

Promoting access to TB products: GDF's 2023 updates

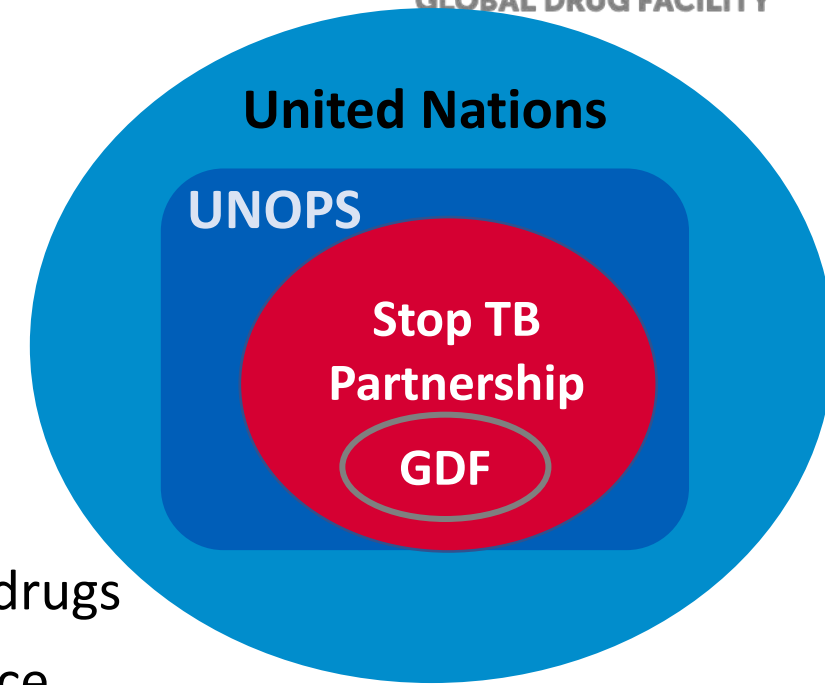
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2023 Joint UNICEF, UNFPA, and WHO Meeting, Copenhagen, 27 November – 1st December 2023

Global Drug Facility (GDF)

- Established in 2001
- Headquartered in Geneva
- Funded by USAID, plus other donor project funding (e.g., Japan)
- ISO 9001 certified
- Original mandate: promote access to quality-assured, first-line TB drugs
 - Integrated pooled procurement coupled with technical assistance
- Subsequent expansion of products & services for all products to prevent, diagnose, and treat TB
- Now largest procurer of TB products, open to all countries, regardless of funding source
- End-to-end approach along entire product lifecycle, coordinating TB market stakeholders
- **UN Political Declaration on the Fight Against TB: “We, Heads of State and Government and representatives of States and Governments [...] (15) encourage all nations to use the Stop TB Partnership/Global Drug Facility.”**



