25 February 2019

Re: Statement of support for the addition of pediatric formulations to the World Health Organization Model List of Essential Medicines for Children

Dear Expert Committee,

We are writing to suggest the addition of pediatric formulations of moxifloxacin, levofloxacin, linezolid, cycloserine, ethambutol, and ethionamide to the World Health Organization (WHO) Model List of Essential Medicines for Children (EMLc). As activists committed to advancing access to effective TB treatments, we appeal to the Committee to add moxifloxacin 100 mg dispersible tablet, levofloxacin 100 mg dispersible tablet, linezolid 150 mg dispersible tablet, cycloserine 125 mg solid oral tablet, ethambutol 100 mg dispersible tablet, and ethionamide 125 mg dispersible tablet to the EMLc.

The challenges of administering to children medicines that were designed for adults are well known. Medicines for drug-resistant tuberculosis (DR-TB) are especially notorious for being hard to split, bitter when crushed, and difficult to administer to children.1 Important progress has been made by drug manufacturers in response to the urgent need for child-friendly formulations of medicines for the treatment of DR-TB. Since the 21st Expert Committee meeting in 2017, the pediatric formulations listed above have been quality assured by the WHO Pre-Qualification Program or the Global Fund Expert Review Panel, with the exception of the dispersible tablet of linezolid, which is still in development.2 Moxifloxacin, levofloxacin, linezolid, and cycloserine are core components of the treatment regimens recommended by the WHO for DR-TB and ethambutol is important for the treatment of drug-sensitive TB (DS-TB) in children, especially those co-infected with HIV, and similar to ethionamide, may also be used to build a regimen for DR-TB for certain children.3

Adding these formulations to the EMLc will help raise awareness of the existence of quality assured child-friendly formulations among national TB programs and support activists in calling for children to benefit from access to effective TB treatment regimens composed of medicines that are easier for care providers to administer at appropriate doses and for children to tolerate.

We appreciate your consideration of this letter written to suggest the addition to the EMLc of WHO pre-qualified pediatric formulations of medicines that are important components of the DS-TB and DR-TB treatment regimens currently recommended by the WHO. If you have any questions or interest in further discussion, please contact Lindsay.mckenna@treatmentactiongroup.org.

Respectfully submitted,

On behalf of:
Treatment Action Group (TAG) and the Global TB Community Advisory Board (TB CAB)

2 World Health Organization. Medicines/finished pharmaceutical products prequalified lists. Geneva: World Health Organization; 2018. Available from: https://extranet.who.int/prequal/content/prequalified-lists/medicines?label=&field_medicine_applicant=&field_medicine_fpp_site_value=&search_api_aggregation_1=&field_medicine_pq_date%5Bdate%5D=&field_medicine_pq_date_1%5Bdate%5D=&field_therapeutic_area=23&field_medicinestatus=&field_basis_of_listing=All.