India plans to expand access to new tuberculosis drug

The Government of India is planning to increase access to a new drug for drug-resistant tuberculosis after a landmark court ruling. Dinesh C Sharma reports from New Delhi.

With 2·8 million new cases a year, India has the highest tuberculosis burden in the world, according to WHO's *Global Tuberculosis Report 2016* released in October last year. The disease kills almost 500 000 Indians a year. Free treatment is provided under the government's Revised National Tuberculosis Control Programme (RNTCP). Yet access to drug susceptibility testing and treatment remains a problem, especially for those with drug-resistant forms of tuberculosis. This issue was brought into sharp focus in a recent landmark lawsuit filed by Shreya, an 18-year-old girl with extensively drug resistant tuberculosis (XDR-TB). She approached the Delhi High Court after having failed to access bedaquiline—a new drug for the treatment of multidrug-resistant (MDR-TB) and XDR-TB—in a government facility. The court intervention that facilitated treatment for the girl could now help thousands of other patients with drug-resistant tuberculosis.

The access to bedaquiline is regulated under the government's guidelines for management of drug-resistant tuberculosis and only six government-run health facilities in the country are permitted to administer it. Despite being clinically qualified for enrolment, Shreya was denied the treatment because she was not a resident of New Delhi, where one of the six centres she approached is located. After initially defending its position in the court case, the government opted for a settlement agreeing to provide the drug to Shreya and also to abandon the residency or domicile criterion.

"The domicile rule was never a part of the government policy, but it was in practice. Now patients clinically eligible for bedaquiline cannot be denied treatment on the basis of their residence. This will enable many more to get treatment and expand overall access", noted Anand Grover of Lawyers Collective, a New Delhi-based human rights group that fought the case for Shreya. At present, only about 200 XDR-TB patients are on bedaquiline treatment. In the court settlement, government lawyers stated that bedaquiline treatment would be scaled up to more centres soon. However, when and how many states is unclear as yet. The RNTCP did not respond to *The Lancet*'s requests for comment.

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Encouraged by the court's intervention, health advocates are also seeking inclusion of delamanid, another new drug for treatment of MDR-TB and XDR-TB in the RNTCP. The drug has been patented in India by Japanese firm Otsuka since 2008 but the company has not sought regulatory approval for its marketing. "It is time the government enforces public health safeguards in the patent law and licenses the drug to generic firms so that they can manufacture it for government supplies", said Paul Lhungdim from the Delhi Network of Positive People. Patients' groups have also appealed to the health ministry to expand the network of certified laboratories for undertaking drug susceptibility testing to handle drug resistant cases speedily.

Experts suggest striking a balance between the need to regulate use of new tuberculosis drugs and rights of those in dire need of such drugs. "Not allowing sale of such drugs on the open market, for example, would be a reasonable restriction. But what governments like India are doing now—and those in other high-burden countries like Peru and Nigeria—is rationing the drug in a severe way. This actually defeats the purpose of having a new therapeutic tool like bedaquiline", said Jennifer J Furin, Harvard Medical School, MA, USA, who gave her opinion as an expert in the court case.

However, Clifton E Barry III from the National Institute of Allergy and Infectious Diseases, MD, USA, supports a more cautious approach. He said that "since we have a very finite supply of new agents in development for TB, there is a need to be careful to not lose them by encouraging widespread use before we have a combination that has a low probability of rapid emergence of resistance that can be launched at the same time. Individual agents are not likely to save people's lives because resistance emerges so easily to most agents."

In a related development, the supreme court has directed the government to introduce a daily fixed-dose regimen, replacing the current regimen of multiple tablets three times a week for all tuberculosis patients. The health ministry says that it needs 9 months to roll out the new plan. The new regimen is likely to ease the problem of poor adherence that leads to resistance. At the same time, introduction of new drugs for people diagnosed with drug-resistant forms could increase survival rates. "The trust people had in the TB programme has eroded over the years with resurgence of TB in high numbers, especially with MDR and XDR-TB. It's time RNTCP takes concrete steps to make itself relevant and responsive to the communities' needs", adds Grover.

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For **WHO's Global Tuberculosis Report 2016** see http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf?ua=1

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