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 removing multiple formulations of second-line antituberculous medications from 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 removal of multiple formulations of second-line antituberculous medications from 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.

- Because a majority of children with DR-TB should be treated with all-oral regimens, we ask that you remove the following amikacin products: amikacin, 100mg powder for injection; amikacin 500mg powder for injection, and amikacin 1gm powder for injection;
- Because there is a scored and dispersible tablet of ethionamide, 125mg available and because ethionamide is only recommended for salvage DR-TB regimens, we ask that you remove the 125mg tablet of ethionamide;
- Because linezolid can be administered orally and achieve the same bioavailability, we ask that you remove the intravenous infusion of linezolid; given the current dosing recommendations for linezolid of 10-15mg/kg, we also ask that you remove the 400mg tablet formulation of linezolid as there are other more appropriate formulations to achieve this dosing according to current WHO weight bands;
- Because tablets of PAS are difficult to administer, because PAS is only recommended for salvage DR-Tb regimens, and because there are other forumulations of PAS that are more appropriate to achieve weight-based dosing, we ask that you remove the PAS 500mg tablet formulation;

- Finally, because there are other formulations of amoxicillin/clavulanic acid that are more appropriate for weight-banded doses, we ask that you remove the 125mg/31.25mg/5mL suspension.

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,

Jennifer Furin, MD., PhD.

Director of Capacity Building

Sentinel Project on Pediatric Drug-Resistant TB