**EMBARGOED UNTIL 9am CET on TUESDAY 8 NOVEMBER 2022**

**New MSF report warns that major opportunity to increase access to newer, safer DR-TB drugs is at risk**

*With newer TB drugs to go off patent in 2023, MSF calls on J&J, Otsuka, and TB Alliance to remove additional barriers blocking generic manufacturers from entering the market*

*Geneva, 8 November 2022 –* A report released today by Doctors Without Borders (MSF) finds that two newer tuberculosis (TB) drugs – bedaquiline and delamanid – going off patent in 2023 presents a critical opportunity to increase access to shorter, safer and better treatment for people with drug-resistant forms of the disease (DR-TB), but that additional barriers need to be removed so more manufacturers can enter the market and bring prices down.

The report – *DR-TB Drugs Under the Microscope, 8th edition* – surveys the pricing and patent landscape of DR-TB medicines for adults and children and finds that extremely high prices are still being charged for newer TB drugs; a key factor hampering treatment scale-up. With DR-TB cases [increasing](https://www.who.int/teams/global-tuberculosis-programme/tb-reports/global-tuberculosis-report-2022) for the first time in years, MSF called on pharmaceutical corporations and other drug developers to immediately dismantle the barriers blocking generic manufacturers from entering the market, so that production of these drugs can be scaled up, leading to increased access to affordable, safer, and more effective medicines for people who need them.

“I was diagnosed with DR-TB in 2013 and was treated with older medicines with terrible side effects that left me in significant pain, did not cure me, and ultimately resulted in the loss of one of my lungs,” said Meera Yadav, XDR-TB survivor in Mumbai, India and co-petitioner in a [TB survivors’ court case](https://msfaccess.org/msf-supports-tb-survivors-court-case-indian-government-override-patents-lifesaving-tb-drugs) for the Indian government to override patents on bedaquiline and delamanid. “When I was finally able to access the newer, lifesaving TB drugs, I realised that no one should have to go through such a harrowing experience – it is outrageous that patents and other barriers are stopping anyone who needs these TB drugs from accessing them.”

Currently, bedaquiline and delamanid are still patented medicines for which the originator pharmaceutical corporations, Johnson & Johnson (J&J) and Otsuka respectively, have a global monopoly blocking price-lowering competition among generic manufacturers. According to [research](https://pubmed.ncbi.nlm.nih.gov/28073970/) that estimates the cost of production plus a profit, delamanid is a shocking 13-18 times more expensive than it could be; ranging from US$1,250 to $1,700 for a 6-month treatment course, when it could be priced at $96. Bedaquiline is almost three times more expensive than it could be, at $270 for a 6-month treatment course, when it could be $102.

With the patents on bedaquiline and delamanid expiring in 2023, generic manufacturers could enter the market and lower prices. However, barriers may prevent this, including secondary patents that extend the term of the monopoly for J&J and Otsuka in several countries; and opaque and restrictive licenses that undermine competition, such as the restrictive voluntary license between J&J and the not-for-profit organisation TB Alliance. In addition, generic manufacturers require samples of the originator product (i.e. delamanid or bedaquiline) in order to conduct the studies necessary to bring quality-assured generic medicines to market. However, pharmaceutical corporations generally do not make their products available for such studies. The World Health Organization (WHO) should address this additional barrier to entry by establishing a process for obtaining the necessary samples.

"In ourMumbai clinic, we are receiving increasing numbers of patients with TB with complex resistance who are in need of bedaquiline and delamanid to form an effective treatment regimen,” said Dr Mabel Morales, Medical Coordinator for MSF in India. “There is an urgent need for delamanid to be more widely available for patients for whom an effective regimen cannot otherwise be formulated. The high price of delamanid is not only limiting our capacity to treat more patients but is also limiting the efforts of national TB Programmes to scale up the treatment.”

In addition to bedaquiline and delamanid, pretomanid remains an important component of DR-TB treatment regimens, including in the new BPaLM regimen evaluated in MSF’s [TB PRACTECAL](https://msf.org.uk/tb-practecal) clinical trial and [recommended](https://www.who.int/news/item/02-05-2022-who-issues-rapid-communication-on-updated-guidance-for-the-treatment-of-drug-resistant-tuberculosis) by WHO in May 2022.1 However, the current lowest global price for this regimen is out of reach at around $700 for a six-month course, with pretomanid alone accounting for nearly half the cost at $336. Given the significant public funding that the TB Alliance received for the development of pretomanid, this is unacceptable, especially considering that [research](https://pubmed.ncbi.nlm.nih.gov/28073970/) estimates it could be produced and sold at profit for $210, much less than its current price. MSF has contended that in total, the price of a complete DR-TB treatment course should be no more than $500 per person.

“Bedaquiline, delamanid, and pretomanid are game-changing TB drugs that could help save many more lives, so everyone with DR-TB should be able to access them,” said Christophe Perrin, TB advocacy pharmacist with MSF’s Access Campaign. “Drug corporations should not put their profits over people’s lives. It’s time for all three newer TB drugs to be affordable.”

Additionally, the limited number of children being diagnosed and treated for DR-TB means that manufacturers may not consider the paediatric TB market viable, even though children affected by DR-TB can now be treated with complete regimens made up of medicines in child-friendly formulations. Governments need to urgently step-up efforts to diagnose and treat more children with DR-TB, and pool their needs and procurement across countries to help secure sustainable supply. There needs to be more competition among generic and originator companies to bring prices of newer medicines, bedaquiline and delamanid, down after patents expire.

***Notes to the Editor:***

MSF is one of the largest non-governmental providers of TB treatment in the world. In 2021, 17,221 people in MSF’s care were started on TB treatment, including 2,309 with drug-resistant TB.

1 MSF is mindful of high level of resistance to fluoroquinolones in some regions (e.g., India) and that BPaLM (specifically the “M” = moxifloxacin belonging to the fluoroquinolone drug class) may not always be appropriate, which is why individualised [regimens](https://www.msf.org/delamanid-must-be-more-affordable-tuberculosis) containing the other new drug delamanid combined with bedaquiline, linezolid, clofazimine and other DR-TB drugs are important in such contexts. In addition, alternative regimens are being tested in the MSF sponsored endTB-Q clinical trial and were tested in the TB-PRACTECAL trial.