

Extreme TB: No licence to heal

On September 19, 2017, a panel chaired by Dr. Soumya Swaminathan, then Director-General of the Indian Council of Medical Research and currently the Deputy Director-General of the World Health Organisation (WHO) recommended, among other steps, that the Health Ministry consider issuing a compulsory licence (CL) for the two TB drugs.

Dr. Swaminathan said recently that India should consider the CL option for the two drugs, if the country runs out of options. "We need better access to new TB drugs. We need to think of some feasible strategies," she said. "One particular strategy would be to think about compulsory licensing. We have enough companies in India that can manufacture and market these drugs and cost can be brought down, and at the same time, the innovator company will get their royalties," she said.

A CL can be issued by the government under the World Trade Organization's trade-related intellectual property regime, in case of 'extreme urgency' and 'national emergency,' without waiting for voluntary licensing.

Union Health Ministry sources said it had requested Janssen and Otsuka, to grant Voluntary Licenses.

A VL would allow them to pay a royalty to the innovators and manufacture affordable generic versions. *The Hindu* found that both companies turned down the Health Ministry's request. While Janssen said it will increase its donations, Otsuka did not respond to a query. Otsuka has appointed Mylan India, subsidiary of a US pharma company, as a distributor (not manufacturer).

A Janssen spokesperson said, Bedaquiline is manufactured in India and exported. This has upset domestic TB patients, who would have face rationing or uncertainty after donations are phased out in 2019. "Only 1,000 Indians have access to this medicine. What will they do after the donations run out," asks Ketholelie Angami, an activist.

Active transmission

An estimated 1,300 Indians die due to TB everyday. India is home to the largest number of TB patients, at 2.8 million. Around 1,30,000 have become resistant to medicines.

The Health Ministry has made little progress on Dr. Swaminathan's recommendations. The compulsory licensing committee has not met since 2014 and senior Ministry officials said they would not consider a CL due to pressure from the US government. The Joint Secretary, Health Ministry, Sudhir Kumar, said the government was unable to issue a CL because "no company has come forward to apply for compulsory licence for the drugs before the competent authority."

India used the CL option first in 2012, and the Supreme Court upheld manufacturer Natco's move to make a generic version of Bayer's cancer drug Nexavar. The move cut the price by 97%, from Rs. 2.8 lakh to Rs. 8,800. D.G. Shah, Secretary-General, Indian Pharmaceutical Alliance, said no generics company wanted to apply for a CL after the "harassment" that Natco faced since it sought a CL.

Health Ministry sources said Bedaquiline could cost \$900 for a 6-month course and Delamanid, \$1,700.

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