



26 October 2016

To: Access to Rights and Knowledge Foundation (ARK) (India), DR-TB Scale-up Treatment Action Team (DR-TB STAT) (Global), Global TB Community Advisory Board (TB CAB) (Global), Nagaland Users' Network (NUN) (India)

RE: Requests to improve affordability and availability of bedaquiline

Dear Wim Vandeveld, Lindsay McKenna and Members of ARK, DR-TB STAT, TBCAB and NUN:

Thank you for your letter dated 19 September 2016, and for the acknowledgement of our ongoing commitment to combatting TB. Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), shares the collective vision of ending TB. We remain committed to responsible global access for our medicines, and are committed to effectively partnering with global stakeholders to ensure the appropriate use of current and new treatment options.

While our drug development and access activities are most visible, Janssen's engagement extends far beyond the pill to include: Investments in the collection of real-world data from our TB registries; implementation of a global antibacterial surveillance program and impactful collaboration with global partners to help address patient and system needs. We also take pride in the degree of engagement and effort deployed against this disease by a growing number of our employees around the world.

We share your concern for the underuse of bedaquiline and, as a committed partner within the global TB community, we would like to draw your attention to a number of considerations regarding the comments within your letter:

- Currently, 136 countries, representing more than 67% of the global MDR-TB burden, are included in the IDA/GDF agreement, and when coupled with our own supply chain, current distribution capabilities can responsibly deliver drug to countries representing 98% of the global burden;
- Of the 4,663 donation "orders" that have been placed to date, Janssen has been asked to deliver just over 1,800 treatments since the program's inception in April 2015, and;
- Neither Russia nor South Africa participate in the USAID Bedaquiline Donation program, but account for nearly 50% of all bedaquiline utilization worldwide, which far outnumbers what has been donated. This underscores the extent and severity of extraneous factors (not referenced in your letter) that slow the uptake of innovative treatments.



The aspirational modelling work conducted by Gotham et al that you have referenced describes a scenario in which programmatic capacity yields bedaquiline access (at lower prices) to one million patients every year. In 2014, just 111,000 patients were treated.¹ Our collaboration with USAID on a global donation program was borne of similar ambitions: 30,000 bedaquiline treatments, underpinned by technical assistance to accelerate programmatic scale-up.

As we near the midpoint of that program, however, our goal of reaching one million patients has become more challenging. We are continuing to actively explore opportunities to work with high burden countries to support policies that promote access and availability to bedaquiline, while also working with partners to generate additional data supportive of guidelines that would expand utilization beyond the current World Health Organization (WHO) "Add-on Agent" designation within the 20-month MDR-TB regimen.²

Ensuring that bedaquiline reaches patients requires a collective effort and we look forward to continuing our dialog with you and other partners to help mitigate access barriers to this important treatment. Furthermore, we are committed to ensuring informed antibacterial stewardship and to serving as global advocates for this vital health issue. We will commit to a holistic assessment of challenges – including but not limited to drug pricing - and subsequent discussion of challenges and opportunities as we progress through the 4-year Donation Program.

Respectfully yours,

Ross Underwood

On behalf of the Compound Development Team

Cc: Chrispin Kambili, Tine De Marez, Myriam Theeuwes

Footnotes:

1. WHO 2015 progress report: http://www.who.int/tb/publications/global_report/en/
2. 2016 WHO guidelines for MDR-TB: <http://apps.who.int/iris/bitstream/10665/250125/1/9789241549639-eng.pdf>