



# WHO launches plan for cheaper TB drugs

Invites proposals from pharma industry to produce affordable medicines

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The World Health Organization (WHO), on Tuesday, invited pharmaceutical companies around the world to submit proposals to manufacture affordable versions of newer medicines for treatment of drug resistant tuberculosis.

A WHO spokesman said the aim was to replicate the success of addressing the HIV epidemic. Competition among Indian drug producers had then brought down the price of HIV medicines by 99% from \$15,000 per patient per year to less than a dollar a day.

WHO has now requested drug makers to submit an Expression of Interest (EoI) for Bedaquiline and Delamanid, two new-generation drugs, recommended for drug resistant-TB. Under WHO norms, drugs submitted upon such requests and complying with its standards are included in a list for procurement by the UN and other organisations.

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the world, but the Health Ministry gets only 10,000 doses of Bedaquiline and 400 doses of Delamanid. The medicines are obtained as donations from Janssen (US) and Otsuka Pharmaceuticals (Japan), the respective manufacturers.

"One of the aims of pre qualification is to ensure that a greater number of manufacturers are supplying quality medicines, which, in turn, means a more competitive market and more affordable prices. We have seen this with HIV, where the pre-qualification of many predominantly Indian manufactured products brought the

price down of many anti-retrovirals. Inclusion within the scope of PQ has also incentivised the development of fixed dose combinations, which have yielded much better results for patients," said Daniela Bagozzi, communication manager, WHO.

In the case of HIV, one company, Cipla, came up with a 'AIDS cocktail' combination of Stavudine, Lamivudine and Nevirapine, enabling effective treatment.

Cheaper drugs to treat HIV became possible at the time as the Indian Patents Act did not provide for product patents on pharmaceutical products, until required by the Trade Related Intellectual Property Rights (TRIPS) framework of the World Trade Organization (WTO). India became TRIPS compliant with pharma product patents in 2005.

## Open to generics

"The whole world looks to India to provide access to affordable drugs because of our capabilities. With WHO's backing, we will be able to accelerate introduction of

generics," said D.G. Shah, secretary general, Indian Pharmaceutical Alliance (IPA).

Inclusion of the two new drugs, Bedaquiline and Delamanid, in the pre-qualification call is being interpreted by aid agency Médecins Sans Frontières (MSF) as WHO's backing for generics.

Christophe Perrin, pharmacist at MSF, said, "It is clear from the EoI that WHO considers the two drugs key compounds to address challenges of drug-resistant TB. It also means that they want to encourage generic competition to start finding ways to make these medicines available in countries where they are not yet registered. The EoI allows generics manufacturers interested in producing these two drugs, and currently facing technical challenges, to address their questions to WHO's pre-qualification team."

Arun Kumar Jha, Economic Advisor, Union Health Ministry, said, "We are not wasting a single moment in ensuring affordable versions of these medicines are scaled up."