

Johnson & Johnson's Non-exclusive License to Stop TB's Global Drug Facility for Distribution of Approved Generics of SIRTURO 100mg (Bedaquiline 100mg) and Results of the Global Drug Facility's International Tender for Bedaquiline

Frequently Asked Questions

1. What are the key aspects in this license to the Global Drug Facility?

The license supports Stop TB's Global Drug Facility (GDF) to supply close to 100 low- and middle-income countries with quality-assured generic versions of SIRTURO 100mg, including in countries where patents remain in effect.

Clarification August 2023: The license allows GDF to supply quality-assured generic bedaquiline to all low- and middle-income countries (LMICs), except for the 11 countries noted below. The 100 LMICs mentioned above refer to the countries that have procured bedaquiline via GDF to date. There are numerous low- and middle-income countries that have not procured any quality-assured bedaquiline to date but remain eligible to procure via GDF.

2. Are there any low- and middle-income countries excluded from this license?

The license covers all low- and middle-income countries except for the following: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia¹, Tajikistan, Turkmenistan, and Ukraine as Johnson and Johnson licensed the production and distribution of bedaquiline in these territories to Pharmstandard. Additionally, China is excluded from the license.

3. When does the license go into effect?

The license between GDF and Johnson & Johnson is effective 18 July 2023.

4. What is the duration of the license?

The duration of the license is until the last to expire of the licensed patents.

5. When was the license agreement made?

A verbal agreement was reached between Johnson & Johnson and GDF on 25 January 2023; Johnson & Johnson provided the license to GDF on 13 June 2023; and, GDF finalized processes to operationalize the license on 15 July 2023.

6. When will GDF list additional bedaquiline suppliers in the GDF medicines catalog?

GDF intends to launch a global, competitive tender for bedaquiline by the end of July 2023. Products from any new supplier(s) contracted as a result of this tender are expected to be added to the GDF catalog by the end of August 2023.

Update August 2023: The GDF medicines catalog is now updated. GDF launched an international, competitive tender for bedaquiline on 20 July 2023. Tender results are detailed below.

¹ Pharmstandard Annual Report 2013. Available from: https://pharmstd.com/pdfs/2013_annual_report_EN.pdf

7. How many suppliers are eligible to bid on the upcoming GDF tender for bedaquiline?

As of today, there are three eligible suppliers of bedaquiline that meet GDF quality criteria to bid on the bedaquiline tender. We welcome additional qualified suppliers to participate in future GDF bedaquiline tenders.

8. What are GDF's quality requirements for medicines?

GDF's full quality assurance policy is available here: <https://www.stoptb.org/suppliers/quality-assurance>. Medicines that are prequalified by the WHO's Prequalification for Medicines Programme, are recommended for procurement by the Global Fund's Expert Review Panel, or are authorised for use by a WHO-recognized Stringent Regulatory Authority are eligible for procurement via GDF.

9. Are suppliers and the Global TB Community aware of the upcoming GDF bedaquiline tender?

Yes. On 5 April 2023, GDF shared its plans for the bedaquiline tender with the broader TB Community during a presentation at the WHO BPALM Accelerator meeting. On 11 May 2023, GDF held a webinar to update all GDF medicine suppliers on changes to the 2022 WHO Recommendations on Treatment of DR-TB, including implications on medicine demand and GDF's tender plans for bedaquiline. On 21 June 2023, GDF held a virtual TB Procurement and Market-Shaping Action Team meeting and reiterated its bedaquiline tender plans with TB stakeholders. Over late June and early July 2023, GDF held multiple calls with each of the three suppliers eligible to bid on the upcoming GDF tender. Information was provided to all three suppliers with regards to the tender goals, processes, and timelines. Generic suppliers were informed of the license agreement.

10. Would GDF have been able to launch a bedaquiline tender and supply generic versions of Sirturo 100mg without this license agreement?

GDF always planned to launch a bedaquiline tender and supply generic versions of Sirturo 100mg. GDF publicly announced its tender plans as noted above in question 9. The license expands the list of countries to which GDF can supply generic versions of Sirturo 100mg.

Clarification August 2023: The primary patent on bedaquiline compounds expired on 18 July 2023 in most countries.² The primary patent expiration allowed for introduction of generic bedaquiline in countries:

- Where secondary patents (e.g., for the fumarate salt of bedaquiline) were not filed,
- Where secondary patents were filed but not granted by the government, and
- Where secondary patents were granted, but successfully opposed.

GDF always planned to launch a bedaquiline tender and supply generic versions of bedaquiline 100mg in these territories. GDF publicly announced its tender plans as noted above in question 9.

The license increases the countries where GDF can supply generic versions of bedaquiline 100mg. GDF can now supply generic bedaquiline 100mg to all low- and middle-income countries (less the 11 excluded countries), including countries where secondary patents were granted by the government.

11. Can I procure generic bedaquiline directly from a generic supplier or via other mechanisms under this license agreement?

This license between the GDF and Johnson & Johnson covers procurement through GDF only.

