



**ДЗЯРЖАЎНАЯ УСТАНОВА
«РЭСПУБЛІКАНСКІ НАВУКОВА-
ПРАКТЫЧНЫ ЦЭНТР
ПУЛЬМАНАЛОГІІ
І ФТЫЗІЯТРЫІ»**

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БИК АКВВВ Y21510
УНН 600052478, АКПА 02017708

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На _____ ад _____

**ГОСУДАРСТВЕННОЕ УЧРЕЖДЕНИЕ
«РЕСПУБЛИКАНСКИЙ НАУЧНО-
ПРАКТИЧЕСКИЙ ЦЕНТР
ПУЛЬМОНОЛОГИИ
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Минский ф-л №510 АСБ «Беларусбанк»
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Mr. Joaquin Duato
Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
USA
jduato@its.jnj.com

Dear Mr. Joaquin Duato!

Open Letter: Urgent action by Johnson & Johnson needed to improve equitable access to bedaquiline-based regimens in all countries with a high burden of tuberculosis

We are writing on behalf of the National Tuberculosis (TB) Programme of Belarus which is listed by the World Health Organization (WHO) as a:

- high-burden country for TB
- high-burden country for HIV-associated TB
- high-burden country for multidrug/rifampicin-resistant TB (MDR/RR-TB)

Johnson & Johnson (J&J) has held a monopoly on the lifesaving tuberculosis drug bedaquiline for the past 20 years. Its primary base compound patent expires in July 2023 in a majority of countries, including India, which is a critical producer and supplier of generic medicines for use in low- and middle-income countries. However, J&J has sought to further extend its monopoly by filing for patents on the fumarate salt formulation of bedaquiline.

This secondary patent has been granted in many countries with a high burden of TB, hampering their ability to produce or import quality-assured bedaquiline from alternative suppliers until 2027 and therefore keeping this lifesaving medicine out of the hands of many people who need it.

We know that two Indian generic manufacturers, Macleods and Lupin, will be able to market quality-assured bedaquiline after July 2023 in India and in any country where the secondary patent was not granted to J&J.¹

¹ https://www.theglobalfund.org/media/4757/psm_productstb_list_en.pdf

As a result of competition between generic manufacturers in India, our National TB Programme could have been in a position to procure more affordable bedaquiline and scale up its access to more patients in need of the medicine that is now the backbone of all WHO-recommended MDR/RR-TB regimens.

But instead, our country will continue to pay a high price for this medicine until the secondary patent granted to your company expires in 2027. While the current globally negotiated price of bedaquiline is US\$272 for a 6-month treatment course, researchers have estimated it could be sold profitably for a price that is three to six times lower, between \$48 and \$102.²


We ask J&J to take the following actions urgently in our country and in every other high TB burden country (see attached list):

- 1) Commit to not enforcing any secondary patents, including on the fumarate salt or any other versions of bedaquiline, and to not pursuing any action against generic manufacturers who export this medicine from or to countries where these patents have been granted.
- 2) Withdraw and abandon all pending secondary patent applications related to bedaquiline.

We call on J&J to take these actions before, or at, the upcoming United Nations High-Level Meeting on Tuberculosis in September 2023. J&J's commitment will go a long way in broadening access to bedaquiline and ensuring that people suffering from this killer disease have a real chance to get cured.

Sincerely,

Head of the National Tuberculosis (TB)
Programme of Belarus
Professor



H.Hurevich

² <https://pubmed.ncbi.nlm.nih.gov/28073970/>

Countries where Johnson & Johnson secondary patent on fumarate salt is granted*	TB high burden countries	MDR-TB high burden countries	TB/HIV high burden countries
1. Azerbaijan		X	
2. Belarus		X	
3. Botswana			X
4. Brazil (secondary patent rejection under appeal)	X		X
5. Cameroon			X
6. Central African Republic	X		X
7. Congo	X		X
8. Eswatini			X
9. Gabon	X		X
10. Guinea			X
11. Guinea Bissau			X
12. Indonesia	X	X	X
13. Kazakhstan		X	
14. Kenya	X		X
15. Kyrgyzstan		X	
16. Lesotho	X		X
17. Malawi			X
18. Moldova		X	
19. Mozambique	X	X	X
20. Namibia	X		X
21. Pakistan (secondary patent filed)	X	X	
22. Peru		X	
23. Philippines	X	X	X
24. Russian Federation		X	X
25. Sierra Leone	X		
26. South Africa	X	X	X
27. Tajikistan		X	
28. Tanzania	X		X
29. Thailand (opposition filed)	X		X
30. Uganda	X		X
31. Ukraine		X	
32. Vietnam	X	X	
33. Zambia	X	X	X
34. Zimbabwe		X	X

* <https://www.medspal.org/?product%5B%5D=Bedaquiline+100+mg&page=1>