



*International Office*

*140 Route de Ferney, Case Postale 1224*

*CH-1211 Geneva 1, SWITZERLAND*

*Phone: +41 (0)22 849 84 00*

*Fax: +41 (0)22 849 84 88*

*www.msf.org*

## **C.6 Delamanid – removal of age restriction**

MSF supports the WHO Global Tuberculosis Programme proposal to remove the age limit for the use of delamanid in both the WHO Model List of Essential Medicines (EML) and the WHO Model List of Essential Medicines for Children (EMLc).

Currently, delamanid is listed in the Complementary List of Section 6.2.5 “Antituberculosis medicines” of both the EML and the EMLc for use in children with multi-drug and rifampicin resistant tuberculosis (MDR/RR-TB), aged 3 years and older.

According to the 2022 WHO “Consolidated guidelines on tuberculosis, Module 5 Management of tuberculosis in children and adolescents”, in children with multi-drug and rifampicin resistant tuberculosis (MDR/RR-TB), aged below 3 years delamanid may be used as part of longer regimens. Delamanid can therefore be used in children of all ages to treat MDR/RR-TB in individualized longer regimens<sup>1</sup>.

In 2015, MSF has supported the inclusion of delamanid 50 mg tablet in EML and in 2017, MSF has supported its inclusion in the complementary list of the EMLc, as a reserve second-line drug for the treatment of multidrug-resistant tuberculosis, for use in children aged 6 years and older.

In 2019, following the 2018 update of the WHO “Treatment guideline for multidrug- and rifampicin-resistant tuberculosis” recommending that the minimum age for delamanid administration be lowered to 3 years, MSF has supported the WHO Global Tuberculosis Program proposal to lower the minimum age of administration of delamanid in children, from 6 to 3 years. MSF has also emphasized that the 50 mg film-coated tablet formulation, was not an optimal paediatric dosage form for children below 20 kg, requiring the tablet to be split and crushed, and that child-friendly formulations such as scored tablets and dispersible tablets easily dissolved in water should be promoted and should reach internationally agreed quality standards.

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<sup>1</sup> WHO consolidated guidelines on tuberculosis. Module 5: management of tuberculosis in children and adolescents. Geneva: World Health Organization; 2022. <https://www.who.int/publications/i/item/9789240046764>

The 2019 Expert Committee did not recommend the requested change to the age restriction that applies to the listing of delamanid on the Model Lists. The Committee noted that pharmacokinetic data used to inform the guideline development process used a different formulation of delamanid to that which is currently included on the Model Lists, which is not commercially available at this time, nor has it been demonstrated to be bioequivalent to the available, listed formulation<sup>2</sup>.

In 2021, MSF has strongly supported the WHO Global Tuberculosis Program proposal to include a delamanid 25 mg dispersible tablet, a child-friendly formulation essential to increase ease and safety of administration as well as adherence to treatment, in the EMLc. MSF has also supported the request to change the delamanid age restriction for children from “6 years and older” to “3 years and older”.

The 2021 Expert Committee noted the acceptable pharmacokinetic data indicating therapeutic delamanid exposure at the recommended dose in children using the proposed 25 mg dispersible tablet formulation, and that there were no additional safety signals beyond those already known in adults. The Expert Committee therefore recommended the addition of the new formulation of delamanid (25 mg dispersible tablets) to the Complementary list of the EMLc for the treatment of multidrug-resistant tuberculosis in children aged 3 years and older, in line with the updated WHO treatment guidelines<sup>3</sup>.

MSF has been using delamanid 50 mg tablet in its programs since January 2015 and delamanid 25 mg dispersible tablet since 2021.

MSF urges the 24<sup>th</sup> Expert Committee on the Selection and Use of Essential Medicines to remove the age restriction for delamanid in both the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children.



**Dr. Daniela Belen Garone**

Infectious Diseases specialist and DTM&H  
International Medical Coordinator

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<sup>2</sup> The selection and use of essential medicines: report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2019 (including the 21st WHO Model List of Essential Medicines and the 7th WHO Model List of Essential Medicines for Children). Geneva: World Health Organization; 2019 (WHO Technical Report Series, No. 1021). <https://www.who.int/publications/i/item/9789241210300>

<sup>3</sup> The selection and use of essential medicines: report of the WHO Expert Committee on Selection and Use of Essential Medicines, 2021 (including the 22nd WHO Model List of Essential Medicines and the 8th WHO Model List of Essential Medicines for Children). Geneva: World Health Organization; 2021 (WHO Technical Report Series, No. 1035). <https://www.who.int/publications/i/item/9789240041134>