GDF Goal and Objectives for Procurement & Supply

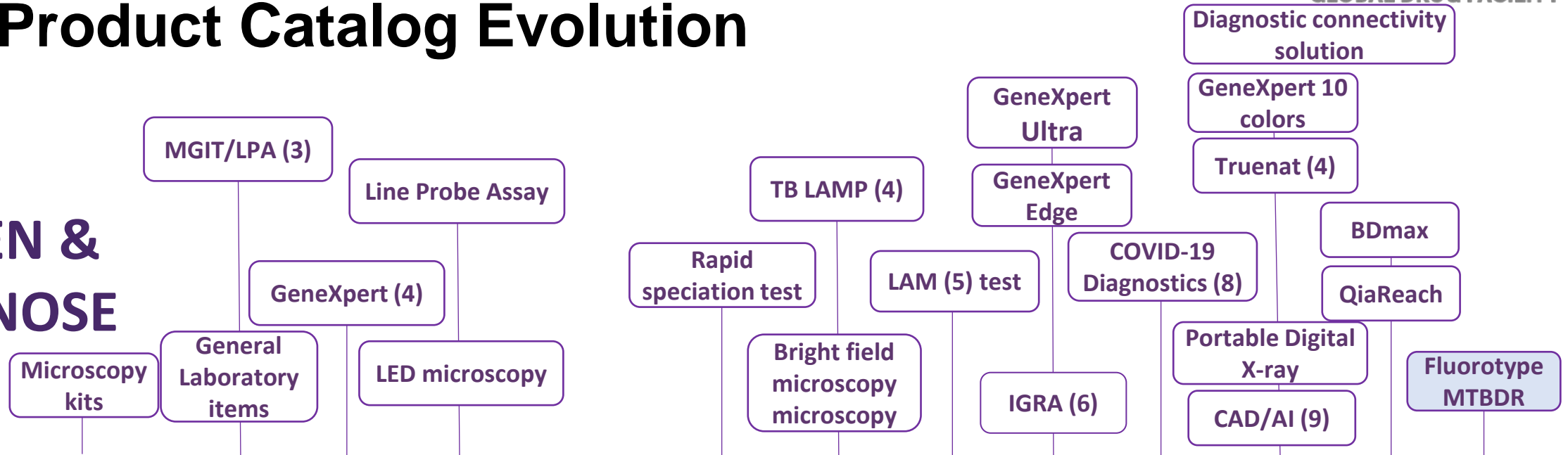
GOAL: facilitate access to TB medicines, diagnostics, medical devices and other health products for the fight against TB

Objectives for procurement and supply:

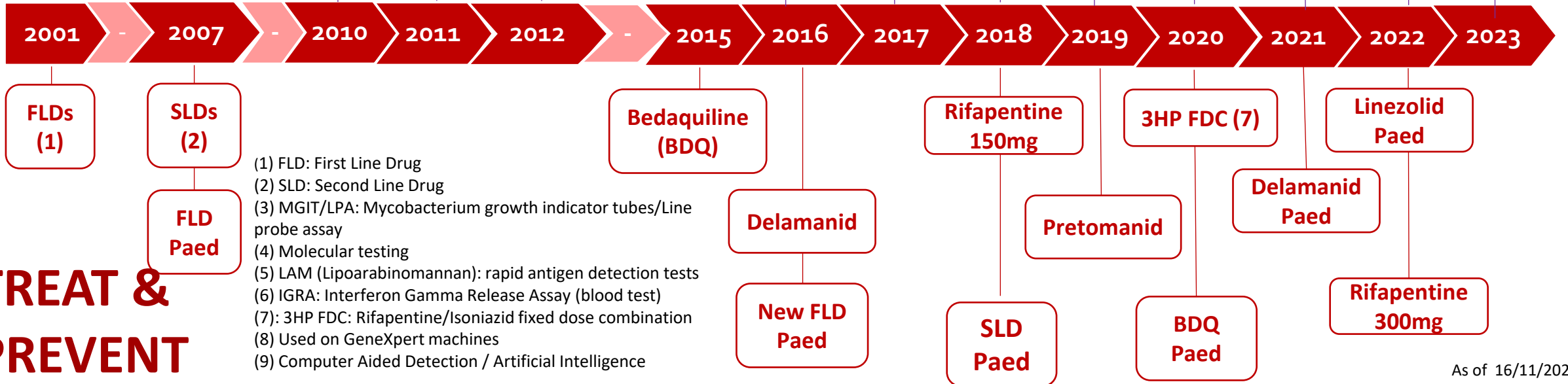
- ✓ Ensure access to TB products, including new tools recommended by WHO TB program through **strategic procurement** for timely inclusion into the GDF Catalog
- ✓ Ensure the **best possible sustainable affordable price** and **terms and conditions** for procurement and supply of TB products for increased access
- ✓ Ensure **quality of TB products** supplied to countries
- ✓ Ensure **timely supply** of TB products to countries to protect against stockouts

