Health, Ethics, and Law
Institute for Training, Research, and Advocacy

ijme Indian Journal of Medical Ethics

Covid-19 Insights: Analysis from Ethics, Human Rights and Law Perspectives

Jan Swasthya Abhiyan

Blog 22 | HEaL Institute & IJME – Covid-19 Insights | April. 28, 2021

Requesting Indian Government to issue government use Compulsory Licence for TB drugs bedaquiline and delamanid | Jan Swasthya Abhiyan

To,

Minister of Commerce and Industry Piyush Goyal
Health Minister Harsh Vardhan

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 andconcerned 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 ofBombay 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 governmentto ensure uninterrupted supply of these medicines to every needy TB patient in the country by taking activesteps to issue such a license.

Tuberculosis (TB) is a communicable disease which is the leading cause of death from a single infectiousagent. It is one of the top 10 causes of death worldwide. Globally, nearly 1 crore people fell ill with TB in2019 and nearly 14 lakh died (WHO's Global TB Report 2020). In 1993, the World Health Organizationdeclared TB as a public health emergency. Later, in 2014, India's Union Ministry of Health and FamilyWelfare 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 andhas higher fatality rates. India is the worst effected country worldwide. Past many years' data shows thatIndia accounts for more than a quarter of global DR-TB cases. In 2019, the country had an estimated124,000 DR-TB cases, according to Global Report 2020. The Indian Government has set a target ofelimination of TB by 2025, five years ahead of the global target of 2030. However, till patients of DR-TB arenot 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 permanenthearing loss, peripheral neuropathy and loss of vision. There was a serious gap in research anddevelopment 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. Togetherwith re-purposed drugs, they now provide opportunity to countries with a high burden of TB to improvethe 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 suchas kanamycin and streptomycin. The World Health Organisation has repeatedly recommended theirdiscontinuation due to severe side-effects. The new drugs are safer with lesser side-effects and bettertreatment success rates. Being oral, they are also easier to consume and hence improve adherence rateamong patients.

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

The Programmatic Management of Drug-Resistant TB (PMDT) guidelines of the Ministry of Health andFamily 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 while49,679 DR-TB cases were diagnosed in 2020, only 10,489 were initiated on Bdq and Dlm (10,140 on Bdqand 349 on Dlm). The report also admits that the notifications went down by as much as 25% last yeardue to Covid-19.

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

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

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

Jan Swasthya Abhiyan

LokManch

Peoples Training & Research Centre- Baroda

SAHAYOG- Odisha

Vidhyayak Trust- Pune

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