



TO: Secretary of the Expert Committee on the Selection and Use of Essential Medicines
Medicines Selection, IP and Affordability (MIA)
Department of Health Products Policy and Standards (HPS)
World Health Organization
By email via emlsecretariat@who.int

April 5, 2023

Re: Letter of Support for Removal of Age Cutoff for Delamanid on the World Health Organization Model List of Essential Medicines (EML) and EML for Children (EMLc)

Dear Expert Committee,

On behalf of the Supporting, Mobilizing, and Accelerating Research for Tuberculosis Elimination (SMART4TB) Consortium, we write in strong support of the application from the World Health Organization (WHO) Global Tuberculosis Programme to remove the age cutoff for delamanid.

As we expressed in our similar letter of support for removing age restrictions for bedaquiline, children bear a heavy burden of TB, with an estimated [1 million pediatric cases of TB](#) each year. [TB is a leading cause of death in children](#) under five. While children do very well on treatment – [almost all \(96 percent\)](#) childhood TB deaths occur in children not on treatment – with [cases of drug-resistant TB on the rise](#), the importance of effective, safe, and tolerable TB treatment options for children is greater than ever.

Delamanid is a key component of shorter, all-oral regimens, that benefit patients, caregivers, and program alike. While delamanid is currently included in both the EML and EMLc for use in children aged three years and older, even younger children stand to benefit from its use. Based on evidence regarding the safety, efficacy, and dosing of delamanid in children, we support the removal of the age limit to encourage the availability of delamanid for people of all ages with drug-resistant TB. Importantly, this will bring the EML and EMLc in line with the most recent [WHO guidelines](#), which include recommendations on the use of delamanid in children of all ages.

SMART4TB intends to transform TB care using person-centered methods and tools, especially for neglected populations including children. Making delamanid accessible for people of all ages, including and especially young children, is critical to achieving these goals. Removing unnecessary age barriers for delamanid will be a vital step forward toward this end.

We appreciate your consideration of this application and look forward to the EML and EMLc coming into alignment with evidence and with WHO guidelines by removing age restrictions for delamanid. Please do not hesitate to contact Erica Lessem, ellessem1@jh.edu, if you need any further information.

Disclaimer: The views and opinions of authors expressed herein do not necessarily state or reflect those of the U.S. Government or USAID.



Thank you in advance,

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