GDF Product Catalog Evolution

SCREEN & DIAGNOSE



TREAT & PREVENT



- (1) FLD: First Line Drug
- (2) SLD: Second Line Drug
- (3) MGIT/LPA: Mycobacterium growth indicator tubes/Line probe assay
- (4) Molecular testing
- (5) LAM (Lipoarabinomannan): rapid antigen detection tests
- (6) IGRA: Interferon Gamma Release Assay (blood test)
- (7): 3HP FDC: Rifapentine/Isoniazid fixed dose combination
- (8) Used on GeneXpert machines
- (9) Computer Aided Detection / Artificial Intelligence

As of 16/11/2023

Pediatric DR-TB Initiative: Child-Friendly, DR-TB Formulations*

Cycloserine 125mg
Ethambutol 100mg
Ethionamide 125mg
Levofloxacin 100mg
Moxifloxacin 100mg
Pyrazinamide 150mg

Clofazimine 50mg
Isoniazid 100mg

Bedaquiline 20mg

Delamanid 25mg

Linezolid 150mg

All 11 WHO-Recommended
DR-TB Medicines
Now Available & Accessible
Despite Market Size of
<1,000 Treatments/Year

2018

2019

2020

2021

2022



*Blue indicates 2 suppliers

GDF Catalogues



GDF Medicines Catalogue



GDF Diagnostics, Medical Devices and other Health Products Catalogue

> 600 items

Stop TB Partnership GLOBAL DRUG FACILITY		GDF TB Diagnostics Ordering List April, 2023					Quantity to order	Product price <small>Conventional prices for the region (country) are listed here: http://www.stoptb.org/gdf/conventional-prices. For the non-conventional prices of the non-eligible countries, please contact the GDF Country Supply Officer in charge.</small>		
Sarsted	Product Name	Pack size	Minimum remaining Shelf life	Product technical specifications	Supplier		Indicative FCA Price	Currency	Total Cost	
1. DETECTION AND RESISTANCE OF MTB										
1.1 MOLECULAR TESTING: POC / NEAR-POC										
1.1.1 Truenat MTB equipment										
106689	Truelab Uno Dx Workstation (623010001)	1 set	N/A	Truelab Real Time Quantitative micro PCR System to run 10-12 samples / 8 hours. The workstation has Optics: Fluorescence, Three Wavelength with a speed of 40 cycles of PCR/35 minutes. Interface: Wi-Fi, 3G, Bluetooth with Auto-calibration with a memory of 20,000 test results. Operating temperature: 15-40°C, RH: 10-80%; Display Capacitive 5" Touch Screen LCD Display. The instrument warranty is 12 months from the date of installation. This item includes: 1 Truelab Uno Dx Real Time Quantitative micro PCR Analyser (603021001); 1 Trusprep AUTO v2 Universal Cartridges based sample prep device (603042001); 1 Truelab micro PCR Printer (603050001); 1 Trusprep SPA fixed volume precision micropipette-6 µl (604070000); 1 Field carry case (603120001) and accessories relevant to the equipment. Truelab Software updates are offered for FREE- subject to Internet /WiFi connectivity of the installed devices at their respective sites.	Molbio Diagnostics		10000.00	USD	\$	
106690	Truelab Duo Workstation (643010001)	1 set	N/A	Truelab Real Time Quantitative micro PCR System to run 22-25 samples / 8 hours. The workstation has Optics: Fluorescence, Three Wavelength with a speed of 40 cycles of PCR/35 minutes. Interface: Wi-Fi, 3G, Bluetooth with Auto-calibration with a memory of 20,000 test results. Operating temperature: 15-40°C, RH: 10-80%; Display Capacitive 5" Touch Screen LCD Display. The instrument warranty is 12 months from the date of installation. This item includes: 1 Truelab duo Real Time Quantitative micro PCR Analyser (603022001); 1 Trusprep AUTO v2 Universal Cartridges based sample prep device (603042001); 1 Truelab micro PCR Printer (603050001); 1 Trusprep fixed micropipette-6 µl (604070000) and accessories relevant to the equipment. Truelab Software updates are offered for FREE- subject to Internet /WiFi connectivity of the installed devices at their respective sites.	Molbio Diagnostics		14000.00	USD	\$	
106691	Truelab Quattro Workstation (653010001)	1 set	N/A	Truelab Real Time Quantitative micro PCR System to run 42-45 samples / 8 hours. The workstation has Optics: Fluorescence, Three Wavelength with a speed of 40 cycles of PCR/35 minutes. Interface: Wi-Fi, 3G, Bluetooth with Auto-calibration with a memory of 20,000 test results. Operating temperature: 15-40°C, RH: 10-80%; Display Capacitive 5" Touch Screen LCD Display. The instrument warranty is 12 months from the date of installation. This item includes: 1 Truelab Quattro Real Time Quantitative micro PCR Analyser (603023001); 1 Trusprep AUTO v2 Universal Cartridges based sample prep device (603042001); 1 Truelab micro PCR Printer (603050001); 1 Trusprep fixed micropipette-6 µl (604070000) and accessories relevant to the equipment. Truelab Software updates are offered for FREE- subject to Internet /WiFi connectivity of the installed devices at their respective sites.	Molbio Diagnostics		18000.00	USD	\$	

