



Protect Antibiotics, Protect Humanity:

Safeguarding Bedaquiline for Drug-Resistant Tuberculosis (DR-TB) Treatment

Antimicrobial resistance (AMR) is one of the greatest public health threats facing the world today. Due to various factors including overuse and misuse, antibiotics are increasingly losing their effectiveness against the very diseases they are supposed to treat.¹

It is estimated that by 2050, AMR infections could cause 10 million deaths annually—more deaths than are caused by cancer or diabetes today.² It's clear that we need to take action—now—to protect antibiotics, so that they can continue to protect us in the future.



Tuberculosis: The Biggest Contributor to AMR

Drug-resistant tuberculosis (DR-TB) accounts for one-third of all AMR-related deaths.³ Currently, only one in three people with DR-TB is diagnosed,² and every untreated individual has the potential to infect up to 15 additional people over the course of a year, posing a major threat to global health security.² Therefore, turning the tide on AMR will require a concerted effort to address DR-TB.

Johnson & Johnson is committed to supporting this effort. When we first introduced bedaquiline in late 2012, it was the first TB medicine with a new mechanism of action in more than 40 years.³ Based on current evidence, the World Health Organization (WHO) now classifies bedaquiline as a Group A anti-TB drug—a group of medicines that are strongly recommended to be included in all long course DR-TB regimens – and the medicine is included on WHO's Essential Medicines List.^{4,5}

As a relatively new antibiotic with a new mechanism of action, pre-existing drug resistance to bedaquiline is expected to be low. As with all antimicrobial agents, however, there is the potential for resistance to bedaquiline to emerge. It is therefore critically important to take proactive steps to protect the long-term effectiveness of bedaquiline. That's why Johnson & Johnson is focused on two interconnected priorities: Stewardship and Innovation.

WHAT IS ANTIBIOTIC RESISTANCE?

Antibiotic resistance occurs when bacteria develop changes that allow them to continue to survive and grow even in the presence of antibiotics designed to stop or kill them. The issue of resistance can become a serious public health problem when commonly used treatments lose their effectiveness. In TB therapy, different levels of drug resistance have been documented with varying levels of clinical impact depending on how many TB medicines are affected.¹

A recent report from the Economist Intelligence Unit (EIU), made possible with support from Johnson & Johnson, estimated that DR-TB deaths in a single year (i.e., 230,000 in 2017)² could cost the global economy US\$17.8 billion in future GDP loss and an additional US\$3 billion due to work absences.²



Stewardship

Stewardship efforts are crucial to ensure that antibiotics are used safely and correctly and, ultimately, to protect their long-term effectiveness. Johnson & Johnson is ensuring appropriate use of bedaquiline through continuing medical education (CME) activities and the dissemination of relevant resources to physicians who request information about our products. In addition, we have a rigorous pharmacovigilance framework in place to track, document, and analyze safety data related to our products, including bedaquiline, that we receive from around the world. This allows the company to see any emerging safety and efficacy trends with ongoing use of bedaquiline in the field.

Beyond this, we also support efforts in high-burden countries to improve diagnostic capacity, including drug sensitivity testing to ensure that patients are put on the right drug regimens to avoid resistance from developing. And we participate in an antibiotic resistance surveillance program in collaboration with WHO-recognized reference laboratories.



SPOTLIGHT ON: MEDICAL EDUCATION

In December 2017, Johnson & Johnson provided educational grants in India to several non-governmental organizations to provide CME events for physicians on TB, including DR-TB, in seven high TB burden states in India.

At the end of the one-year program period, over 11,000 healthcare providers took part in CME events that covered the epidemiology of TB and MDR-TB, current treatment guidelines for both types of the disease, and various aspects of infection control and TB prevention.



SPOTLIGHT ON: SURVEILLANCE

In 2015, J&J embarked on a prospective drug resistance surveillance project to assess the evolution of resistance to bedaquiline over a five-year period. When completed in 2020, results of the study will be made publicly available.



Innovation

Despite the positive impact of bedaquiline, we can't end the TB pandemic with today's tools alone. We urgently need new innovations, including shorter and simpler regimens that are highly effective and well tolerated; faster and more accurate diagnostics that can be used at the point of care; safer regimens for children; and a more effective preventive vaccine. At Johnson & Johnson, we are doing our part to contribute to the much-needed TB innovation pipeline.



SPOTLIGHT ON: STRATEGY

In September 2018, Johnson & Johnson announced a comprehensive 10-year commitment to help achieve a world without TB by:

- Continuing to improve access to treatment;
- Accelerating patient finding efforts, including the 'missing millions' who remain undiagnosed and therefore untreated; and
- Advancing research and development (R&D) to create tomorrow's TB treatment regimens through innovative partnerships and collaborations.



SPOTLIGHT ON: PARTNERSHIP

Ultimately no single organization can end TB. We need to join forces with experts in the public, private, philanthropic, and academic sectors. Johnson & Johnson is driving progress and building momentum to end TB by forging new global R&D partnerships with numerous organizations around the world.

Additionally, in the lead-up to the first-ever UN High-Level Meeting on Tuberculosis in September 2018, Johnson & Johnson co-hosted the landmark TB Innovation Summit, a first-of-its-kind event to promote a new, urgently needed dialogue to kick-start innovative thinking and partnerships in the TB space. We were proud to organize this event

in collaboration with the Stop TB Partnership, the World Economic Forum, the United Nations Foundation, and the Global Fund to Fight AIDS, TB and Malaria.



Our Commitment

Johnson & Johnson is working to enable a world without TB, both by preserving therapeutic options like bedaquiline, and by advancing the next generation of innovation. The threat of AMR is real and rising, but with the right investments and commitments, we can win this fight. We will continue to play our part—because patients are waiting.

1. Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. Review on Antimicrobial resistance; 2014 Available at: https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf Last accessed October 2019. 2. A call to action: It's time to end drug-resistant tuberculosis. The Economist Intelligence Unit; 2019. Available at: <https://pages.eiu.com/rs/753-RIQ-438/images/its-time-to-end-drug-resistant-tuberculosis-full-report.pdf> Last accessed October 2019. 3. Johnson & Johnson. Tuberculosis. Available at: <https://www.jnj.com/tb>. Last accessed October 2019. 4. WHO consolidated guidelines on drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2019. Available at: <https://www.who.int/tb/publications/2019/consolidated-guidelines-drug-resistant-tb-treatment/en/> 5. Tuberculosis (TB), New additions to the WHO Essential Medicines: World Health Organisation; 2019 List related to TB treatment Available at: https://www.who.int/tb/features_archive/essential_medicines_2015/en/. Last accessed October 2019.