



Jan Swasthya Abhiyan

To,
Minister of Commerce and Industry Piyush Goyal
Health Minister Harsh Vardhan

Cc:
Secretary, Health
DDG, Central TB Division
DPIIT
WHO SEARO
UNAIDS
WHO-India

Date: 27th April

Sub: Requesting Indian Government to issue government use Compulsory Licence for TB drugs bedaquiline and delamanid

Dear Sir

We are writing to you as TB survivors, health activists, academicians, civil society organisations and concerned individuals. We are aware of the public interest litigation (PIL) (PUBLIC INTEREST LITIGATION (L) NO. 495 OF 2021 Meera Yadav & Anr. v Union of India & Ors.) has been filed before the High Court of Bombay seeking issuance of government use Compulsory Licence for two anti-TB drugs — bedaquiline (Bdq) and delamanid (Dlm). We would like to extend our support to the PIL and urge the Indian government to ensure uninterrupted supply of these medicines to every needy TB patient in the country by taking active steps to issue such a license.

Tuberculosis (TB) is a communicable disease which is the leading cause of death from a single infectious agent. It is one of the top 10 causes of death worldwide. Globally, nearly 1 crore people fell ill with TB in 2019 and nearly 14 lakh died (WHO's Global TB Report 2020). In 1993, the World Health Organization declared TB as a public health emergency. Later, in 2014, India's Union Ministry of Health and Family Welfare issued a statement that TB is a national emergency in India.

Drug-resistant TB (DR-TB) has emerged as a major public health challenge. It is more difficult to treat and has higher fatality rates. India is the worst effected country worldwide. Past many years' data shows that India accounts for more than a quarter of global DR-TB cases. In 2019, the country had an estimated 124,000 DR-TB cases, according to Global Report 2020. The Indian Government has set a target of elimination of TB by 2025, five years ahead of the global target of 2030. However, till patients of DR-TB are not treated properly, this target cannot be achieved.

Treatment of DR-TB has been a nightmare for patients. It leads to serious side-effects such as permanent hearing loss, peripheral neuropathy and loss of vision. There was a serious gap in research and development of new TB treatments which could save lives and give better quality of life to TB survivors.

After a gap of 50 years, two new TB drugs, Bdq and Dlm, were discovered in the last decade. Together with re-purposed drugs, they now provide opportunity to countries with a high burden of TB to improve the safety and efficacy of DR-TB treatment regimens and thus, prevent further infections, resistance and deaths.

These new drugs are safer, efficacious and oral. Older treatment regimens contain injectable drugs such as kanamycin and streptomycin. The World Health Organisation has repeatedly recommended their discontinuation due to severe side-effects. The new drugs are safer with lesser side-effects and better treatment success rates. Being oral, they are also easier to consume and hence improve adherence rate among patients.

Last year itself WHO had recommended that TB patients be put on oral medicines so that they can be treated in the safety of their homes. As we are living through the worst pandemic of our lifetime, shift to oral drugs from injections is all the more crucial. We witnessed last year that due to suspension of transportation and restriction of movement patients were unable to visit health centres to get their injections which put their treatment in a disarray. In the light of second wave of Covid-19, there is danger that similar situation may arise. Even if transport services are available, visiting health centres further exposes TB patients to Covid-19.

The Programmatic Management of Drug-Resistant TB (PMDT) guidelines of the Ministry of Health and Family Welfare recommend Bdq in treatment regimens for all MDR-TB patients above age 6 years of age. Dlm is crucial for younger children as the guidelines as it is safe for children aged 3 years and above. Older treatments force them to take injections which are painful and lead to disabilities.

However, the uptake of these medicine has been paltry so far. The India TB report 2021 shows that while 49,679 DR-TB cases were diagnosed in 2020, only 10,489 were initiated on Bdq and Dlm (10,140 on Bdq and 349 on Dlm). The report also admits that the notifications went down by as much as 25% last year due to Covid-19.

In such a scenario, scaling up of Bdq and Dlm is of utmost importance. However, monopoly of originator companies on these life-saving drugs pose serious barriers to their access. Johnson and Johnson holds the patent for Bdq and is the sole producer. Japanese company Otsuka is the patent holder for Dlm. Last year, Indian government's tender for Bdq failed and the government could not procure the medicine. This is in addition to the barrier of high price of Bdq at about INR 26,464 for a six-month course. Similarly, Dlm costs more than a lakh for a six-month course. A number of critical patients require both the medicines for longer periods, hence increasing the cost.

The government is required to immediately take measures to break monopoly of these companies so that generic manufacturers can start to produce these medicines. This will bring the prices down and ensure adequate supply as there will be multiple producers.

We urge the Indian government to issue compulsory licence for both the drugs as requested in the petition. International trade rules allow countries to issue licences when pharmaceutical companies fail to make patented medicines available and affordable to patients and governments. This has been affirmed in the Doha Declaration on the TRIPS Agreement and Public Health and by the United Nations High-Level Panel on Access to Medicines (UNHLP). India, too, supports the use of TRIPS flexibilities, the Doha Declaration and the UNHLP recommendations on access to medicines.

If the government is serious about making TB a history by 2025, then it has to make TB treatment accessible to all. Otherwise, it will remain an empty promise.

Signatories:

CEHAT (Centre for Enquiry Into Health and Allied Themes)

CHARM (Centre for Health And Resource Management)

Forum for Medical Ethics Society- Mumbai

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LokManch

Peoples Training & Research Centre- Baroda

SAHAYOG- Odisha

Vidhyayak Trust- Pune