**Lifesaving TB medicines must be affordable and available to make all-oral treatments for children a reality**

*Paediatric formulations of bedaquiline and delamanid are still out of reach*

*Geneva, 3 September 2021* – The World Health Organization (WHO) recently released [new rapid guidance](https://www.who.int/publications/i/item/9789240033450) recommending that children of all ages with drug-resistant tuberculosis (DR-TB) have access to all-oral treatment using the drugs bedaquiline and/or delamanid. All-oral regimens simplify DR-TB treatment for children and caregivers by eliminating the use of injectable drugs that can cause deafness and by making the treatment regimens shorter, less toxic, and more effective.

However, adopting these new recommendations in high TB burden countries requires access to the paediatric formulations of bedaquiline (produced by Johnson & Johnson) and delamanid (produced by Otsuka and its local partner Viatris). In addition to the slow pace of national guideline changes, access to children’s formulations has been a challenge in high TB burden countries due to high prices and the lack of registration and generic competition. In Doctors Without Borders’ (MSF) experience, the registration and supply of paediatric formulations are not prioritised by pharmaceutical corporations, and having only one manufacturer for a given drug often results in these formulations being more expensive than the adult versions.

**Paediatric formulations of delamanid**: Dispersible 25mg tablets are *only* available under Otsuka’s compassionate use programme for children weighing more than 10 kg, until the end of 2021. The drug will be supplied next year through the Global Drug Facility (GDF) at a currently unknown price. For children and adolescents weighing more than 30 kg, GDF is supplying Otsuka’s adult 50mg tablets at US$1700 for a 6-month treatment course. Patent barriers prevent generic manufacturers, particularly in India, from supplying delamanid at lower prices to enable rapid scale-up of this drug.

**Paediatric formulations of bedaquiline**: Dispersible 20mg tablets produced by Johnson & Johnson (J&J) are available through the GDF at a price of $200 for a 6-month treatment course for children 5-12 years old, weighing at least 15 kg. For children and adolescents over 12 years old, J&J’s adult 100 mg tablets are available through GDF for $270 for a 6-month treatment course. Prices of both these bedaquiline formulations remain too high to allow the scale-up of DR-TB care in children, especially for those in need of regimens combining bedaquiline and delamanid.

**Dr. Mabel Morales, MSF Medical Coordinator in India**

“The WHO’s updated rapid guidance is an important step forward for younger children with drug-resistant TB to receive all-oral treatment without painful injectable drugs. However, this new guidance will remain a distant reality for children unless access barriers to paediatric formulations of bedaquiline and delamanid are overcome, allowing them to be rolled out by national TB programmes in all high-burden countries.

The high price of delamanid of $1700 per treatment course has significantly limited access in many countries. In India, negotiations with Otsuka and Viatris have been unsuccessful, with the manufacturers refusing to lower the price to the $942 currently being offered to South Africa by Viatris. The price of paediatric formulations of bedaquiline also remain too high. It’s time to smash the status quo: pharmaceutical corporations Johnson & Johnson and Otsuka must open up to generic supply and lower prices in order for TB programmes to scale up all-oral treatment regimens.

MSF also calls on governments of high-burden countries to take measures to overcome patent barriers and allow production of these lifesaving drugs through generic manufacturers.

As treatment providers, we see kids with drug-resistant TB on an almost daily basis in our independent clinic in Mumbai. We no longer want to see these younger children suffer the terrible side effects of the older and painful injection-based drugs, when safer and more effective oral medicines are available elsewhere.”