

11 November 2024

## Results of the Global Drug Facility’s 2024 Tender for Delamanid

### Frequently Asked Questions (FAQ)

#### 1. What is delamanid and why is it important for treating drug-resistant tuberculosis (DR-TB)?

The World Health Organization (WHO) has recommended delamanid since 2014 for the treatment of multidrug-resistant tuberculosis (MDR-TB). According to WHO’s most recent rapid communication from August 23, 2024<sup>1</sup>, delamanid is now also recommended as part of two new six-month regimens that combine bedaquiline, delamanid, and linezolid, alongside levofloxacin or clofazimine, as tested in the BEAT-Tuberculosis clinical trial. Delamanid is also included in nine-month regimens for treating MDR/RR-TB without fluoroquinolone resistance, as tested in the endTB clinical trial.

#### 2. How many suppliers were eligible to bid on the recent GDF tender for delamanid?

There were two (2) eligible suppliers of delamanid 50mg—Otsuka being the innovator and Mylan/Viatris operating under a territorially-restricted licensing agreement. Only one supplier—Otsuka—is eligible for delamanid 25mg supply. Additional qualified suppliers are encouraged to participate in future GDF delamanid tenders.

#### 3. What are GDF’s quality requirements for medicines?

GDF’s quality assurance policy is detailed on the Stop TB Partnership website: <https://www.stoptb.org/suppliers/quality-assurance>. Medicines eligible for procurement via GDF must be prequalified by WHO’s Prequalification of Medicines Programme (PQP), authorized by a Stringent Regulatory Authority (SRA), or recommended by the Global Fund’s Expert Review Panel (ERP).

#### 4. What are the results of the GDF tender?

Under ITB-Iplus/GDF-MED/2024/1, the awards for delamanid supplies are as follows:

Product	Supplier	Price (USD)/Pack	Pack Size (Tablets)	Price USD)/ Treatment (Tx)	Shelf Life (Months)	QA Status/Notes
Delamanid 50mg Tablets	Otsuka	\$85.00	48	\$1,190*	60	Authorized by SRA
	Mylan/Viatris	\$57.14	48	\$800*	24	WHO PQP–approved
Delamanid 25mg Dispersible Tablets	Otsuka	\$85.00	48	\$595**	60	Authorized by SRA Sole source supplier

\*672 tablets of delamanid 50mg tablets

\*\*10-16kg weight band: 336 tablets of delamanid 25mg dispersible tablets

#### 5. What is the significance of the recent price reduction for delamanid?

Effective September 1, 2024, the price of a Mylan/Viatris delamanid 50mg treatment course (tx) decreased from US\$1,125/tx to US\$800/tx, representing a 29% price reduction. This marks a

<sup>1</sup> <https://www.who.int/news/item/23-08-2024-who-issues-rapid-communication-on-key-updates-to-the-treatment-of-drug-resistant-tuberculosis>

significant decrease from the original Otsuka price of US\$1,700/tx in 2016, and a 33% decrease from the recent Otsuka price of US\$1,190/tx in July 2023. This price reduction will enhance the accessibility of delamanid in low- and middle-income countries.

**6. How does the current price compare to previous prices?**

Below is a breakdown of the changes in delamanid 50mg treatment course pricing over time:

**Price Per Adult Treatment Course (672 Tablets/tx)**

	2016-2021	2022	2023	2024
<b>Otsuka</b>	\$1,700	\$1,700	\$1,190	\$1,190
<b>Mylan/Viatris</b>	NA	\$1,125*	\$1,125*	\$800

\*Only a very limited supply was available in 2022. No supply was available in 2023.

**7. Why is this price reduction happening now?**

GDF's tender was launched in response to the entry of a new quality-assured supplier of delamanid to the market – Mylan/Viatris received WHO PQP approval to manufacture delamanid with their own active pharmaceutical ingredient. In 2024, the TB Procurement and Market-Shaping Action Team (TPMAT)—a global initiative focused on improving access to TB products and addressing market challenges—set new target prices for key TB medicines, including delamanid 50mg. GDF incorporated this target price in its 2024 tender. This contributed to Mylan/Viatris decreasing their price of delamanid 50mg by 29%, bringing the cost to US\$800 per treatment course.

This approach highlights the importance of partner collaboration and dedicated suppliers in securing affordable TB medicines. With additional supply capacity and new lower prices for delamanid, GDF aims to offer more affordable treatment options and ensure a steady supply of delamanid.

**8. How can countries access delamanid 50mg from Viatris at the new reduced price?**

Countries that can procure delamanid 50mg supplied by Mylan/Viatris and, thus, access delamanid at the new reduced price are listed in Annex 1, Tables 1 and 3. To place an order through Stop TB Partnership's GDF, please follow the procurement process outlined on the Stop TB website: <https://www.stoptb.org/buyers/place-order>.