GDF Ordering List: help in planning and budgeting and contain information on each available product

All are available online! [GDF Product Catalog | Stop TB Partnership](http://www.stoptb.org/gdf)



GDF's Digital Transformation: Innovation for Success



Since 2018, GDF has started its digital transformation with the objective of leveraging technology to enhance processes, automation, data/analytics, building operational efficiencies, and constantly improving customer experience.



Meet changing business and market requirements

The Centralized Data store and analysis Platform (CDP)

Transforms the data captured from various data sources within different GDF dataflow procedures into useful information and knowledge for decision making, piloting the end-to-end supply chain process, measuring performance and communicating to stakeholders



Data warehouse



CDP Portal

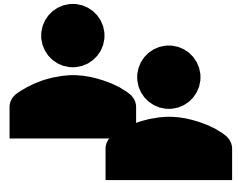


Reports/Dashboards via PowerBI

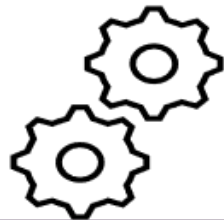
CDP Portal

Innovative GDF's web platform for supplier's data collection, validation, and processing for API, TB medicines in the market and under development, status of TB medicines registration in countries, and for tendering process of TB medicines

Coming soon!!!
CDP module for
product
complaint
management



Early interaction with suppliers to closely track development of new TB medicines and formulations to accelerate their inclusion in GDF catalog.



User-friendly compared to other existing sourcing platform, to ease entries by suppliers and validation by GDF of TB medicines technical information



Live availability of reliable and up-to-date technical information on TB medicines and status of medicine country registration to facilitate and speed up strategic sourcing



Technical bid submission in few "clicks" to speed up tender process and inclusion of TB medicines in GDF catalog

GDF DR-TB Regimen Prices, Adult*

Regimen	Regimen Composition	Regimen Duration	Age/Weight Band	Lowest Regimen Price**
BPaLM	6 Bdq Pa Lzd Mfx	6 months	≥ 14 years	\$ 426
BPaL	6 Bdq Pa Lzd	6 months	≥ 14 years	\$ 399
BDQ-based, all-oral shorter regimen	4 Bdq _{6 months} Cfz E Hh Lfx Eto Z / 5 Cfz E Lfx Z	9 months	46 – 55 kg	\$ 370
BDQ-based, all-oral shorter regimen w/ LZD	4 Bdq _{6 months} Cfz E Hh Lfx Lzd _{2 months} Z / 5 Cfz E Lfx Z	9 months	46 – 55 kg	\$ 348
BDQ-based, all-oral, longer regimen	18 Bdq _{6 months} Lfx Lzd Cfz	18 months	46 – 55 kg	\$ 540

