



Treatment Action Group

Secretary of the Expert Committee on the Selection and Use of Essential Medicines
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211, Geneva 27, Switzerland

20 May 2021

Re. Statement of support for the addition of bedaquiline 20 mg dispersible tablet to the World Health Organization Model List of Essential Medicines for Children

Dear Expert Committee:

Treatment Action Group (TAG) submits this letter **in support** of adding a 20 mg dispersible tablet formulation of bedaquiline to the World Health Organization (WHO) Model List of Essential Medicines for Children (EMLc) for the treatment of tuberculosis (TB). TAG is an independent, activist, and community-based research and policy think tank committed to racial, gender, and LGBTQ+ equity; social justice; and liberation, fighting to end the HIV, TB, and hepatitis C virus (HCV) epidemics, including in children. TAG has been a leading voice in advocacy to support the earlier inclusion of children in TB research and development and efforts to expand access to child-friendly formulations of TB medicines.

Bedaquiline is currently recommended by the World Health Organization (WHO) as a Group A drug, included as a core component of nearly all regimens recommended for the treatment of drug-resistant TB.¹ Bedaquiline has been especially important to the global scale up of all-oral regimens, serving as a replacement for the injectable agents.

We note that the bedaquiline 20 mg dispersible tablet is one of very few pediatric TB formulations assessed in controlled trials in children with drug-resistant TB. Based on pediatric pharmacokinetic and safety studies conducted by Janssen and the IMPAACT network (NCT02354014 / NCT02906007), the WHO recommends bedaquiline for the treatment of adolescents and children down to six years old with drug-resistant TB.² The WHO is currently undertaking a review to inform whether bedaquiline will be recommended for the treatment of children younger than six years old.³

¹ World Health Organization. WHO consolidated guidelines on tuberculosis. Module 4: Treatment; Drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2020. <https://www.who.int/publications/i/item/9789240007048>.

² World Health Organization. WHO consolidated guidelines on tuberculosis. Module 4: Treatment; Drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2020. <https://www.who.int/publications/i/item/9789240007048>.

³ World Health Organization [Internet]. Development of updated WHO guidelines on the management of tuberculosis in children and adolescents. Geneva; World Health Organization; May 2021. <https://www.who.int/news/item/07-05-2021-development-of-updated-who-guidelines-on-the-management-of-tuberculosis-in-children-and-adolescents>.

In August 2019, the U.S. Food and Drug Administration (FDA) approved bedaquiline for use in adolescents ($12 \leq 18$ years old) and in May 2020, approved Janssen's 20 mg bedaquiline dispersible tablet for children $5 < 12$ years old weighing at least 15 kg.⁴ The Janssen- and IMPAACT-sponsored studies are currently recruiting children younger than five years old.⁵ In June 2020, the bedaquiline 20 mg dispersible tablet was added to the Stop TB Partnership Global Drug Facility (GDF) catalogue and Pediatric DR-TB Initiative.⁶

More than 30,000 incident cases of drug-resistant TB in children are estimated globally each year, however the number of children 0-14 years old reported to WHO as enrolled in treatment for drug-resistant TB was just 5,568 in 2019.⁷ Access to child-friendly formulations of second line TB medicines, especially bedaquiline, will be critical to closing this gap and ending unnecessary morbidity and mortality among children affected by drug-resistant TB.

Thank you for the opportunity to share our views on the importance of adding the bedaquiline 20 mg dispersible tablet to the WHO EMLc. If you need additional information on our support of this application, please contact Lindsay McKenna, Lindsay.McKenna@treatmentactiongroup.org.

Respectfully submitted,



Lindsay McKenna, MPH
TB Project Co-Director
Treatment Action Group

⁴ Johnson & Johnson [Internet]. U.S. FDA Approves New Pediatric Formulation of SIRTURO® (bedaquiline) as Part of Combination Therapy to Treat Children with Pulmonary Multidrug-Resistant Tuberculosis. 27 May 2020. <https://www.jnj.com/u-s-fda-approves-new-pediatric-formulation-of-sirturoo-bedaquiline-as-part-of-combination-therapy-to-treat-children-with-pulmonary-multidrug-resistant-tuberculosis>.

⁵ McKenna L. Tuberculosis Treatment Pipeline Report 2020. New York: Treatment Action Group; 2020. https://www.treatmentactiongroup.org/wp-content/uploads/2020/11/pipeline_tb_treatment_2020_final.pdf.

⁶ Stop TB Partnership [Internet]. Following US FDA Approval, Child-Friendly Bedaquiline Available from Stop TB Partnership's GDF Pediatric DR-TB Initiative. 11 June 2020. http://www.stoptb.org/news/stories/2020/ns20_021.html.

⁷ Global tuberculosis report 2020. Geneva: World Health Organization; 2020. <https://www.who.int/publications/i/item/9789240013131>.