



To: Shri Mansukh L. Mansaviya  
Honorable Minister of Health and Family Welfare

Shri Piyush Goyal  
Honorable Minister of Commerce and Industry

Shri Rajesh Bhushan  
Secretary, Ministry of Health and Family Welfare

Dr. Shri Guruprasad Mohapatra  
Secretary, Department for Promotion of Industry and Internal Trade

Cc: Dr. Sudarsan Mandal  
DDG, Central TB Division

30 September 2021

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

Dear Sir,

We are writing as members of the Global Tuberculosis Community Advisory Board (TB CAB)—a group of research-literate tuberculosis (TB) treatment activists from around the world—to express our concern for patients struggling to access drug-resistant TB (DR-TB) treatment regimens that include bedaquiline (BDQ) and delamanid (DLM) in India. Increased access to both drugs is necessary to address the ongoing DR-TB crisis.

We welcome the announcement of the new 2021 Guidelines on the Programmatic Management of Drug-Resistant TB (PMDT),<sup>1</sup> in which the Ministry of Health and Family Welfare (MoHFW) recommends shifting to injectable-free regimens for DR-TB. The PMDT Guidelines also recommend that people with fluoroquinolone (FQ) resistance receive treatment with an 18–20-month regimen that includes BDQ and DLM. However, patients with FQ resistance in India are often provided access to regimens containing just BDQ, as DLM is not widely available. The inclusion of just one new drug is not enough to address the DR-TB crisis in India. An uninterrupted and continuous supply of BDQ and DLM is required for the National TB Elimination Program (NTEP) to scale up the new PMDT Guidelines and ensure optimized DR-TB treatment regimens are available across the country.

**Procurement – Challenges on Pricing**

We recognize the effort from NTEP to increase access to BDQ-containing regimens across the country. Several generic manufacturers could support this effort by further bringing down the price of BDQ for the TB program. One Indian generic manufacturer already has an application for 100 mg BDQ tablets under review by the World Health Organization (WHO) Pre-Qualification Program,<sup>2</sup> but a patent barrier restricts the company from entering the global market until July 2023.

---

<sup>1</sup>National TB Elimination Programme, Central TB Division, Ministry of Health & Family Welfare, Government of India. Guidelines for Programmatic Management of Drug Resistant Tuberculosis in India. March 2021. Available from: <https://www.tbcindia.nic.in/WriteReadData/1892s/8368587497Guidelines%20for%20PMDT%20in%20India.pdf>.

<sup>2</sup>World Health Organization – Prequalification of Medical Products. FPPs Under Assessment [Internet]. Accessed 10 September 2021. Available from: <https://extranet.who.int/pqweb/medicines/dossier-status>.

The DLM access crisis in India is grave. As of the end of March 2020, fewer than 400 courses of DLM had been administered by the NTEP, and the remaining NTEP stock of DLM is dwindling and inadequate to meet the program's needs. The NTEP is paying Viartis \$1,275 USD per six-month course of DLM. Despite several rounds of attempted negotiations by the NTEP, Viartis has refused to reduce the price of DLM in India. The DLM that Viartis currently supplies to the NTEP relies on Otsuka-sourced active pharmaceutical ingredient (API), which is very expensive. The development of API in India by generic manufacturers will bring the prices of DLM down. However, a patent barrier impedes alternative supplies of DLM API until after October 2023.

### **Challenges During Monopoly – Lack of Negotiation Power**

Negotiations for price reductions on a patented drug are more successful when pharmaceutical companies fear that governments will issue a compulsory license for generic supply if necessary. For example, in October 2001, the United States Secretary of Health and Human Services wanted to stockpile ciprofloxacin, the most effective anthrax treatment. Bayer, the patent owner, initially demanded a higher price from the government for ciprofloxacin. After the U.S. government announced it was considering issuing a compulsory license, Bayer significantly reduced the price of ciprofloxacin.<sup>3</sup> As another example, in August 2005 after failed negotiations, the National Health Council of Brazil (the top deliberating forum of the Brazilian national health system and chaired by the Ministry of Health) approved a resolution recommending compulsory licenses for lopinavir/ritonavir, efavirenz, and tenofovir and recommended the creation of public-private partnership for local production. After the resolution was announced the Ministry of Health succeeded in obtaining price reductions for lopinavir/ritonavir (from US\$1.17 to \$0.63 per capsule) and tenofovir (from US\$ 7.68 to \$ 3.80).<sup>4</sup> For efavirenz, the Ministry of Health eventually issued a compulsory license successfully reducing the price from US\$ 1.57 to \$ 0.60 per tablet via local production.<sup>5</sup> Thus, considering the policy option to issue a compulsory license may effectively increase the negotiation power of the NTEP to reduce the prices of DLM and BDQ in India. If not, the compulsory license can be acted on.

