

## **Johnson & Johnson's Non-exclusive License to Stop TB's Global Drug Facility for Distribution of Approved Generics of SIRTURO 100mg (Bedaquiline 100mg)**

### **Frequently Asked Questions**

#### **1. What are the key aspects in this license agreement?**

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.

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

The license covers the majority of low- and middle-income countries except for the following: Armenia, Azerbaijan, Belarus, China, Kazakhstan, Kyrgyzstan, Moldova, Russia<sup>1</sup>, Tajikistan, Turkmenistan, and Ukraine.

#### **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.

#### **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

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<sup>1</sup> Pharmstandard Annual Report 2013. Available from: [https://pharmstd.com/pdfs/2013\\_annual\\_report\\_EN.pdf](https://pharmstd.com/pdfs/2013_annual_report_EN.pdf)

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.

**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.

**12. What are the procurement options for the 9 Eastern European, 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.

**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.