1 August 2023

Mr. Joaquin Duato
Chief Executive Officer
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
USA

cc: Ms. Anna Carvaggio, Managing Director & Vice President, Johnson & Johnson;
Dr. Brenda Waning, Chief, Global Drug Facility, Stop TB Partnership

Open letter: Requesting clarification on the recent deal on generic bedaquiline supply

Dear Mr. Duato:

We write to follow up on prior correspondence, dated 13 January 2023 and 11 July 2023, in which we sought Johnson & Johnson (J&J)'s public commitment to non-enforcement of existing—and withdrawal of pending—secondary patent applications on bedaquiline (SIRTURO®). With the expiry of the primary patent more than 1 week ago, it is even more urgent that J&J make public its commitment to ending exclusivity on this lifesaving drug.

On 12 July 2023, J&J announced on Twitter that it had «entered into a collaboration with the Stop TB Partnership's Global Drug Facility…which enables them to invite potential generic suppliers and purchase generic version of SIRTURO® 100mg.» This arrangement falls far short of a commitment to non-enforcement/withdrawal of secondary patents. Since this statement was posted to Twitter, J&J has released no further information about the deal.

We read with great interest the Stop TB Partnership's Global Drug Facility (GDF) statement about the deal with J&J on 13 July 2023 and its FAQ released 6 days later. However, the agreement remains opaque. We seek clarity from J&J on the terms of its agreement with GDF and answers to the specific questions detailed below. These queries are inspired by feedback received from contact persons in countries potentially impacted by the J&J/GDF deal.

1. Is the deal a license from J&J to GDF granting access to patents on bedaquiline and other exclusive rights? Or, does the deal only permit GDF to purchase and distribute generic bedaquiline? Please explain what rights are granted to GDF in the deal.
2. The FAQ lists 11 countries that are excluded from the deal; all but one of these is a high TB- and/or MDR-TB-burden country.[1] This leaves doubt about the overlap between countries that most need this generic competition for bedaquiline, and the coverage of the deal, and whether the resulting market size will be large enough to engender meaningful price reduction. The FAQ further notes that the deal "covers the majority of low- and middle-income countries (LMICs)" citing an approximate number of "close to 100 LMICs" included in the deal." This leaves tremendous ambiguity about the scope of the deal. According to the World Bank 2022 classifications,[2] there are 186 low-, lower-middle-, and upper-middle-income countries. A simple "majority" could exclude as many

[1] https://www.who.int/news/item/17-06-2021-who-releases-new-global-lists-of-high-burden-countries-for-tb-hiv-associated-tb-and-drug-resistant-tb. Accessed 26 July 2023.
[2] https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups. Accessed 26 July 2023.

as 93 of these from the deal. **Please provide (a) an exhaustive list of all the countries covered by the J&J/GDF deal; and (b) the criteria and rationale used to determine exclusion of countries from the deal.**

3. The FAQ reports that the deal expands the list of countries to which GDF can supply generic bedaquiline; the implied comparator is the number of countries to which GDF could have supplied generic bedaquiline without the deal. Please provide the number and list of countries to which this "expansion" applies.
4. The deal between the GDF and J&J covers procurement through GDF only. Will countries (covered by the territory of the deal) be able to procure generic bedaquiline under this deal without going through GDF, i.e., through other UN agencies?
5. Are humanitarian organizations and other global health institutions permitted to procure generic bedaquiline under the deal, either through GDF or directly from the generic manufacturer? Would this be permitted in countries included in the deal? What about in countries excluded from the deal?
6. Does the deal include clauses enabling supply to markets excluded from the deal under defined conditions and/or exceptions? For instance, if a country issues a compulsory license or if there is a change in the legal status of the remaining patents (i.e., they became nullified, invalidated, or withdrawn) held by J&J in the country of concern, can that country benefit from the deal?
7. Are there other aspects of the deal that limit GDF's ability to secure competitive prices?
8. If any manufacturers that are based in excluded countries (and where secondary patents have been granted) are able to produce generic bedaquiline and are (or become) eligible to join the GDF tender, does the deal include terms allowing these companies to supply generic bedaquiline to their local markets?
9. How will J&J inform the authorities of countries included in the deal?
10. What guarantees will procurement entities have in those countries included in the deal, and where there are J&J patents in force, that procurement of generic bedaquiline will not lead to prosecution for patent infringement?
11. The FAQ says that the duration of the license is "until the last to expire of the licensed patents". Since the exact time of patent expiration will depend on how the terms of the deal are written, it is unclear what the actual duration is. Questions are:
    a. Will J&J please provide an exhaustive list of all the patents held on bedaquiline, their expiry dates, and any planned patent extensions in each country included in and excluded from the deal?
    b. If the legal status of a patent changes in one country covered by the deal, does the deal remain in force in that country?
    c. If J&J files new patent applications for bedaquiline in countries covered by the deal, would the possible expiry dates of the new applications extend the duration of the deal?
12. The 20 mg tablet of bedaquiline is recommended for use in pediatric populations. When a generic version is eligible per GDF quality-assurance standards, will this formulation/dose also enter in the deal?

We request a public, written response by Wednesday, 9 August 2023. We would also be happy to discuss these issues on a video/teleconference call before that date. And, we continue to request and would welcome a public announcement of non-enforcement of secondary patents on bedaquiline in all low-, lower-middle, upper-middle, and high-TB- or MDR-TB-burden countries. Your response can be directed to lpalazuelos@pih.org.

Sincerely,

MSF Access Campaign

Partners In Health

Treatment Action Group