public health safeguards in the patent law should be operationalised to ensure the life saving drug becomes available in India and there is no abuse of the monopoly enjoyed by Otsuka the Japanese company.
3. **expansion of drug susceptibility testing** — The lack of access to second line drug susceptibility testing (DST) impacts access to appropriate M/XDR treatment for patients and will impact the scale up of new TB drugs and regimens. By late 2016, just 25 laboratories were certified to perform DST⁴. As a result, only one in five DR-TB cases in India are laboratory confirmed⁵. The young woman with XDR in the above illustrated court case was treated in 2013 with MDR TB drugs without a comprehensive DST report which may have amplified her resistance to TB drugs. Now, instead of owning up for and rectifying its failure to implement both appropriate diagnosis and treatment, the TB programme is denying her bedaquiline, which is extremely shameful.⁶ DST is an essential component of management of DR TB and as such we urge you to step in to ensure that RNTCP is implementing its promises that second line DST will be accessible throughout India to guide proper treatment.

We, the undersigned, strongly urge you to take action to save the young woman from Bihar who has been diagnosed with XDR TB and is struggling to access new TB drugs from RNTCP. Her plea to access bedaquiline from RNTCP and to import delamanid in small quantities for personal use on compassionate use grounds is pending before the Delhi High Court. Every day's delay brings her closer to death. We request you to direct RNTCP to provide her with life-saving drug on an immediate basis.

Please keep your promises to your people to end TB, and ensure access to innovations on diagnostics and treatment in India.

² Bonnet M, Bastard M, du Cros P, et al. Identification of patients who could benefit from bedaquiline or delamanid: a multisite MDR-TB cohort study. *Int J Tuberc Lung Dis* [Internet]. 2016 February; 20(2):177–86. doi: 10.5588/ijtld.15.0962.

³ World Health Organization. The use of delamanid in the treatment of multidrug-resistant tuberculosis in children and adolescents: Interim policy guidance. Geneva: World Health Organization; 2016. http://who.int/tb/publications/Delamanid_interim_policy/en/

⁴ Government of India, Central TB Division. TB India 2016: Revised National TB Control Programme Annual Status Report. India: Government of India; 2016.

⁵ World Health Organization. India: Tuberculosis profile. Geneva: World Health Organization; 2016.

⁶ <https://scroll.in/latest/826258/access-to-life-saving-drug-may-make-the-tb-patient-more-drug-resistant-and-spread-it-in-society>

So many lives depend on it.

Sincerely,



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Organizational Signatories:

ARK foundation, Nagaland (India)
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Global TB Community Advisory Board (Global)
Health GAP (Global Access Project) (Global)
HepCoN, Nagaland (India)
Hepatitis Coalition of Sikkim (India)
IMAXI Cooperative (Global)
Indian Drug Users Forum (IDUF) (India)
Kekhrie Foundation, Nagaland (India)
Mon Users' Network, Nagaland (India)
Nagaland Users' Network (India)
Network of Naga People Living with HIV/AIDS, Nagaland (India)
Network of Nagaland Drugs and AIDS organisation (NNagaDAO) (India)
Sankalp Rehabilitation Trust
Sikkim Drug Users' Network (India)
South Indian Drug Users Forum (India)
South Indian Harm Reduction Network (India)
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Individual Signatories:

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CC:

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