

**StopTB Partnership’s Global Drug Facility (STBP/GDF) FAQs
on bedaquiline price reduction and free goods**

1. What are the key changes in this agreement?

There are two components to this announcement, a price reduction and free goods. Beginning on 6 July 2020, the price of a bottle of bedaquiline containing 188 tablets has been reduced to 340 USD (ex works). Additionally, a percentage of bedaquiline that is ordered will be provided free of charge. The percentage of free goods will be applied for a calendar year and will be reassessed each year based on estimated yearly forecasts. The agreed to thresholds and associated free goods percentages are:

Thresholds for receiving free goods (in bottles of bedaquiline ordered per year)	Percent of free goods to be applied
> 55,000	10%
> 125,000	20%
> 200,000	30%

For the calendar year 2020, STBP/GDF and partners have estimated that the 125,000 bottle threshold will be reached and 20% free goods will be applied for all orders that are confirmed and paid in 2020.

2. Is my programme eligible for the reduced price and free goods?

The reduced price and free goods are available to 139 countries and territories when procuring through GDF. A full list of eligible countries and territories is available at the end of this document.

3. What are the estimated savings to programmes from the price reduction and free goods?

It is estimated that the price reduction and the 20% free goods will **save programmes 16 million USD in 2020¹** – enough to treat an additional 30,000 people with drug-resistant tuberculosis (DR-TB). This should help programmes increase the number of people with TB diagnosed and treated – helping programmes reach their United Nations High-Level Meeting targets².

4. What is the current role of bedaquiline in the treatment of Drug-Resistant TB?

The World Health Organization’s Global TB Programme released updated guidance on the treatment of DR-TB in June 2020³. Bedaquiline is a key component of the all-oral, standardized, shorter regimen which is the preferred regimen for most people affected by DR-TB. Bedaquiline is also a primary medicine used in the all-oral longer regimen which is the regimen for those unable to use the shorter regimen. Bedaquiline is also used in the 6-9 month “BPaL” regimen (bedaquiline, pretomanid, linezolid) under operational research conditions for multidrug resistant TB with additional resistance to fluoroquinolones.

¹ Savings calculation: 125,000 bottles of bedaquiline at 400 USD minus 125,000 bottles of bedaquiline at 272 USD; 272 USD per bottles is the prorated price accounting for the price reduction and 20% free goods.

² United Nations High-Level Meeting on TB targets by country are available here: http://www.stoptb.org/global/advocacy/unhlm_targets.asp

³ WHO Consolidated Guidelines on Tuberculosis, Module 4: Treatment – Drug-Resistant Tuberculosis Treatment. Available here: <https://www.who.int/publications/i/item/9789240007048>

5. How will free goods be applied in 2020?

All new STBP/GDF quotations will automatically include free goods applied as follows: for every 10 bottles of bedaquiline ordered, 8 of those bottles will be invoiced at 340 USD and 2 of those bottles will be provided free of charge. It is highly recommended that programmes place orders in multiples of 10 bottles to fully benefit from the 20% free goods.

For the calendar years 2021 and 2022, the percent of free goods will be negotiated between GDF and Janssen based on the expected volumes for that year.

6. My programme paid and confirmed an order for bedaquiline earlier in 2020 – is that order eligible for free goods?

Yes. Any order paid and confirmed in 2020 is eligible for free goods. Programmes that paid and confirmed an order for bedaquiline earlier this year can add the free goods corresponding to multiples of 10 in their next order. The STBP/GDF Country Supply Officers will be reaching out to Programmes with next steps on how to receive free goods.

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

No. STBP/GDF works closely with Janssen to develop production plans to ensure adequate supply. GDF will monitor the supply situation closely.

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

Yes. GDF, through Regional Technical Advisers and GDF-trained Procurement and Supply Management (PSM) consultants, provides support to countries to expedite introduction of all new TB medicines, formulations, and regimens. GDF has already provided technical assistance on adoption of new DR-TB regimens to 49 and 42 countries in 2019 and 2020, respectively. Specific activities include development of costed plans to phase out old medicines and phase in new medicines, donor requests to write-off costs for obsolete, injectable medicines, and revision of procurement budgets.

9. Can GDF provide technical assistance to revise national TB medicine supply plans, incorporating the new bedaquiline price and free goods offer?

Yes. GDF can provide technical guidance and support to revise TB medicine costed supply plans, taking into account the new price decrease and free goods offer. Please contact STBP/GDF at gdf@stoptb.org to request support.

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

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

11. What are the new estimated costs for DR-TB treatment regimens?

Estimates of the costs of different regimens for DR-TB are available in Table 1. These estimates are valid through the end of the current long-term agreements with suppliers (December 2020).