² Information on patent status taken from the MedsPal database available here: <https://www.medsPal.org/>

12. What are the procurement options for the Eastern European and Central Asian countries excluded from this license?

These countries can continue procuring the Johnson & Johnson version of bedaquiline via GDF at the global access price.

Clarification August 2023: To date, 9 of these countries (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, and Ukraine) have procured bedaquiline from GDF. These countries have been able to procure Johnson and Johnson bedaquiline via GDF at the global access price and/or procure Pharmstandard bedaquiline via other procurement mechanisms. This remains unchanged under the license and these countries can continue procuring the Johnson & Johnson version of bedaquiline via GDF at the global access price.

13. Are there any anticipated limitations with bedaquiline supply? Is there any risk that any new orders for bedaquiline will be delayed or cannot be fulfilled?

No. There are no supply issues with bedaquiline and GDF does not foresee any delays in processing orders. In addition, bedaquiline is stored in the GDF Strategic Rotating Stockpile, a mechanism that allows GDF to expedite delivery of medicines to countries.

14. Does GDF provide technical assistance on adoption of new, all-oral DR-TB medicines?

Yes. GDF, through its Regional Technical Advisers and GDF-trained Procurement and Supply Management consultants, provides support to countries to expedite introduction of all new TB medicines, formulations, and regimens. GDF has already provided technical assistance and capacity building to >40 countries on adoption of BPaLM for treatment of DR-TB as per December 2022 WHO Recommendations. Specific activities include development of transition plans to phase out old medicines and phase in new medicines, development of procurement budgets and supply plans, and estimations of financial gaps.

15. How can GDF support National TB programs with ongoing supply planning to ensure uninterrupted access to TB medicines?

GDF supports 52 priority countries in establishing functional forecasting, quantification, and early warning systems that predict future risks of both stockouts and overstock of TB medicines. Timely, forward-looking identification of these risks then allows GDF to work with National TB Programmes, suppliers, and partners to take appropriate actions to ensure uninterrupted access to TB medicines.

16. How can I place an order for bedaquiline with GDF?

The procurement process is outlined on the Stop TB website. Please follow this link to view the steps for ensuring timely processing of your order: <https://www.stoptb.org/buyers/place-order>

17. Is there any additional information in the license agreement that is not covered in this Frequently Asked Questions document?

No. The FAQ document actually provides more information than what is provided in the license agreement.

18. Can Non-Governmental Organizations (NGOs), humanitarian organizations, United Nations entities and other similar entities access generic bedaquiline via GDF under the license?

Yes. These types of organizations can continue procuring the Johnson & Johnson product via GDF. These organizations can procure generic bedaquiline via GDF in accordance with the terms of the license.

Updated information 30 August 2023: Results of GDF’s International Competitive Tender for Bedaquiline 100mg tablets

20. What are the results of the GDF tender? What are the product characteristics and prices?

Two quality-assured suppliers of bedaquiline 100mg tablets were awarded market share from the GDF tender. These suppliers will serve the GDF market until at least the end of December 2024. Product details and pricing are in table 1 below.

Table 1: Product Characteristics and Prices for Bedaquiline to be Supplied by GDF

	Johnson & Johnson	Lupin
Quality Assurance Status	Stringent Regulatory Approval	Global Fund Expert Review Panel (WHO PQ Submitted)
Packaging	188 tablets per bottle	100 tablets blister (10 x 10)
Shelf Life	36 months	24 months
Price per Package	US\$122.20 (prorated) Buy 1 @ US\$244.20, Get 1 free.	US\$96.97
Price per 6-Month Regimen	US\$130 (prorated)	\$194

These new bedaquiline prices represent a 55% and 33% price decrease for J&J and Lupin, respectively, compared to the previous global access price of \$289 per 6-month treatment course. More information is available in the [GDF product catalog](#).

21. Which countries are eligible to receive these products and prices through GDF?

GDF will provide bedaquiline to programmes in accordance with the license. In summary:

- Johnson and Johnson’s bedaquiline – except for China and Russia, all low- and middle-income countries are eligible. This includes 9 of the 11 countries excluded from the license (Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, and Ukraine) when procuring via GDF.
- Lupin’s bedaquiline – all low- and middle-income countries except the 11 countries excluded from the license.

22. What is the new estimated lowest price of the BPALM regimen via GDF?

The estimated lowest price for one BPALM regimen, consisting of bedaquiline, pretomanid, linezolid and moxifloxacin, is \$426 (see calculations in Table 2 below).

Table 2: BPALM Lowest Regimen Price

<i>Medicine</i>	<i>Lowest Price via GDF (USD)</i>
Bedaquiline	130
Pretomanid	238
Linezolid	31
Moxifloxacin	27
Lowest treatment price	426

22. How does the new BPaLM regimen price compare with the previous price?

The lowest price of a BPaLM regimen via GDF of \$426 is a 28% reduction from the previous lowest price of \$588.

24. What are the estimated savings to programmes from the bedaquiline tender?

It is estimated that the tender will result in 8 million USD in savings for programmes through the end of 2024 – enough to procure more than an additional 51,000 bedaquiline treatment courses. This should help programmes increase the number of people with TB diagnosed and treated.