

## FAQs regarding procurement of Bedaquiline (BDQ) through the Global Drug Facility (GDF)

1. How to procure BDQ through GDF?

*The manufacturer Janssen Pharmaceutica NV has signed a contract with IDA Foundation, the procurement agent for the Stop TB Partnership's Global Drug Facility (GDF), to facilitate access to BDQ.*

*For more information regarding BDQ procurement conditions and prices please contact [GDF](mailto:gdf@stoptb.org) at [gdf@stoptb.org](mailto:gdf@stoptb.org)*

2. Can BDQ also be procured directly from the manufacturer (Janssen)

*With few exceptions, access to BDQ for the majority of low and middle income countries is only available from the GDF.*

3. Is there special funding available to cover the cost of BDQ?

*Purchase of BDQ should be financed through the normal channels of financing of MDR-TB through the NTP; there is no special funding. **However, since April 1<sup>st</sup>, 2015, there is a donation program (more information at: <http://www.stoptb.org/gdf/drugsupply/bedaquiline.asp>)***

4. Can NGOs and private health care providers procure BDQ through the GDF?

*Yes, the GDF will provide access for all NGO's and private health care providers with treatment programmes endorsed by the National Tuberculosis Programme (NTP) in a given country. Check with the NTP in your country to find out which NGO's or private providers would be eligible.*

5. What requirements have to be fulfilled in order to procure BDQ through GDF?

*The Procurement Request Form (PRF) will need to be completed, and is available at:*

*[http://www.stoptb.org/gdf/drugsupply/procurement\\_forms.asp](http://www.stoptb.org/gdf/drugsupply/procurement_forms.asp).*

*After the PRF has been submitted and processed by the GDF, countries will receive a price quotation from IDA. Once approved and funds are deposited with IDA, order delivery is initiated with the supplier, freight forwarder and quality control agent.*

6. How long is the lead time between placing an order for BDQ and its availability in the country?

*For accelerated or urgent requests, this can be within a month. For standard requests, the lead time typically ranges from 4 to 6 months. Factors that influence the lead time include availability of stocks, availability of funds, completeness of order submitted to IDA, regulatory requirements, and transportation/logistics issues.*

7. What is the shelf life of BDQ?

*The product shelf life is 36 months.*

8. How is BDQ supplied and how should it be stored?

*BDQ is supplied as uncoated white to almost white round biconvex 100 mg tablets. The tablets are packaged in white high density polyethylene (HDPE) bottles with child-resistant polypropylene (PP) closure with induction seal liner. Each bottle contains 188 tablets (enough to treat one patient for the 6 month period indicated).*

*The storage should be below 25°C (77°F).*

9. How long is the treatment with BDQ? What is the dose?

*BDQ should be given for a maximum of six months on top of the WHO recommended combination treatment regimen. The manufacturer recommends 400 mg daily (4 tablets) for 2 weeks followed by 200 mg 3 times per week for the remaining 22 weeks.*

10. What is the quality assurance status of BDQ?

*To date, BDQ regulatory approvals have been granted in the following countries: United States, Russian Federation, The European Commission (EC), South Korea, India, Peru, South Africa, Philippines, Turkmenistan,*

*Since the US Federal Drug Administration (FDA) and European Medicines Agency are Stringent Regulatory Authorities, and BDQ has been included in a WHO Guideline, BDQ meets the requirement of being a quality-assured drug eligible for procurement through GDF.*

11. Is BDQ currently registered in my country?

*Regulatory submissions have been filled by Janssen in a certain number of countries including but not limited to China, Columbia, Kazakhstan, Georgia, Armenia, UzbekistanThailand and Vietnam.*

12. When will BDQ be registered in my country?

*Regulatory filings are a complex process. As part of the agreement between Janssen and IDA, Janssen has prioritized registration in high MDR-TB burden countries and in jurisdictions where fast-track review processes have been made available.*

13. Can I procure BDQ through GDF even if the product is not yet registered in my country?

*Yes. Many countries have a “waiver process” in place on a shipment-by-shipment basis to allow access to drugs that are procured via GDF. National Tuberculosis Programme will work together with IDA to facilitate issuance of such a waiver as needed for each product shipment. In addition, under the IDA agreement, Janssen is committed to use reasonable commercial efforts to obtain registrations in high burden countries, where registration is mandatory.*