**9. Which countries are eligible to receive these products and prices through GDF?**

GDF will supply delamanid 50mg tablets and 25 mg dispersible tablets in accordance with the territorial restrictions imposed by each supplier, as described in Annexes 1 and 2.

A total of 136 countries or territories are eligible to procure delamanid 50mg via GDF.

The majority of countries (94 out of 136) are eligible to procure delamanid 50mg from both Otsuka or Mylan/Viatris; however, 32 countries may only procure delamanid 50mg produced by Otsuka, and 10 countries may only procure delamanid 50mg produced by Mylan/Viatris.

Delamanid 25mg dispersible tablets are currently only produced by Otsuka, with 126 countries eligible to procure via GDF (Annex 2).

For the countries which wish to procure delamanid via GDF but are not included in these lists, GDF will contact the suppliers on a case-by-case basis; however, supplier approval cannot be guaranteed.

**10. Are there any anticipated limitations with the delamanid supply?**

No. There are currently no anticipated limitations or supply issues with delamanid, and GDF does not foresee any delays in processing orders.

**11. Can we expect additional delamanid suppliers and lower prices in the near future?**

Yes. Additional suppliers are developing delamanid. Once their products meet the GDF quality assurance requirements for procurement eligibility, new competitive tenders should lead to lower prices.

**12. Is delamanid included in GDF’s Strategic Rotating Stockpile?**

Yes. Delamanid is included in GDF’s strategic Rotating Stockpile (SRS).

GDF has reached an agreement with Otsuka to provide delamanid 50mg and 25mg dispersible tablets to the SRS as consignment stock thereby allowing GDF to pay Otsuka for these formulations only after GDF clients purchase them. This arrangement eliminates the financial risk for GDF in the event that SRS inventories for both products remain unsold. It also improves GDF’s cash flow: GDF is able to redirect funds that would otherwise be used to purchase these products for the SRS towards increasing safety stock of other TB medicines as a buffer against unexpected fluctuations in demand.

Otsuka is the second supplier to offer GDF products on consignment for its SRS. Janssen has offered bedaquiline 100mg and 20mg tablets to GDF on consignment since September 2020.

**13. What are the estimated prices of delamanid-based regimens?**

Estimated prices for selected delamanid-based regimens are provided in the table below, and also are available on the GDF website: <https://www.stoptb.org/buyers/plan-order>.

Regimen Type	Regimen Composition	Regimen Duration	Weight Band	Estimated Regimen Prices (USD) <sup>2</sup> From Oct 2024	Estimated Lowest Regimen Prices <sup>3</sup> (USD) From Oct 2024
Adult DR-TB	6 Bdq Dlm Lzd Lfx (BEAT-TB) <sup>4</sup>	6 months	> 50 kg	\$ 1,140	\$ 972
	6 Bdq Dlm Lzd Cfz (BEAT-TB) <sup>5</sup>	6 months	> 50 kg	\$ 1,225	\$ 1,060
	9 Bdq Dlm Lzd Lfx Z (endTB) <sup>5</sup>	9 months	55 – 70 kg	\$ 1,840	\$ 1,570

<sup>2</sup> Estimated regimen prices are calculated using 1) the average weighted price for each medicine (average weighted price accounts for the different prices for each supplier of that medicine weighted by the market share allocation received from each GDF tender) and 2) the duration indicated in months, assuming 30 days of treatment per month. Actual, final prices may differ based on the product(s) delivered.

<sup>3</sup> Lowest prices use 1) the lowest price available for that product from all suppliers contracted with GDF and 2) the duration indicated in months, assuming 30 days of treatment per month. Actual, final prices may differ based on the product(s) delivered.

<sup>4</sup> Regimen and dosing from WHO Rapid Communication, June 2024. <https://www.who.int/publications/i/item/B09123>.

**Annexes**

**Annex 1: Country Lists for Delamanid 50mg Supplies by Manufacturer**

Table 1. Countries that can procure delamanid 50mg supplied by **both** Otsuka and Viatrix

1	Afghanistan	33	Ethiopia	64	Myanmar
2	Algeria	34	Gabon	65	Namibia
3	Angola	35	Gambia, The	66	Nicaragua
4	Argentina	36	Ghana	67	Niger
5	Armenia	37	Guatemala	68	Nigeria
6	Bangladesh	38	Guinea	69	Pakistan
7	Belize	39	Guinea-Bissau	70	Papua New Guinea
8	Benin	40	Haiti	71	Paraguay
9	Bhutan	41	Honduras	72	Peru
10	Bolivia	42	India	73	Philippines
11	Botswana	43	Indonesia	74	Rwanda
12	Brazil	44	Iran, Islamic Rep.	75	Samoa
13	Burkina Faso	45	Iraq	76	São Tomé and Príncipe
14	Burundi	46	Jordan	77	Senegal
15	Cabo Verde	47	Kenya	78	Sierra Leone
16	Cambodia	48	Kiribati	79	Solomon Islands
17	Cameroon	49	Korea, Dem. People's Rep.	80	Somalia
18	Central African Republic	50	Lao PDR	81	South Sudan
19	Chad	51	Lebanon	82	Sudan
20	Colombia	52	Lesotho	83	Syrian Arab Republic
21	Comoros	53	Liberia	84	Tanzania
22	Congo, Dem. Rep.	54	Libya	85	Thailand
23	Congo, Rep.	55	Madagascar	86	Timor-Leste
24	Côte d'Ivoire	56	Malawi	87	Togo
25	Djibouti	57	Maldives	88	Tunisia
26	Dominican Republic	58	Mali	89	Uganda
27	Ecuador	59	Mauritania	90	Vanuatu
28	Egypt, Arab Rep.	60	Mexico	91	Vietnam
29	El Salvador	61	Micronesia, Fed. Sts.	92	Yemen, Rep.
30	Equatorial Guinea	62	Morocco	93	Zambia
31	Eritrea	63	Mozambique	94	Zimbabwe
32	Eswatini (Swaziland)				