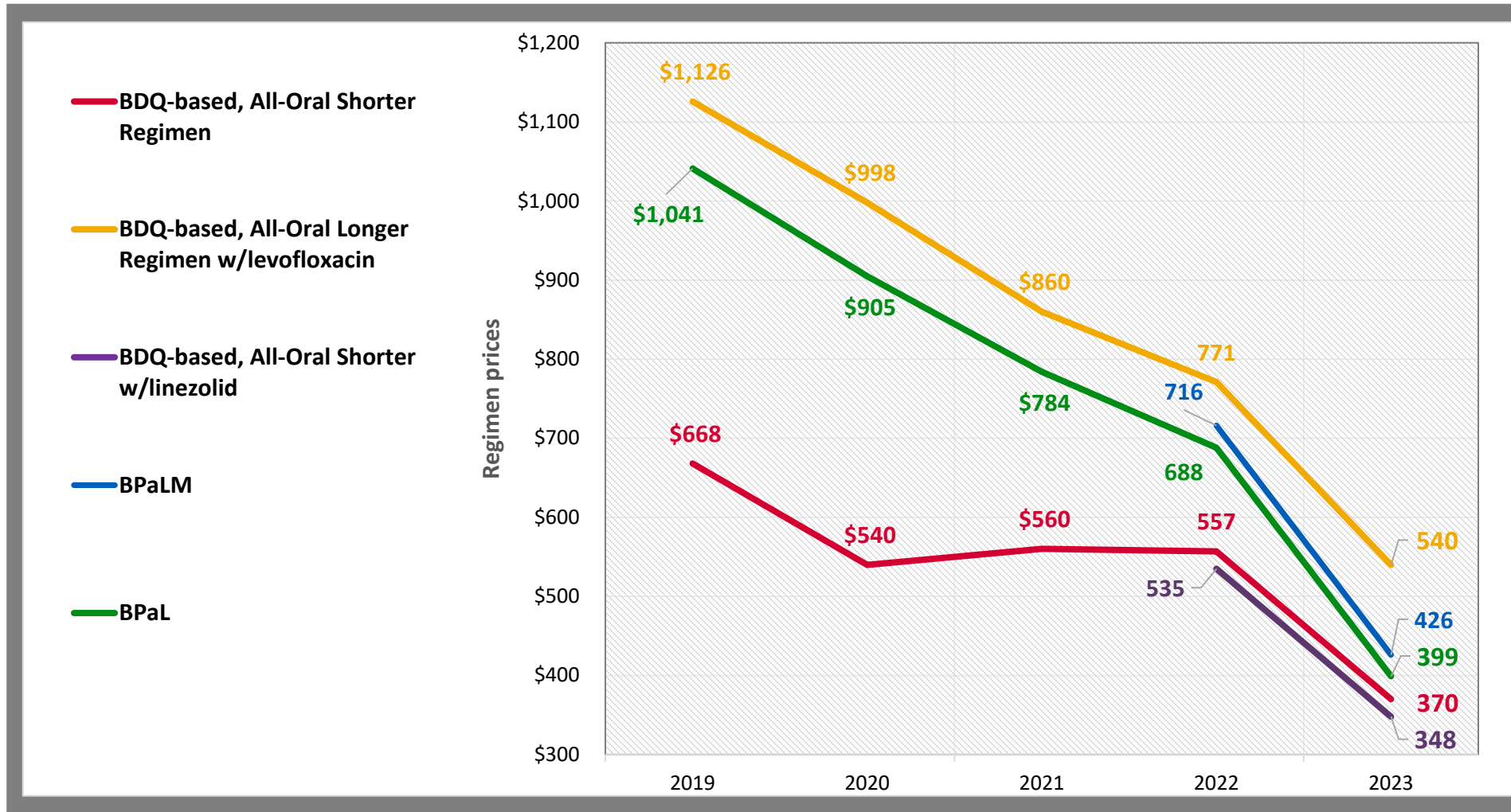
Historic price reduction up to 55% for Bedaquiline

