

**September 15, 2023**

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

**Mr. Joaquin DUATO  
Chief Executive Office**

**Dear Mr. Duato,**

We are writing to you on behalf of Moldova civil society organizations 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. In the first half of 2023, Moldova has registered 1114 newly diagnosed cases of tuberculosis and relapses, including 275 cases of drug-resistant tuberculosis.

Bedaquiline is included in the standard of care recommended by the WHO and included in the national TB treatment protocols for adults and children with drug-resistant tuberculosis. J&J's submission of a secondary patent application in 2023 could limit the ability to produce or import high-quality bedaquiline from alternative suppliers until 2027 in many countries worldwide, including Moldova. This may lead to limited access to this life saving medication for many individuals suffering from tuberculosis.

Currently, 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)).

Due to the competition between generic manufacturers, Moldova could potentially procure bedaquiline at a more affordable price and expand access to it for individuals suffering from tuberculosis throughout the country.

At the same time, considering the current global price of Bedaquiline (on 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. At the same time, it is currently known that 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, the agreement between J&J and GDF might hinder healthy competition among generics and price reduction, which could have been possible if a secondary patent was not applied. Therefore, the countries will still have to pay more than they would for generics and the issue of secondary patents remains relevant for Moldova.

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

We emphasize that these measures are expected to be implemented 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.

On behalf of the Moldovan TB affected community and civil society, we rely on your understanding 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,

1. Asociația Națională a Bolnavilor de TB din Republica Moldova „SMIT”, Bălți, Oxana RUCȘINEANU
2. Uniunea pentru Echitate și Sănătate, Bălți, Ala IAȚCO
3. AFI, Chișinău, Svetlana DOLTU
4. Speranța Terrei, Bălți, Feodora RODIUCOVA
5. Centrul de Asistență Socială Casa Speranțelor, Soroca, Valentina ONICA
6. Asociația Psihologilor din Tighina, Căușeni, Vera CIUCHITU
7. AFI, Anenii Noi, Ina PUȘOI
8. Programe Medico-Sociale, Bender, Marina MIHAILOVA
9. Activ, Bender, Victoria URSACHII
10. Kovceg Dobry Del, Rabnita, Natalia ANTONIUC
11. GENDERDOC-M, Chișinău, Veaceslav MULEAR
12. Inițiativa Pozitivă, Chișinău, Ludmila MARANDICI
13. PAS cu PAS Regiunea Sud, Svetlana CIOBANU
14. Centrul comunitar PULS, Vitalii RABINCIUC
15. Centrul pentru Politici și Analize în Sănătate, Sergiu GHERMAN
16. Credința, Chișinău, Ludmila UNTURA
17. Liga Persoanlor care traiesc cu HIV, Chișinău, Igori CHILCEVSCHI
18. RP UCIMP, Victor VOLOVEI