

01 July 2022

To,

Shri. Mansukh Mandaviya Union Minister of Health, India & Chair of the Stop TB Partnership Board	Shri. Rajesh Bhushan Secretary Ministry of Health & Family Welfare Union of India	Shri. Rajendra P Joshi DDG (TB) National TB Elimination Programme (NTEP) India
Shri. Piyush Goyal Honorable Minister of Commerce and Industry PMO India	Dr. Shri Guruprasad Mohapatra Secretary, Department for Promotion of Industry and Internal Trade	Prof. (Dr) Unnat P. Pandit Controller General of Patents, Designs & Trade Marks

Urgent: Support for Compulsory License to Address Access Barriers to Life-saving Tuberculosis Medicines, Bedaquiline and Delamanid

Dear Sirs,

We are writing as members of Tuberculosis (TB) affected communities, TB survivors, and civil society to bring to your immediate attention to urgent issue of patients struggling to access drug-resistant TB (DR-TB) treatment regimens that include bedaquiline and delamanid in India. Increased access to both drugs are necessary to address the ongoing DR-TB crisis in the country.

After a gap of 50 years, the new antibiotics, bedaquiline and delamanid, together with re-purposed drugs, provide opportunities to countries with a high burden of TB to improve the safety and efficacy of its DR-TB treatment regimens and thus, prevent further infections, resistance and deaths from TB.

In recent years bedaquiline has become a cornerstone of treatment regimens for DR-TB— a tough-to-treat form of the disease that affects an estimated 500,000 people every year worldwide. Prior to the introduction of this transformational drug, DR-TB was treated using toxic regimens lasting up to two years, with rates of treatment success below 50 percent. With bedaquiline given in combination with other new and repurposed TB medicines, DR-TB can now be treated in as little as six months, with rates of treatment success ranging from 70–90 percent depending on the regimen. Bedaquiline and delamanid are therefore, essential to the roll-out of injection-free regimens under the NTEP for adults and children. Delamanid particularly is of interest for treating children affected by Dr-TB.

. Bedaquiline and delamanid have a patent monopoly over them, which expires only in July and October 2023, respectively.

However, awaiting expiry of patent expiry in 2023, a number of Indian manufacturers are unable to move forward with any plans for the production of these drugs. With a singular player supplying bedaquiline and delamanid to the National TB Elimination program, there is limited scope for challenging the high prices being charged by the patentees. At INR 20,000 for Bedaquiline for a single course per patient, and INR 140 per tablet of delamanid, the DR-TB treatment in India, imposes a huge burden on the NTEP. Even though the primary patent on bedaquiline expires in 2023, but there are pending patent applications on the drug that could lead to evergreening.

Bedaquiline and delamanid are in short supply across various centres, and civil society from across the country is reporting their stock out.

The Indian Patents Act, 1970 empowers the government to issue a compulsory license can notify that compulsory license be issued in cases of national emergency, extreme urgency or for public non-commercial use. Further, special qualification is made in case the national emergency, extreme urgency or for public non-commercial use has arisen in context of tuberculosis.

This provision upholds the tenets affirmed in the Doha Declaration on the TRIPS Agreement and Public Health and even more recently, by the United Nations High-Level Panel on Access to Medicines (UNHLP).

Time and again, multiple countries have made use of this provision. Most recently, the Malaysian government affirmed its commitment to help the more than 400,000 people living with hepatitis C and scale up access to affordable treatment in the public health system throughout the country by issuing a 'government use' licence that enables its Ministry of Health to procure generic sofosbuvir at the lowest possible price.

India's generic companies, have supported many health responses within and outside the country, rendering India as the pharmacy of the world. Numerous health responses in India rely on generic medicines- that has resulted in affordable and timely access for treatment of many.

The grant of a government use license on grounds of public non-commercial use (under section 92 or under section 100 of the Patents Act) would create competition, significantly reducing government expenditure, provide impetus to the scaling up of access to these new TB drugs globally and help kick start the generic supply of new TB drugs to the NTEP.