* GDF Prices as of September-2023 located here <https://www.stoptb.org/buyers/plan-order>

** BDQ treatment duration used 26 (rather than 24) weeks. Lowest prices use the lowest price available for that product from all suppliers contracted with GDF,



DR-TB Regimen Price Reductions



As of 16/11/2023

GDF TB Preventive Therapy (TPT) Regimen Prices, Adult*

Regimen Composition	Regimen Duration	Age/Weight Band	Estimated Regimen Price*
3HP (Using rifapentine/isoniazid 300/300mg FDC, tabs)	3 months	≥ 14 years	\$ 10
3HP (Using single Rpt 300mg tabs and H 300mg tabs)	3 months	≥ 14 years	\$ 13
1HP (Using single Rpt 300mg tabs and H 300mg tabs)	1 month	≥ 14 years	\$ 19

3HP FDC, 30% price reduction

* GDF Prices as of Sep-2023 located here: <https://www.stoptb.org/buyers/plan-order>. Estimated regimen prices are calculated using 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)

GDF Quality Assurance (QA) Policy and GDF Quality Monitoring Program (QMP)

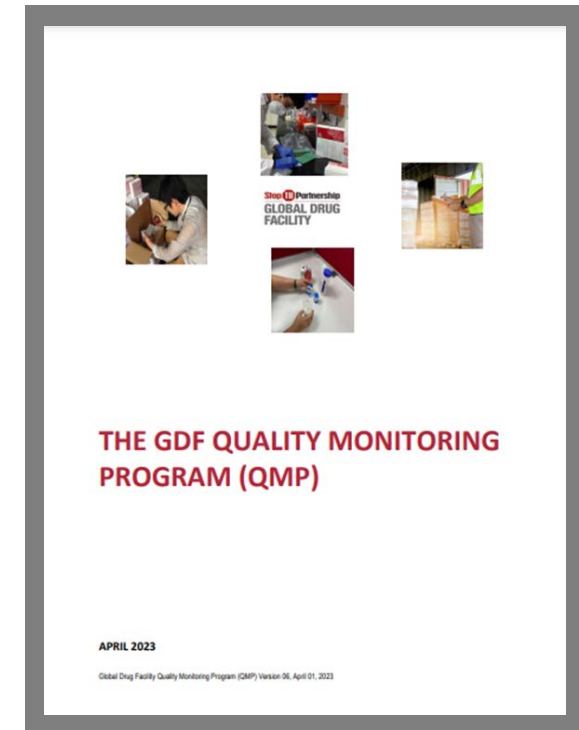
GDF is committed to supply quality-assured TB products for its customers through a stringent quality product management system

GDF updated its
QA Policy in
September
2022

(updates for TB
diagnostics
products)



GDF updated
its QMP in
April 2023



<https://www.stoptb.org/suppliers/quality-assurance>

QA for Medicines

To be eligible for GDF procurement, Finished Pharmaceutical Products (FPPs) shall be

- (A) **Prequalified by WHO PQ programme** OR authorized for use by a **Stringent Regulatory Authority (SRA)**, defined as either an ICH member country, observer or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement

In the absence of FPP meeting the standard A) as described above, FPP may be approved for procurement by GDF if:

- (B) Recommended for procurement through a quality/clinical risk assessment process managed by the WHO-coordinated **Expert Review Panel (ERP)**. FPP recommended by the ERP for a limited period shall meet the following conditions:
 - a. The FPP is manufactured at a site compliant with GMP standards that apply for the relevant product formulation as verified after inspection by::
 - i. WHO PQP (refer to <https://extranet.who.int/pqweb/medicines/>) ; or
 - ii. an SRA defined as above; or
 - iii. inspectors of a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) .
 - b. The manufacturer of the FPP has submitted an application/dossier for pre-qualification of the product by the WHO PQP or for marketing authorization to an SRA and the application/dossier has been accepted for assessment either by WHO PQP or an SRA .
 - c. The procurement of an ERP recommended FPP shall be valid for a period of no more than 12 months from the time of the ERP recommendation or until the FPP is WHO-prequalified or SRA-authorized, whichever is the earlier unless otherwise advised by the ERP recommendation letter.