Table 1. Estimated costs of DR-TB treatment regimens containing bedaquiline

Estimated Costs of DR-TB Treatment Regimens containing Bedaquiline <i>Comparison of 2019 BDQ price (400 USD per pack) and 2020 BDQ pro-rated price (272 USD per pack*)</i>				
Description of treatment regimen	Regimen composition	Estimated Regimen Costs (USD)**		% Difference
		2019	2020	
2020 WHO All-Oral Shorter Regimen	4 Bdq (6 M) Cfz E Hh Lfx Pto Z / 5 Cfz E Lfx Z	668	540	-19%
2020 WHO All-Oral Longer Regimen with levofloxacin	18 Bdq (6 M) Lfx Lzd Cfz	1,126	998	-11%
2020 WHO All-Oral Longer Regimen with moxifloxacin	18 Bdq (6 M) Mfx Lzd Cfz	1,184	1,056	-11%
BPAL	6 Bdq Pa Lzd	1,041	905	-13%

* Pro-rated price calculation: new price for bedaquiline bottle of 188 tablets = 340 USD; 20% free goods are applied as follows, for every 10 bottles of bedaquiline ordered, 8 of those bottles will be invoiced at 340 USD each and 2 of those bottles will be provided free of charge

** Estimated regimen costs are calculated using the average weighted cost for each medicine (average weighted cost account for the different prices for each supplier of that medicine weighted by the market share allocation received from each GDF tender) the duration indicated (in months) and assuming 30 days of treatment per month. Estimates use the 46-55 kg weight band in the WHO Consolidated Guidance 2020 for medicine dosages (i.e., number of tablets per day).

11. How can I place an order for bedaquiline with STBP/GDF?

The procurement process is outlined on our website. Please follow this link to view the steps for ensuring timely processing of your order: <http://www.stoptb.org/gdf/placeOrder.asp>

Table 2. 139 countries and territories eligible when procuring via GDF

1	Afghanistan
2	Albania
3	Algeria
4	Angola
5	Antigua and Barbuda
6	Argentina
7	Armenia
8	Azerbaijan
9	Bahamas
10	Bangladesh
11	Barbados
12	Belarus
13	Belize
14	Benin
15	Bhutan
16	Bolivia (Plurinational State of)
17	Bosnia and Herzegovina
18	Botswana
19	Brazil
20	Burkina Faso

21	Burundi
22	Cabo Verde
23	Cambodia
24	Cameroon
25	Central African Republic
26	Chad
27	Chile
28	China
29	Colombia
30	Comoros
31	Congo
32	Costa Rica
33	Côte d'Ivoire
34	Korea (Democratic People's Republic of)
35	Congo, Democratic Republic of the
36	Djibouti
37	Dominica
38	Dominican Republic
39	Ecuador
40	Egypt
41	El Salvador
42	Equatorial Guinea
43	Eritrea
44	Eswatini
45	Ethiopia
46	Fiji
47	Gabon
48	Gambia
49	Georgia
50	Ghana
51	Grenada
52	Guatemala
53	Guinea
54	Guinea-Bissau
55	Guyana
56	Haiti
57	Honduras
58	India
59	Indonesia
60	Iran (Islamic Republic of)
61	Iraq
62	Jamaica
63	Jordan
64	Kazakhstan

65	Kenya
66	Kiribati
67	Kyrgyzstan
68	Lao People's Democratic Republic
69	Lebanon
70	Lesotho
71	Liberia
72	Libya
73	Madagascar
74	Malawi
75	Malaysia
76	Maldives
77	Mali
78	Marshall Islands
79	Mauritania
80	Mauritius
81	Mexico
82	Micronesia (Federated States of)
83	Mongolia
84	Montenegro
85	Morocco
86	Mozambique
87	Myanmar
88	Namibia
89	Nepal
90	Nicaragua
91	Niger
92	Nigeria
93	Pakistan
94	Palau
95	Panama
96	Papua New Guinea
97	Paraguay
98	Peru
99	Philippines
100	Moldova, Republic of
101	Rwanda
102	Saint Kitts and Nevis
103	Saint Lucia
104	Saint Vincent and the Grenadines
105	Samoa
106	Sao Tome and Principe
107	Senegal
108	Serbia
109	Seychelles

110	Sierra Leone
111	Solomon Islands
112	Somalia
113	South Sudan
114	Sri Lanka
115	Sudan
116	Suriname
117	Syrian Arab Republic
118	Tajikistan
119	Thailand
120	Macedonia, the former Yugoslav Republic of
121	Timor-Leste
122	Togo
123	Tonga
124	Trinidad and Tobago
125	Tunisia
126	Turkmenistan
127	Tuvalu
128	Uganda
129	Ukraine
130	Tanzania, United Republic of
131	Uruguay
132	Uzbekistan
133	Vanuatu
134	Venezuela (Bolivarian Republic of)
135	Viet Nam
136	Yemen
137	Zambia
138	Zimbabwe
139	Kosovo