In fact, there have been requests filed before the High Court of Bombay¹ seeking issuance of compulsory license on patents on Bedaquiline and delamanid. The petitioners therein have noted that their request to the DPIIT to issue such a notification has been rejected.

We urge

- Notify issuance of compulsory license over patents on bedaquiline (patent no. 236811) and delamanid (patent no. 250365);
- Immediately take stock of the tenders issued for procurement of bedaquiline and delamanid;
- Assess and put on record the available courses of Bedaquiline and delalamananid for the period of July-December 2022;
- Encourage generic suppliers to register the adult and child formulations of delamanid with the CDSCO to ensure timely access to this essential drug.

We hope the Indian government will issue compulsory licenses for patents on bedaquiline and delamanid to encourage and expedite entry of Indian generics versions of these drugs, This will be

¹ *MeeraYadav & Anr. v. Union of India*, PIL no. 495 of 2021 before the High Court of Judicature at Bombay

step towards making DR-TB treatment accessible for the communities that are being ravaged by the DR-TB crisis in India.

We look forward to your cooperation, and immediate action on these issues, as access to treatment of people is at stake.

Signed by:

Organisations:

1. Andhra Pradesh Drug Users' Forum, Andhra Pradesh
2. ARK Foundation, Nagaland
3. Association of TB People.in
4. Centre for Health and Mental Health, Mumbai
5. Delhi Drug Users' Network, Delhi
6. Evergreen Welfare Society, Nagaland
7. Longleng District Users' Network
8. Mlshbah
9. Mizoram Drug Users; Forum, Mizoram
10. Mon Users' Network, Nagaland
11. Mumbai AIDS Forum, Mumbai
12. Mumbai TB Collective, Mumbai
13. National Coalition of People Living with HIV in India (NCPI+), India
14. Network of Maharashtra by People Living with HIV/AIDS (NMP+)
15. Prayas Network of Positive People Welfare, Punjab
16. Sahara Aalhad
17. School of Social Work, Mumbai
18. Shansham Organisation, Nagaland
19. Sikkim Drug Users' Forum, Sikkim
20. TISS, Mumbai
21. Umeed Wellness Centre, Delhi
22. Users Network of Assam, Assam

Individuals:

1. Alokh Mohan, Activist, Delhi
2. Brinelle D'souza, Chairperson, CHMH, Mumbai
3. Daisy David, District Network for Chennai People living with HIV
4. Deepak Tripathi, Program Lead, Committed Communities Development Trust
5. Eldred Tellis, Sankalp Rehabilitation Trust, Mumbai
6. Elizabeth Selhore, Sahara CFRCAR
7. Ganesh Acharya, TB Survivor & Activist, Mumbai
8. Girish Kumar Kurra, Health Activist
9. Henry Zohmingthanga, PLHIV, Manipur
10. Karthik Krishnan, Activist, Chennai
11. Ketho Angami, Health Advocate, Nagaland
12. Kunal Kishore, Delhi
13. L. G. Hanghal, PLHIV, Manipur
14. Meera Yadav, XDR Survivor, Mumbai
15. Merlyn Dsa, Activist

16. Nirseen Ebrahim, CEO, Rangoonwala Fdn Trust, India
17. NK Lian Guite, Manipur
18. O. Harikumar Singh, TB survivor
19. Prabha Mahesh, Governing Board Touched by TB
20. Prashant Sharma, TB Survivor, Sikkim
21. Sashi, TB Activist, Nagaland
22. Shabab Alam, Activist
23. Shabana Patel, President, Network of Maharashtra by people living with HIV

Cc.

Dr Lucica Ditiu , executive Director ,STOP TB Partnership

Dr Tereza Kasaeva , Director , Global Tuberculosis Programme ,World Health Organization
WHO SEARO office