14. What pharmacovigilance measures need to be implemented for BDQ?

*Active pharmacovigilance measures must be in place to ensure early detection and proper management of adverse drug reactions and potential interactions with other drugs. Further*

details on recommendations for pharmacovigilance for TB can be found at:  
[http://www.who.int/medicines/publications/pharmacovigilance\\_tb/en/index.html](http://www.who.int/medicines/publications/pharmacovigilance_tb/en/index.html)

15. How does the availability of BDQ through GDF relate to the WHO Interim Policy Guidance?

*The WHO Interim Policy Guidance on BDQ:*

[http://www.who.int/mediacentre/news/notes/2013/bedaquiline\\_mdr\\_tb\\_20130613/en/](http://www.who.int/mediacentre/news/notes/2013/bedaquiline_mdr_tb_20130613/en/)

*issued in 2013 specifies that BDQ may be used as part of an MDR-TB treatment regimen for specific subgroups of MDR-TB patients and provided the following five conditions are met, as specified in the WHO Interim Policy Guidance on Bedaquiline:*

[http://apps.who.int/iris/bitstream/10665/84879/1/9789241505482\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/84879/1/9789241505482_eng.pdf)

Condition	Description
<b>Effective treatment and monitoring</b>	Treatment must be closely monitored for effectiveness and safety, using sound treatment and management protocols approved by relevant national authorities
<b>Proper patient inclusion</b>	Special caution is required when Sirturo <sup>®</sup> is used in people aged 65 and over, and in adults living with HIV. Use in pregnant women and children is not advised
<b>Informed consent</b>	Patients must be fully aware of the potential benefits and harms of the new drug, and give documented informed consent before embarking on treatment
<b>Adherence to WHO recommendations</b>	All principles on which WHO-recommended MDR-TB treatment regimens are based, must be followed, particularly the inclusion of four effective second-line drugs. In line with general principles of TB therapeutics, Sirturo <sup>®</sup> alone should not be introduced into a regimen in which the companion drugs are failing to show effectiveness
<b>Active pharmacovigilance and management of AEs</b>	Active pharmacovigilance measures must be in place to ensure early detection and proper management of adverse drug reactions and potential interactions with other drugs

*BDQ is recommended for patients who have MDR-TB and when options to treat this condition using existing drugs have been exhausted. The drug is to be given in addition to the multidrug treatment regimen recommended by WHO. Given the limited experience on its use, BDQ is recommended for use in adults (>18 years of age) affected with pulmonary MDR-TB. Special caution is needed when the drug is used in the elderly, in pregnant women, and in persons living with HIV who are taking antiretroviral medication.*

16. When can an NTP place an order for BDQ or for BDQ in combination with other second-line drugs (SLDs)?

*It is highly recommended that whenever feasible the procurement of BDQ is grouped with the procurement of other second-line drugs, since BDQ should always be used as part of comprehensive MDR-TB treatment regimen combination including at least 4 other quality-assured drugs to which a patient is likely to respond. BDQ should never be added alone to a failing regimen or be used without other companion drugs.*

17. Can BDQ be used to treat drug-sensitive TB? Or latent TB?

*Currently BDQ is only licensed for use in MDR-TB, as part of a combination treatment regimen. While studies are underway (under the direction of the TB Alliance) to investigate the utility of BDQ for treating drug-sensitive TB, at the present time the drug must not be used for that indication.*

*BDQ is not indicated for the treatment of latent, extra-pulmonary or drug-sensitive tuberculosis or for the treatment of infections caused by non-tuberculous mycobacteria*

18. Can BDQ be used to shorten treatment of MDR-TB?

*No, there is no evidence as yet that this drug can reduce treatment duration. Moreover there is no experience of the use of this drug in short MDR-TB treatment regimens. While BDQ is expected to improve the likelihood of a successful outcome for individual patients, its overall impact on public health and transmission of MDR-TB in countries cannot as yet be established.*