



The 20<sup>th</sup> 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

30 January 2015

**RE: Support for bedaquiline’s addition to the World Health Organization Model List of Essential Medicines**

Patients on inadequate regimens for drug-resistant tuberculosis (DR-TB) urgently need access to bedaquiline, the first new TB drug from a novel class approved by a stringent regulatory authority in 40 years. In the absence of a new drug to treat TB, patients with DR-TB are often faced with very poor treatment regimens that are difficult to tolerate, can cause permanent disability, and are often ineffective.

The WHO has released interim guidance on bedaquiline.<sup>1</sup> Janssen, bedaquiline’s sponsor, has moved forward with planning a robust phase III trial, and has created a patient registry to track safety data among patients treated with bedaquiline in the United States, where the drug is available on the market. Hundreds of patients have been treated successfully with bedaquiline around the world via compassionate use (early access) programs. Even in the absence of phase III trial data, the existing safety and efficacy evidence for bedaquiline is supported by more clinical trials (11 phase I and 3 phase II trials) than exist for most other second-line TB drugs on the List. While trials to confirm and answer key questions about bedaquiline’s optimal use, safety profile and efficacy are pending, many patients would benefit from bedaquiline’s availability, which inclusion on the List would facilitate.

Countries such as South Africa are incorporating the routine and well-administered use of bedaquiline into their TB treatment programs, and many others are working to roll out bedaquiline per the WHO interim guidance. Providers and activists are also working together with global health actors to provide technical assistance and other support necessary to ensure the appropriate use of bedaquiline.<sup>2</sup> These significant efforts indicate responsible global stewardship of this new drug, which are important given the ever-present threat of resistance development, and

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<sup>1</sup> World Health Organization. (2013). Interim guidance on the use of bedaquiline to treat MDR-TB. Geneva: World Health Organization. Available from: [http://apps.who.int/iris/bitstream/10665/84879/1/9789241505482\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/84879/1/9789241505482_eng.pdf?ua=1). (Accessed 2015 January 25).

<sup>2</sup> SWIFT Response Project. Community of Global DR-TB Implementers Announces the “SWIFT Response Project”. Cleveland, Ohio. 18 December 2014. Available from: <http://swiftresponseproject.org/announcements/>

concerns around the safety of the drug and the need for monitoring. Moreover, we feel that exclusion from the List is not an appropriate mechanism for encouraging appropriate use of the drug.

Bedaquiline's release has triggered enthusiastic discussion around affordability and pricing. We and other advocates, researchers, implementers and providers are also encouraging Janssen to commit to reducing the price of the drug in low- and middle-income countries.<sup>3</sup> Janssen has engaged in these conversations and taken steps to make bedaquiline available, via agreements with the Global Drug Facility and a donation via USAID (about which details are still unknown). As even well-administered donation programs are an unsustainable solution, we will continue engaging Janssen to encourage them to formally lower the price of bedaquiline to ensure affordability and equitable access.

Given the dire need for new treatment to fight DR-TB, we urge the Committee to add bedaquiline to the Model List of Essential Medicines.

We would be happy to engage in further dialogue; if you have questions or would like to discuss, please contact [erica.lessem@treatmentactiongroup.org](mailto:erica.lessem@treatmentactiongroup.org).

Best,  
Community Research Advisors Group  
Global TB Community Advisory Board  
Treatment Action Group  
TB Proof



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<sup>3</sup> AIDS Free World, et al. Open letter: Reducing the price of bedaquiline. 10 September 2014. Available from: [http://www.aidsfreeworld.org/Newsroom/Press-Releases/2014/~/\\_/media/Files/Treatment/Bedaquiline%20pricing%20letter\\_2014%20SEPT%2010.pdf](http://www.aidsfreeworld.org/Newsroom/Press-Releases/2014/~/_/media/Files/Treatment/Bedaquiline%20pricing%20letter_2014%20SEPT%2010.pdf)