ACCESS CAMPAIGN
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Paul Stoffels, MD
Executive Vice President and Chief Scientific Officer
Johnson & Johnson

Geneva, 15 December 2016

Dear Dr. Stoffels

Re: Ensuring widespread access to bedaquiline for the treatment of tuberculosis

We are writing on behalf of Médecins Sans Frontières (MSF) to express our concerns with the lack of availability and affordability of bedaquiline world-wide. We kindly request Johnson & Johnson to meet the minimum expectations of:

- accelerating registration of bedaquiline,
- avoid expanding the duration of your donation program,
- introducing an affordable flat price for the product in all low and middle-income countries
- initiating licensing negotiations with the Medicines Patent Pool.

An estimated one-third, or 41,777, of the 125,000 people who started MDR-TB treatment in 2015 were eligible for bedaquiline, which has been shown to improve treatment outcomes. However, over the past four years, only 7,272 people were treated with bedaquiline outside of clinical trial settings, with the majority in South Africa.

Four years ago, MSF welcomed the US Food and Drug Administration (US FDA) accelerated approval of bedaquiline and your company's efforts to bring bedaquiline to market. However, we note that alongside company investments, the US National Institutes of Health and other partners invested over 40 million USD in the development of bedaquiline, and your company also qualified for a priority review voucher for registration at the US FDA. These public investments were critical to develop the drug, and should be an additional reason for your company to meet the minimum expectations, noted above, placed upon companies when commercialising a new product. We are disappointed that Johnson & Johnson is not meeting those minimum expectations.

We would also note the importance of improving access to existing drugs to save lives and prevent further infections and resistance. Johnson and Johnson committed to increase affordable

access to new and existing drugs world-wide in the 2016 Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance.

Concerning registration, we acknowledge completion of registration in seven high burden countries and on-going efforts in eight other countries. We believe the company should dedicate increased resources to ensure timely registration in the remaining high burden countries. As such we welcome your support to the pilot project launched by the WHO Prequalification Programme aiming at registering bedaquiline in several Sub-Saharan African countries under the Collaborative Registration procedure.

Nevertheless, we outline three steps below that could improve the outlook.

First, Johnson and Johnson should not seek to prolong its donation program. Donation programs are not a substitute for appropriate registration, pricing and licensing strategies, and undermine the decision-making ability of governments and public health agencies and their ability to ensure sustained access of the product. We urge Johnson and Johnson to not prolong its donation program beyond 2019, the current end date for the donation program.

Instead, the company should reduce the price of bedaquiline, especially in middle-income countries so it becomes affordable to public health programs. Your current price is unacceptably high and is a critical barrier limiting access in many middle income countries, causing many patients to suffer. We know of countries cancelling orders because of the price, and other countries citing the high-cost of DR-TB treatment as the reason for not accelerating the scale-up of molecular testing to resistance to the most common first-line drugs. Ultimately, a DR-TB treatment regimen should not cost more than $500 per treatment course.

We are concerned by the use of tiered pricing, and the rationale that middle-income countries are able to pay substantially higher prices for new drugs due to changes in their GNI per capita income. This narrative omits the discrepancy between the GNI per capita income and the severe inequality in access to health care in those countries, and does not recognise the existing challenges facing most drug-resistant TB patients - who are often among the most vulnerable and poor.

Unfortunately, companies and donors are increasingly relying upon income-classification in shaping pricing policies, which is a dangerous approach that belies a lack of understanding of the disease burden and ability of households and governments to pay for treatments at excessive prices. Your company should, at least, seek to extend the price it sells bedaquiline in South Africa to all low and middle income countries, while considering an overall lower price point.

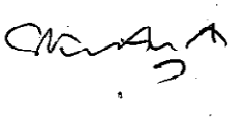
Finally, we call on Johnson and Johnson to initiate negotiations with the UNITAID Medicines Patent Pool (MPP) for a broad, non-exclusive and public health driven voluntary license that would expand access to low-cost, quality versions of the drug in low and middle income countries. Given that your company has relied on donations to distribute the drug, it would be better to offer licenses to companies that could place this drug at the centre of their commercial operations, and not on the periphery.

As a member of the Expert Advisory Group for the UN Secretary General High Level Panel on Access to Medicines, you had the privilege to hear the testimony of governments and patients facing the everyday challenge of high prices and a lack of access. You now have the opportunity to take steps to make a real difference in the lives of patients around the world, including people

afflicted by TB that MSF treats. We urge Johnson and Johnson to re-think how it manages access to bedaquiline.

We look forward to hearing from you at your earliest convenience and would welcome a meeting to discuss the issues raised in the letter.

Sincerely,



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