Table 2. Countries that can procure **only** delamanid 50mg supplied by **Otsuka**

1	Albania	18	Montenegro
2	American Samoa	19	Nepal
3	Azerbaijan	20	North Macedonia
4	Belarus	21	Palau
5	Bosnia and Herzegovina	22	Saint Lucia
6	Costa Rica	23	Saint Vincent and the Grenadines
7	Cuba	24	Serbia
8	Dominica	25	Sri Lanka
9	Fiji	26	Suriname
10	Georgia	27	Tajikistan
11	Grenada	28	Tonga
12	Jamaica	29	Turkmenistan
13	Kyrgyz Republic	30	Tuvalu
14	Marshall Islands	31	Ukraine
15	Mauritius	32	Uzbekistan
16	Moldova, Republic of		
17	Mongolia		

Table 3. Countries that can procure **only** delamanid 50mg supplied by **Viatris**

1	Chile
2	Guyana
3	Kosovo
4	Malaysia
5	Oman
6	Panama
7	Saudi Arabia
8	South Africa
9	UAE
10	Uruguay

**Annex 2: Country List for Delamanid 25mg Dispersible Tablets Supplied by Otsuka**

1	Afghanistan	46	Ghana	91	Papua New Guinea
2	Albania	47	Grenada	92	Paraguay
3	Algeria	48	Guatemala	93	Peru
4	American Samoa	49	Guinea	94	Philippines
5	Angola	50	Guinea-Bissau	95	Rwanda
6	Argentina	51	Haiti	96	Saint Lucia
7	Armenia	52	Honduras	97	Saint Vincent and the Grenadines
8	Azerbaijan	53	India	98	Samoa
9	Bangladesh	54	Indonesia	99	São Tomé and Príncipe
10	Belarus	55	Iran, Islamic Rep.	100	Senegal
11	Belize	56	Iraq	101	Serbia
12	Benin	57	Jamaica	102	Sierra Leone
13	Bhutan	58	Jordan	103	Solomon Islands
14	Bolivia	59	Kenya	104	Somalia
15	Bosnia and Herzegovina	60	Kiribati	105	South Sudan
16	Botswana	61	Korea, DPR	106	Sri Lanka
17	Brazil	62	Kyrgyz Republic	107	Sudan
18	Burkina Faso	63	Lao PDR	108	Suriname
19	Burundi	64	Lebanon	109	Syrian Arab Republic
20	Cabo Verde	65	Lesotho	110	Tajikistan
21	Cambodia	66	Liberia	111	Tanzania
22	Cameroon	67	Libya	112	Thailand
23	Central African Republic	68	Madagascar	113	Timor-Leste
24	Chad	69	Malawi	114	Togo
25	Colombia	70	Maldives	115	Tonga
26	Comoros	71	Mali	116	Tunisia
27	Congo, Dem. Rep.	72	Marshall Islands	117	Turkmenistan
28	Congo, Rep.	73	Mauritania	118	Tuvalu
29	Costa Rica	74	Mauritius	119	Uganda
30	Côte d'Ivoire	75	Mexico	120	Ukraine
31	Cuba	76	Micronesia, Fed. Sts.	121	Uzbekistan
32	Djibouti	77	Moldova, Republic of	122	Vanuatu
33	Dominican Republic	78	Mongolia	123	Vietnam
34	Dominica	79	Montenegro	124	Yemen, Rep.
35	Ecuador	80	Morocco	125	Zambia
36	Egypt, Arab Rep.	81	Mozambique	126	Zimbabwe
37	El Salvador	82	Myanmar		
38	Equatorial Guinea	83	Namibia		
39	Eritrea	84	Nepal		
40	Eswatini (Swaziland)	85	Nicaragua		
41	Ethiopia	86	Niger		
42	Fiji	87	Nigeria		
43	Gabon	88	North Macedonia		
44	Gambia, The	89	Pakistan		
45	Georgia	90	Palau		