

## **TB CAB Access Considerations Statement Regarding Johnson & Johnson Announcement of Bedaquiline Price Reduction**

For comments, please write to TB CAB chair, Patrick Agbassi: [ayjpatrick@gmail.com](mailto:ayjpatrick@gmail.com)

**14 July 2020** – The Global Tuberculosis Community Advisory Board (TB CAB) welcomes the Johnson & Johnson (J&J) and Stop TB Partnership Global Drug Facility (GDF) announcement regarding the reduction in price of bedaquiline from US\$400 to US\$340 per six month treatment course, and additional price reductions in the form of up to 30 percent ‘free goods’ based on the annual number of treatment courses procured. However, the TB CAB notes that even with the maximum percentage of free goods, the net price of a six-month course of bedaquiline (US\$238) falls short of civil society’s demand for bedaquiline to be priced at no more than US\$1 per day (US\$180 per six-month course). Furthermore, in the first year alone, reaching US\$1 per day could lead to an estimated US\$27.5 million in savings for national TB programs, which is equivalent to the amount needed to treat an additional 50,000 people with short-course regimens for drug-resistant tuberculosis (DR-TB). In 2018, there were approximately half a million new cases of DR-TB, yet the number of people initiated on treatment was equivalent to just 32% of the estimated incidence, with most of the gap in low- and middle-income countries (LMICs).<sup>1,2</sup>

Recent WHO guidelines support the use of bedaquiline as a core component of the regimens recommended for the treatment of DR-TB.<sup>3</sup> As governments scale up DR-TB treatment with bedaquiline-based regimens, affordable prices and availability of sufficient manufacturing capacity worldwide will be critical to ensure that the growing demand for bedaquiline can be met. The price reduction announced by J&J and the GDF is an important and welcome step toward increasing the accessibility of bedaquiline in LMICs. At the same time, we note that more effort is needed to ensure fast and extensive scale-up of DR-TB treatment, especially as health programs and resources stretch to respond to the global COVID-19 emergency and to defend against rollbacks to progress made in the global fight against TB.<sup>4</sup>

According to research conducted by the University of Liverpool, at volumes of 108,000 treatment courses per year, the price of a six-month course of bedaquiline could be as low as US\$96, considering the cost to produce the drug and a reasonable profit.<sup>5</sup> Additionally, we note that bedaquiline was developed thanks to significant public investment, including non-profit and philanthropic funding.<sup>6</sup> Taking this into account, and considering the additional burden of the COVID-19 response on state budgets and the urgency of mounting an effective response to DR-TB, we believe that the price reduction should be significantly larger. **The price of bedaquiline should be no more than US\$180 per six-month course of treatment, as has been called for multiple times by the TB CAB, Treatment Action Group, and Médecins Sans Frontières.**<sup>7,8</sup>

J&J is currently the sole manufacturer of bedaquiline as multiple patents in many countries prevent generic companies from producing the drug. Envisaging the proven ability of generics companies to considerably reduce the price of medicines, and medical technology supply chain vulnerabilities revealed by the COVID-19 pandemic, non-exclusive voluntary licenses and

technology transfers to support generics entry are crucial for ensuring stable and more affordable access to bedaquiline. The Medicines Patent Pool (MPP) reported that between 2010 and 2018, antiretroviral medicines were made available in 136 countries providing treatment equivalent to 22 million patient-years through an average price reduction of 73% relative to the originator price. As a result, the number of people receiving antiretroviral treatment increased from 8 million in 2010 to 21.7 million in 2017.<sup>9</sup>

**To ensure equitable access to bedaquiline in LMICs and sufficient and stable manufacturing capacity, we call on J&J to issue non-exclusive voluntary licenses for bedaquiline via the MPP.** While the MPP voluntary licenses will be expected to primarily benefit LMICs, a significant number of people with DR-TB live in upper middle-income countries (UMICs) (e.g. Russia), which are usually excluded from the voluntary licenses negotiated by the MPP. For such countries, given the importance of bedaquiline in the treatment of DR-TB, we call on J&J not to enforce its patents so that generic versions can be produced at more affordable prices.