QA for TB diagnostics

QA Requirements for medical devices, IVDs and medical software are in 3 parts:

Manufacturer/Developer

- Valid Quality management System (QMS) to **ISO 13485** (or equivalent) covering product categories, locations and facilities where relevant activities are performed as assessed by a competent Conformity Assessment Body (CAB) recognized by the regulatory authority of a **former GHTF founding member (e.g., EU, US, Canada, Australia, Japan)**

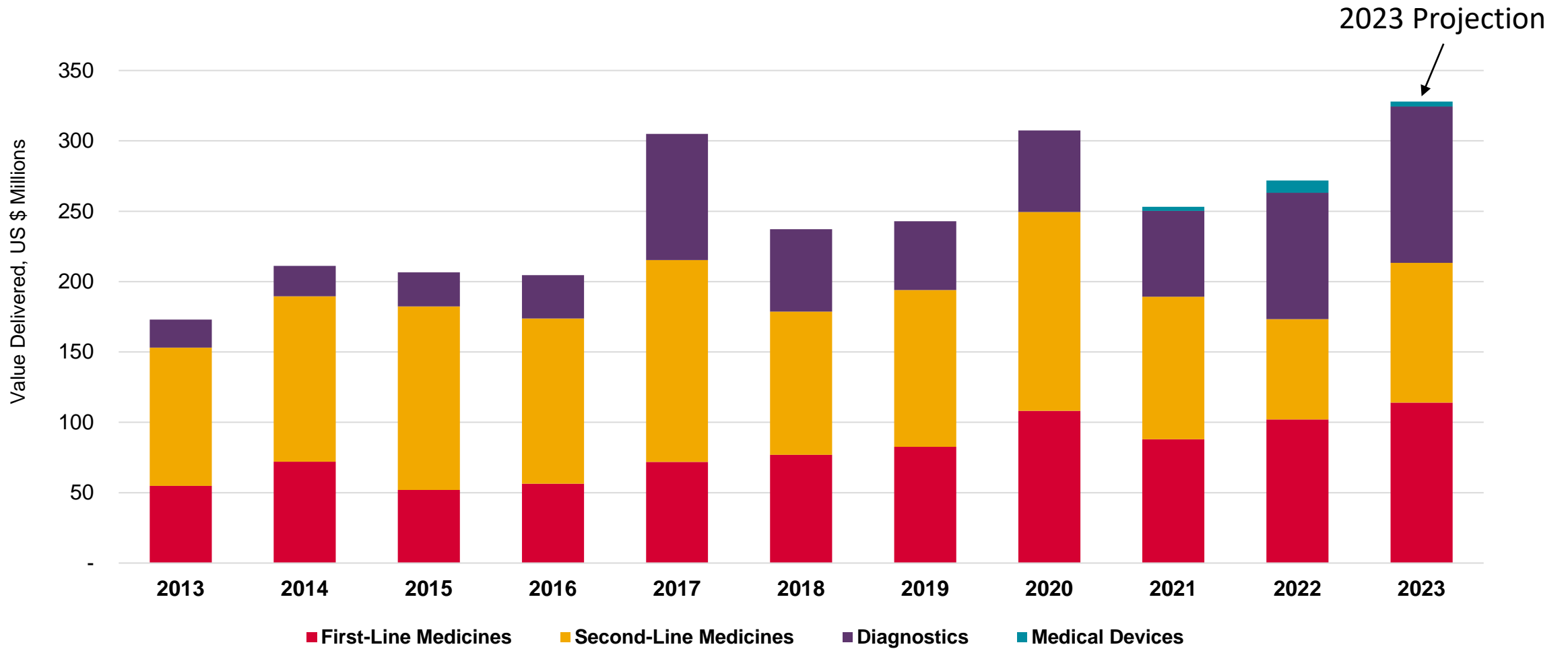
Supplier (if not the manufacturer/developer of the product)

