Information on Bedaquiline donation [1]

General

What is the Bedaquiline (BDQ) donation program?

On March 6, 2015, the United States Agency for International Development (USAID) and the Johnson & Johnson affiliate, Janssen Therapeutics, signed an agreement to provide Bedaquiline free to eligible MDR-TB patients, according to WHO interim recommendations on the use of the drug.

Under the agreement, Janssen will donate $30 million worth (30,000 treatment courses) of the drug SIRTURO® (bedaquiline) over a 4 year period to be used for the treatment of drug-resistant TB. The drug donation will enable over 100 low- and middle-income eligible countries to access the life-saving drug for free within their existing MDR-TB programs. The donation will be provided through USAID's agreement with the Stop TB Partnership's Global Drug Facility to facilitate access to quality-assured medicines.

Why Bedaquiline?

According to the WHO's Global TB Report 2014, an estimated 480 000 people developed MDR-TB in 2013 and 210 000 people died. Only one in four are diagnosed, and only one in five are put on treatment. Of this, less than half are successfully treated.

Left untreated, a single person with MDR-TB may infect 10-15 people every year. Antibacterial resistance to anti-tuberculosis drugs is a major public health problem that arises as a result of improper use of antibiotics and poor patient adherence to a long, often toxic, therapy.
The world needs new solutions for treating MDR-TB patients. Bedaquiline is the first new class of antibiotics that has been FDA approved in over 50 years. The use of this drug in combination with existing drugs could provide new hope for MDR-TB patients with very few treatment options. The World Health Organization has issued interim recommendations on the use of Bedaquiline and has provided guidance to countries on its use.

How does the availability of this donation relate to WHO Interim Policy Guidance?

The WHO Interim Policy Guidance on BDQ:
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

[1] Subject to further updates. This version is reflecting information available on 22.03.2015

Eligibility

Is my country eligible for the Bedaquiline (BDQ) donation program?
Only countries eligible for U.S. foreign assistance are eligible to apply for this program. If using domestic budget, countries shall approach GDF for additional details.

If you have questions regarding country eligibility, please contact Mukadi, Ya Diul (ymukadi@usaid.gov).

What are the requirements countries must meet to qualify?
Countries must declare that they are able to meet all five of the conditions as per the WHO Interim Policy Guidance on BDQ.
http://apps.who.int/iris/bitstream/10665/84879/1/9789241505482_eng.pdf

1. **Effective treatment and monitoring:** Treatment must be closely monitored for effectiveness and safety, using sound treatment and management protocols approved by relevant national authorities.
2. **Proper patient inclusion:** Special caution is required when bedaquiline is used in people aged 65 and over, and in adults living with HIV. Use in pregnant women and children is not advised.
3. **Informed consent:** Patients must be fully aware of the potential benefits and harms of the new drug, and give documented informed consent before embarking on treatment.
4. **Adherence to WHO recommendations:** 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, bedaquiline alone should not be introduced into a regimen in which the companion drugs are failing to show effectiveness.
5. **Active pharmacovigilance and management of adverse events:** Active pharmacovigilance measures must be in place to ensure early detection and proper management of adverse drug reactions and potential interactions with other drugs.

If a country is eligible, but does not meet the requirements in the WHO Interim Guidance are there resources to assist?
Yes, technical assistance will be made available to countries that do not yet meet all five basic WHO conditions. Countries that currently meet all five requirements are still encouraged to seek technical assistance to strengthen any of the five areas listed in the WHO Interim Guidance, if necessary.

Since this is an agreement with USAID, is a country without a USAID presence still eligible?
Eligibility does not depend on a USAID presence. USAID will also work with countries where USAID is not represented officially.

Can countries be added from this Donation Program?
Yes, country participation may change by mutual agreement between USAID and Janssen.

What will happen to a country that has already made a request to procure bedaquiline through its Global Fund grant?
Because this country has a Global Fund grant, it is eligible to receive the bedaquiline donation. We encourage the country to reach out to the Global fund to get more information about how to address the situation. We would expect that the country will coordinate with The Global Fund and reprogram savings resulting from the donation to other MDR TB activities (such as increasing number of patients put on bedaquiline).

When can countries start to request bedaquiline through the donation program?
Countries will be able to begin requesting the donated drugs through the Stop TB Partnership/Global Drug Facility (GDF) starting on April 1, 2015.

Access

If a country is eligible and meets all of the conditions required, how do they access the donation?
The country should continue to use GDF procurement form as found on GDF website http://stoptb.org/gdf/drugsupply/procurement_forms.asp and fill it out for the bedaquiline donation along with other drugs according to GDF standard procedure. While BDQ will be free of charge, countries still need to budget the costs for transportation and insurance to the final destination.

Other

What if bedaquiline is not registered in my country?
Bedaquiline is currently only registered in a small number of countries; however, countries can still access BDQ through GDF. Many countries have a "waiver process" in place on a shipment-by-shipment basis to allow access to drugs that are procured via GDF.

Is there a limit on the amount of bedaquiline a country can request through the donation program?
Requests for BDQ should be based on realistic estimates of those patients who are licensed to receive BDQ according to country guidelines. No limit will be placed on a country.

Can a country request bedaquiline donation program for drug-sensitive patients?

Currently BDQ is only licensed for use in MDR-TB, as part of a combination treatment regimen. While studies are underway 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.

Does the donation include other companion drugs?
Currently the donation is for bedaquiline only.

It is highly recommended that whenever feasible BDQ is grouped with the procurement of other quality assured second-line drugs, since BDQ should always be used as part of comprehensive MDR-TB treatment regimen combination as per WHO treatment guidelines 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.