



**Johnson & Johnson**  
**One Johnson & Johnson Plaza**

**Mr. Joaquin DUATO**  
**Chief Executive Office**

**Dear Mr. Duato,**

We are writing to you on behalf of civil society organizations in Ukraine and communities affected by tuberculosis as well as partner institutions and organizations to address the following.

Our country is among the 30 countries with a high burden of drug-resistant tuberculosis. For over a year and a half, our country has been facing full-scale military aggression from Russia, which has already resulted in a massive humanitarian crisis and is projected to lead to an increased spread of tuberculosis (according to forecasts by WHO and TB experts), as demonstrated by the historical experience of armed conflicts worldwide. In the first half of 2023, Ukraine has registered 10,763 newly diagnosed cases of tuberculosis and relapses, including 2,769 cases of drug-resistant tuberculosis.

Bedaquiline is included in the main treatment regimens recommended by the WHO for individuals with drug-resistant tuberculosis. Therefore, over 2,500 people in Ukraine required bedaquiline treatment in the first half of 2023. The production of bedaquiline has been under the monopoly of Johnson & Johnson (J&J) for the past 20 years. Any additional monopoly could restrict the country's access to more affordable versions of bedaquiline starting from August 2023, following the expiration of the primary patent. J&J's submission of a secondary patent application for the fumarate salt of bedaquiline in 2023 could limit the ability to produce or import high-quality bedaquiline from alternative suppliers until 2027 in many countries worldwide, including Ukraine. This may lead to limited access to this life saving medication for many individuals suffering from tuberculosis.

Currently, it is known that the two Indian manufacturers of non-patented drugs, Macleods and Lupin, will be able to sell high-quality bedaquiline after July 2023 in India and in any country where J&J has not been granted a secondary patent.

[https://www.theglobalfund.org/media/4757/psm\\_productstb\\_list\\_en.pdf](https://www.theglobalfund.org/media/4757/psm_productstb_list_en.pdf)

Thanks to the competition between these generic manufacturers in India, Ukraine could potentially procure bedaquiline at a more affordable price and expand access to it for individuals suffering from tuberculosis in Ukraine.

At the same time, considering the current global price of bedaquiline, including for Ukraine, is USD 272 for a 6-month treatment course, researchers have estimated that its cost could be three to six times lower, ranging from 48 USD to 102 USD.

(<https://pubmed.ncbi.nlm.nih.gov/28073970/>)

In late August 2023, after negotiations between the Global Drug Facility (GDF) and J&J, the price was reduced to \$130 USD for a 6-month course, which is 55% lower than the previous price. This agreement between J&J and GDF raises significant concerns because it supports J&J's monopoly and hinders healthy competition among generics and price reduction, which could have been possible if a secondary patent was not applied.

At the same time, it is currently known that the nine countries of the EECA region, excluded from this agreement (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, and Ukraine), will have access to a lower price offered by J&J if they purchase medications through the GDF. While prices for these countries have become lower in the short term, they will still have to pay more than they would for generics. Therefore, the issue of secondary patents remains relevant for Ukraine.

Therefore, to ensure access to life-saving medications for individuals suffering from tuberculosis and to ensure the continuity of tuberculosis treatment in Ukraine, we demand that J&J refrains from applying patents, including on the fumarate salt of bedaquiline.

We emphasize that these measures should be implemented immediately and in accordance with paragraph 19 of the Political Declaration of the 2018 United Nations High-Level Meeting on the fight against tuberculosis, which declared the promotion of access to affordable medicines, including generic medicines, for the treatment of tuberculosis, in particular, its drug-resistant forms.

To ensure the continuity of tuberculosis treatment in Ukraine in the context of the humanitarian crisis caused by the war, we ask for your assistance in creating conditions for free access to quality medicines at an affordable price for people with tuberculosis.

On behalf of the Ukrainian patients and all those affected by tuberculosis, we hope for your compassion and anticipate your decision by September 22, 2023, when the second United Nations High-Level Meeting on Tuberculosis is scheduled to take place.

Kind regards,

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