



May 9, 2021

The 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

Re: Statement in support of including bedaquiline, 20mg dispersible tablet, in the World Health Organization Model List of Essential Medicines

Dear Colleagues:

I am writing to you to express the strong support of the Sentinel Project on Pediatric Drug-Resistant Tuberculosis for inclusion of the 20mg dispersible tablet pediatric formulation of the antituberculous medication, bedaquiline, in the WHO Model List of Essential Medicines. The Sentinel Project on Pediatric Drug-Resistant Tuberculosis is a network of more than 900 individuals from 73 countries involved in the care of children and adolescents with DR-TB. As such, we understand the unique issues and challenges in the treatment of children with DR-TB and have first-hand experience providing care for thousands of children around the world.

Bedaquiline is currently recommended by the WHO for the treatment of children with DR-TB who are ages six years and above and it is anticipated that dosing recommendations in younger children might be released in 2021.. The current adult formulation of bedaquiline, however, is a non-scored, 100mg tablet that must be cut, crushed, or otherwise manipulated to administer the medication to small children. This process may be difficult for children and their caregivers and could lead to sub-optimal dosing, administration and adherence.

The 20mg dispersible tablet has been assessed in controlled trials in children with DR-TB and is an acceptable formulation. Improving access to it would alleviate the need for extemporaneous manipulation of the adult tablet and result in more optimized dosing for younger children. We thus support the inclusion of this medication on the EML.

Thank you for your attention to this matter and for the work you are doing to improve the care of children with DR-TB. If you need additional information in support of this application, please do not hesitate to contact our team.

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer Furin". The signature is written in a cursive, flowing style.

Jennifer Furin, MD., PhD.

Director of Capacity Building

Sentinel Project on Pediatric Drug-Resistant TB