



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 delamanid, 25mg 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 25mg dispersible tablet pediatric formulation of the antituberculous medication, delamanid, 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.

Delamanid is currently recommended by the WHO for the treatment of children with DR-TB who are ages three years and above. The current adult formulation of delamanid, however, is a non-scored, 50mg tablet that undergoes changes that affect its bioavailability if it is cut, crushed, or otherwise manipulated as must be done to administer the medication to small children. As such, using the current formulation to treat children with DR-TB could potentially result in under- or over-dosing and lead to sub-optimal outcomes and increased adverse events in young children.

The 25mg 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. Our network members have used this 25mg dispersible tablet formulation to treat young children and have found it to be acceptable to both children and their caregivers as well as to providers caring for these children. Although our experience is limited, the overall positive results we have seen in treating young children with the pediatric delamanid 25mg dispersible tablet lead us to 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