### **Failure of the Voluntary Licenses to Deliver Access to Affordable DLM and BDQ**

The terms of the licensing agreement between Otsuka and Viartis has limited Viartis' rights to supply DLM, rather than producing more affordable generic versions of the drug, until Otsuka's patent expires in October 2023. Under the existing agreement and due to delays completing technology transfer, Viartis can produce and supply DLM tablets using API sourced from Otsuka, impacting Viartis' ability to substantially reduce the price of DLM.<sup>6</sup> Johnson & Johnson has only provided a voluntary license to Pharmstandard (a Russian company) for the rights to supply bedaquiline to Russia and CIS countries, which has similarly failed to produce more affordable generic versions of bedaquiline; in fact, the countries covered by the license to Pharmstandard are paying more per six-month course of bedaquiline than other low- and middle-income countries. Without intervention the price of BDQ will remain too high in India and elsewhere until 2023 when Johnson & Johnson's primary patent expires and generics companies can enter the global and Indian markets.

### **Way Forward – Preparing Generics Companies**

Prices could fall by 50% to 90% through generic production of new TB drugs and scale up of procurement. The prices of antiretroviral drugs were driven down from over \$10,000 USD a year to less than \$100 USD a year when generics companies entered the market.

---

<sup>3</sup>Ooms G, Hanefeld J. Threat of compulsory licenses could increase access to essential medicines. *BMJ*. 2019 May 28;365:l2098.

doi: <https://doi.org/10.1136/bmj.l2098>.

<sup>4</sup>Nunn AS, da Fonseca EM, Bastos FI, Gruskin S. AIDS treatment in Brazil: impacts and challenges. *Health Aff (Millwood)*. 2009 Jul-Aug;28(4):1103-13. doi: [10.1377/hlthaff.28.4.1103](https://doi.org/10.1377/hlthaff.28.4.1103).

<sup>5</sup>Rodrigues, W. C. V., and O. Soler. 2009. "Compulsory Licensing of Efavirenz in Brazil in 2007: Contextualization." *Revista Panamericana de Salud Pública* 26: 553–559. doi: [10.1590/S1020-49892009001200012](https://doi.org/10.1590/S1020-49892009001200012).

<sup>6</sup>Médecins Sans Frontières Access Campaign. Voluntary Licenses and Access to Medicines, Technical Briefing Document. October 2020. Available from: [https://msfaccess.org/sites/default/files/2020-10/IP\\_VoluntaryLicenses\\_full-brief\\_Oct2020\\_ENG.pdf](https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf).

**We urge the Indian government to issue compulsory licenses for patents on BDQ and DLM to encourage and expedite Indian generics suppliers to make BDQ and DLM more affordable for the NTEP and other treatment providers and accessible to communities that are being ravaged by the DR-TB crisis in India.**

### **Our Request to MoHFW Policymakers**

In 2013, the MoHFW made recommendations to, what was at the time, the Department of Industrial Policy and Promotion (DIPP) for issuing a compulsory license under Section 92 of the Patents Act on the exorbitantly priced breast cancer drug trastuzumab, which was under a patent monopoly.<sup>7</sup> The MoHFW recommendation led to the Swiss pharmaceutical giant Roche withdrawing its patent and the launch of more affordable biosimilars. The NTEP and MoHFW need to work together to ensure that their recommendations do not undermine the case for compulsory licenses for new TB drugs.

The Indian government has shown leadership in the COVID-19 pandemic and suggested the waiver of intellectual property barriers, including patents, to ensure the swift scale-up of manufacturing capacity of COVID-19 drugs, diagnostics, and vaccines to ensure affordable and timely access around the world. We ask that the same standard and policy be applied to the patent barriers impeding generic manufacture and supply of lifesaving TB drugs to Indian patients.

With an annual incidence of 124,000 cases, India accounts for 27% of the global burden of DR-TB. TB was declared a global emergency by the WHO in 1993 and a national emergency by Government of India in 2014. TB, the leading infectious disease killer in the world until COVID-19, continues to be a global driver of antimicrobial resistance (AMR). In authorizing compulsory licenses for medicines required to treat DR-TB, the Government of India's actions would be in line with the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration on TRIPS and Public Health. A compulsory license can improve access to affordable supplies of new TB drugs to the NTEP, reduce rationing of BDQ and DLM at DOTS plus centers, and prevent further TB drug resistance that will inevitably develop in the absence of consistent access to optimized treatment regimens.

The Government of India's urgent action is necessary to facilitate generic competition and affordable access to the life-saving medicines, BDQ and DLM. We urge the government to act within its sovereign right to invoke lifesaving legal and policy provisions to restore the health and dignity of its citizens, whose lives have been wracked by concurrent public health crises.

Sincerely,  
Patrick Agbassi, Chair  
On behalf of the Global TB CAB

### **About the Global TB Community Advisory Board (TB CAB):**

The TB CAB is a group of strong, research-literate community activists from HIV and TB networks in Asia, Europe, Africa, and North and South America. Founded in 2011, the TB CAB acts in an advisory capacity to: product developers and institutions conducting clinical trials of new TB drugs, regimens, diagnostics, and vaccines; and provide input on study design, early access, regulatory approval, post-marketing, and implementation strategies. The TB CAB is dedicated to increasing community involvement in TB research and access to tools to fight TB, and to mobilizing political will.

---

<sup>7</sup>Mint. Health ministry recommends compulsory license of three anti-cancer drugs [Internet]. 16 January 2013. Available from: <https://www.livemint.com/Companies/F3Rn5jCkKjCJNYzhtuQseO/Health-ministry-recommends-compulsory-licensing-of-three-ant.html>.