Lastly, we note that although a volume-based price reduction is an important step, free-goods status may lead to a lack of transparency in the actual pricing of bedaquiline. Of note, the World Health Assembly resolution on ‘Improving the transparency of markets for medicines, vaccines, and other health products’ (WHA72.8 adopted on 28 May 2019) recognized that the availability of price information may facilitate efforts toward affordable and equitable access to health products.<sup>10</sup> **Therefore, we encourage J&J to position price discounts based on volume as lower prices to be paid by relevant procurement agencies for relevant volumes, and not as donated free-goods.**

**Thus, to meet the growing demand for bedaquiline, we call on J&J: (1) to decrease the price of bedaquiline further to meet the US\$180 evidence-based target price established by civil society organizations and to make this price accessible to all LMICs and UMICs; or (2) to facilitate technology transfer by granting a non-exclusive license of bedaquiline related inventions to the MPP for LMICs, and commit to not enforcing patents on bedaquiline in UMICs.**

# # # # #

**About the Global TB Community Advisory Board (TB CAB):** The TB CAB is a group of strong, research-literate community activists from HIV and TB networks in Asia, Europe, Africa, and North and South America. Founded in 2011, the TB CAB acts in an advisory capacity to: product developers and institutions conducting clinical trials of new TB drugs, regimens, diagnostics, and vaccines; and provide input on study design, early access, regulatory approval, post-marketing, and implementation strategies. The TB CAB is dedicated to increasing community involvement in TB research and access to tools to fight TB and to mobilizing political will.

- 
- <sup>1</sup> World Health Organization. Global Tuberculosis Report 2019. Geneva: World Health Organization; 2019. <https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf?ua=1>.
- <sup>2</sup> In 2018, China and India accounted for 43 percent of the global gap between incidence and treatment enrollments and eight other countries (Indonesia, Mozambique, Myanmar, Nigeria, Pakistan, the Philippines, the Russian Federation and Vietnam) accounted for a further 32 percent of the gap. Global Tuberculosis Report 2019, p. 73.
- <sup>3</sup> World Health Organization. WHO consolidated guidelines on tuberculosis. Module 4: Treatment; Drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2020. <https://www.who.int/publications/i/item/9789240007048>.
- <sup>4</sup> Stop TB Partnership. The potential impact of the COVID-19 response on tuberculosis in high-burden countries: A modeling analysis. Geneva: Stop TB Partnership; 2020. [http://www.stoptb.org/assets/documents/news/Modeling%20Report\\_1%20May%202020\\_FINAL.pdf](http://www.stoptb.org/assets/documents/news/Modeling%20Report_1%20May%202020_FINAL.pdf).
- <sup>5</sup> Gotham D, Fortunak J, Pozniak A, et al. Estimated generic prices for novel treatments for drug-resistant tuberculosis. *Journal of Antimicrobial Chemotherapy*. 2017 April 1; 72(4): 1243–1252. doi: <https://doi.org/10.1093/jac/dkw522>.
- <sup>6</sup> Gotham D, McKenna L, Frick M, Lessem E. Public Investments in the Clinical Development of Bedaquiline. Oral abstract presented at the 50th Union World Conference on Lung Health. October 2019; Hyderabad, India. <https://www.treatmentactiongroup.org/webinar/public-investments-tb-medicine-bedaquiline-far-exceed-those-of-developer-johnson-johnson/>.
- <sup>7</sup> Medecins Sans Frontieres. MSF welcomes Johnson & Johnson price cut on lifesaving TB drug as an important step forward: Company must make the reduced price more widely available and stop blocking generic versions of bedaquiline [Press Release]. 6 July 2020. <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/msf-welcomes-johnson-johnson-price-cut-lifesaving-tb-drug-important>.
- <sup>8</sup> Treatment Action Group. Treatment Action Group Statement on Bedaquiline Unaffordability [Internet]. 6 July 2020. <https://www.treatmentactiongroup.org/statement/treatment-action-group-statement-on-bedaquiline-unaffordability/>.
- <sup>9</sup> Medicines Patent Pool, 2018 Annual Report: Expanding Access to Public Health. <https://annual-report-2018.medicinespatentpool.org/>.
- <sup>10</sup> Seventy-Second World Health Assembly. Agenda item 11.7. Improving the transparency of markets for medicines, vaccines, and other health products. 28 May 2019. [https://apps.who.int/gb/ebwha/pdf\\_files/WHA72/A72\\_R8-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf).