

Date: January 13, 2023

To:

Mr. Joaquin Duato  
Chief Executive Officer  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933  
USA

Cc:

Mr. Sarthak Ranade  
Managing Director  
Janssen India  
Mumbai, Maharashtra  
India

**Open Letter: Urgent action necessary to improve equitable access to bedaquiline-based regimens and achieve 1/4/6x24**

Dear Mr. Duato,

As a coalition of civil society activists, public health leaders, and researchers acting in solidarity with communities affected by tuberculosis (TB), we are writing to share information about the [1/4/6x24 Campaign](#) and to request Johnson & Johnson's urgent contribution to the Campaign through actions necessary to improve equitable access to bedaquiline.

The 1/4/6x24 Campaign's name comes from its central demand: that countries and other duty bearers, including pharmaceutical companies, take action to improve access to the shortest available regimens – one month or once-weekly for TB prevention, four months for drug-sensitive TB, and six months for drug-resistant TB (DR-TB) — by the end of 2024. Stellar medical developments in the form of newer drugs and regimens have the potential to bridge the unmet medical needs of people with TB — especially drug resistant-TB — which has a poor prognosis when older and less effective medicines/regimens are used. The newer regimens, particularly those containing bedaquiline (the “6” in the 1/4/6x24 campaign), lead to faster cure and better treatment outcomes with fewer adverse effects.

Despite these developments, TB remains a leading cause of death from a single infectious agent, killing an estimated 1.6 million people in 2021.<sup>1</sup> DR-TB is also continuing to ravage communities, with 450,000 new cases of rifampicin-resistant TB (RR-TB) in 2021, and a 17% drop in the number of people with RR-TB and multidrug-resistant TB (MDR-TB) receiving treatment since 2019, due in part to COVID-19-related disruptions. During the COVID-19 pandemic, we also witnessed a decline in global spending on essential TB services (from \$6 billion in 2019 to \$5.4 billion in 2021 — less than half of what is needed), further limiting already-constrained national TB program budgets.<sup>1</sup>

This sustained public health crisis is, in part, attributable to a lack of access to affordable TB diagnostics and medicines, including bedaquiline — the backbone of the newer BPaL and BPaLM regimens to treat DR-TB. According to Médecins Sans Frontières (MSF), bedaquiline accounts for 35-70% of the overall price of these newer regimens.<sup>2</sup> With scale-up and generic competition, the price of bedaquiline could fall by up to 80%, i.e., from the current lowest price of \$45 per

person per month to as low as \$8-17 per person per month.<sup>3</sup> This lower price will enable increased roll-out of bedaquiline-containing DR-TB regimens and will save lives.

Despite the large public investment in the research and development of bedaquiline (US\$455–747 million compared to Johnson & Johnson investments of US\$90–240 million),<sup>4</sup> Janssen, Johnson & Johnson’s subsidiary, has enjoyed a monopoly over bedaquiline for over a decade, since the US FDA conditional approval of bedaquiline in 2012.<sup>5</sup> Johnson & Johnson should therefore respect its primary base compound patent expiry slated for July 2023.<sup>6</sup> Yet, Johnson & Johnson has sought to extend, or evergreen, its monopoly by filing for patents for the fumarate salt formulation of bedaquiline, including in 20 of the 30 WHO-defined, high TB-burden countries.<sup>7</sup> Where granted, this patent will extend Johnson & Johnson’s monopoly until 2027, hampering entry of alternative suppliers, diminishing affordability and accessibility of bedaquiline, and leading to excess suffering and death from DR-TB. Furthermore, lack of multiple suppliers will make bedaquiline more vulnerable to shortages and breaches in supply due to unforeseen circumstances.

On November 6, 2019 in a published interview in The Hindu Business Line, Sarthak Ranade, Managing Director of Janssen India, the pharmaceutical arm of Johnson & Johnson, publicly committed Johnson & Johnson to non-enforcement of its pending bedaquiline fumarate salt formulation patent in India saying: “Composition of matter patent on Bedaquiline expires in July 2023. So, after that, any generic manufacturer is *free to manufacture* it. I don’t think there is any issue. ... There has been a lot of misinformation around patent applications, but the fact remains, come July 2023, *generic manufacturers will be able to make their own versions of Bedaquiline* (emphases added).”<sup>8</sup> This non-enforcement, “free-to-manufacture” statement by a Senior Johnson & Johnson official is in itself durable and enforceable.<sup>9</sup> Nonetheless, it would be preferable for Johnson & Johnson to further clarify its 2019 commitment and to withdraw its pending fumarate salt patent applications in India and elsewhere.

In order to ensure that lifesaving bedaquiline is affordable and accessible in sufficient supply, and to help us achieve the goals of 1/4/6x24, we urge Johnson & Johnson to correct its course and stop blocking entry of generic versions of the drug into the global market and into countries. We urge Johnson & Johnson to commit that, in the interest of TB affected communities and public health, the company will not enforce the patent on the fumarate salt or any other versions of bedaquiline beyond the primary patent expiry in 2023. As part of nonenforcement, Johnson & Johnson should pledge to withdraw and abandon its secondary patent applications and those already granted, and not pursue any action against generic manufacturers who export bedaquiline from or to countries where secondary patents were granted. The pledge to withdraw secondary patent applications should include those currently under dispute in Belarus, Brazil, India,<sup>10</sup> Kazakhstan, Kyrgyzstan, Moldova, Thailand, Ukraine, Vietnam. As a precedent we would like to draw Johnson & Johnson’s attention to the withdrawal of patents and pending applications by Sanofi in 2020 in India and other countries on the combination of rifapentine and isoniazid used for TB preventive treatment after the patent opposition highlighted the obviousness and impact of such frivolous patent claims.<sup>11</sup>

We call on Johnson & Johnson to publicly announce before World TB Day, 24 March 2023, its commitment to withdraw and not enforce the fumarate salt patent claims and other secondary patents on bedaquiline, as part of its commitment to the goals of the 1/4/6x24 Campaign to ensure everyone with TB can benefit from access to the shortest, safest possible TB treatment regimens recommended by the WHO. We would like to request a meeting to discuss these issues with you and look forward to your response to our requests no later than January 31, 2023.

Sincerely,

Americas TB Coalition  
ARK Foundation, India  
Asia Pacific Network of People Living with HIV (APN+)  
Belarusian Public Association "Positive Movement"  
Brazilian Interdisciplinary Aids Association (ABIA)  
Brazilian TB Research Network (REDE-TB)  
Children Education Society (CHESO), Tanzania  
Coalition of Women Living with HIV and AIDS, Malawi  
Delhi Network of Positive People (DNP+)  
Drug System Monitoring and Development Center, Thailand  
Ethiopian TB Association, Ethiopia  
For Impacts in Social Health, Cameroon  
FTA Watch, Thailand  
Ghana National TB Voice Network  
Global Coalition of TB Advocates  
Global Tuberculosis Community Advisory Board (TB CAB)  
Health GAP (Global Access Project)  
Health Justice Initiative SA  
Indonesia AIDS Coalition (IAC)  
International Treatment Preparedness Coalition (ITPC) Global  
International Treatment Preparedness Coalition (ITPC) Eastern Europe and Central Asia  
International Treatment Preparedness Coalition-South Asia (ITPC-South Asia)  
Jointed Hands Welfare Organisation, Zimbabwe  
Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN)  
Mask Ethiopia, Ethiopia  
Médecins Sans Frontières (MSF) - Access Campaign  
Pamoja TB Group, Kenya  
Pan African Positive Women's Coalition, Zimbabwe  
Partners In Health  
Partnership Network, Kyrgyzstan  
People PLUS, Belarus  
PF "Answer", Kazakhstan  
"Saglamliga Khidmat" Public Union (SKPU)  
Sentinel Project on Pediatric Drug-Resistant Tuberculosis  
Survivors Against TB  
TB Azerbaijan NGO Coalition  
TB Europe Coalition  
Thai Network of People Living with HIV/AIDS (TNP+)  
Treatment Action Group (TAG)  
Tuberculosis Platform of Non-Governmental Organizations in the Republic of Moldova  
Vietnam Network of People Living with HIV (VNP+)  
Vision Makers CBO, Kenya  
Volunteer Health Services, Ethiopia  
Wote Youth Development Projects CBO

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