- Valid and certified QMS per current versions of **ISO 9001** (or equivalent)

Product shall meet the following to be eligible for GDF's procurement

- Recommended by **WHO Global TB Programme**, OR
- Regulatory approval/marketing authorization by **former GHTF founding member for applicable risk classification**, OR
- Prequalified by **WHO PQ Programme**, OR
- Be recommended by the **Expert Review Panel for Diagnostics (ERPD)** for a time-limited period
- Have a **Declaration of Conformity** in accordance with IMDRF and/or ISO 17050, AND
- Have a Certificate of Analysis that product is compliant with relevant ISO/compendia standards where applicable

GDF Total Cost* of TB Products delivered to countries



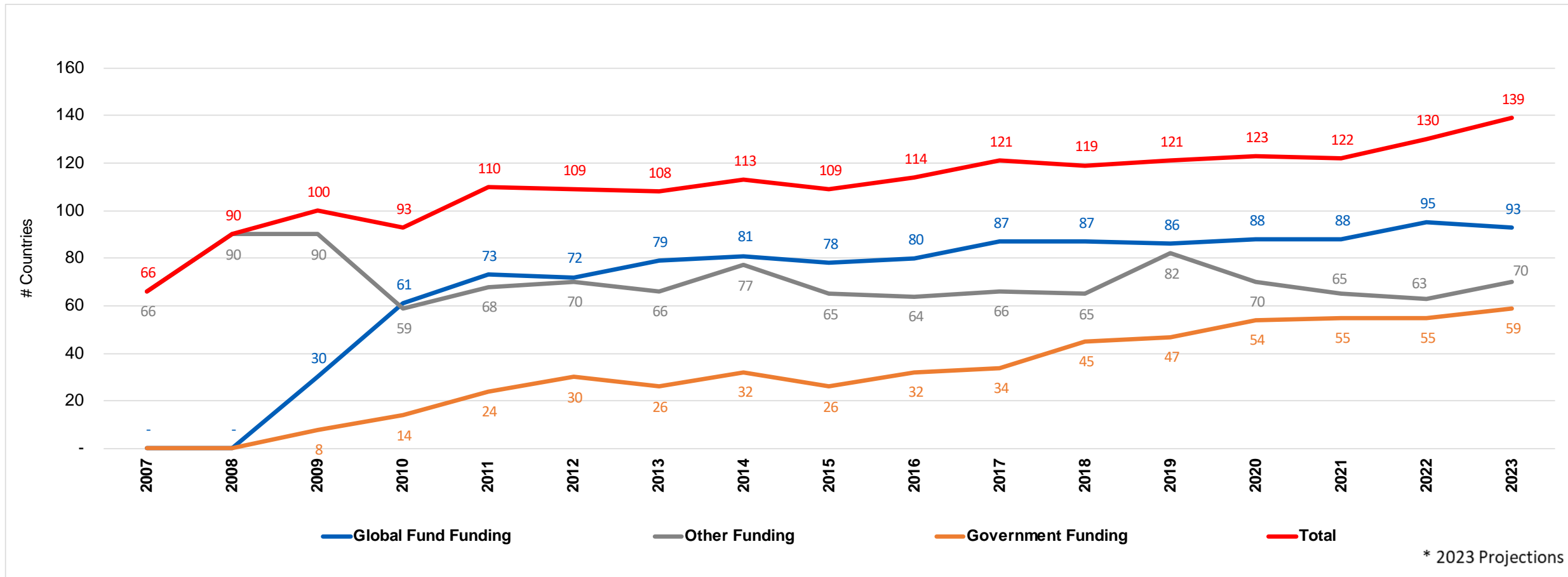
* Value includes product and shipping costs



Funding Sources of GDF's Clients

GDF has clients in more than 130 countries → Increasingly more clients procuring with government funding

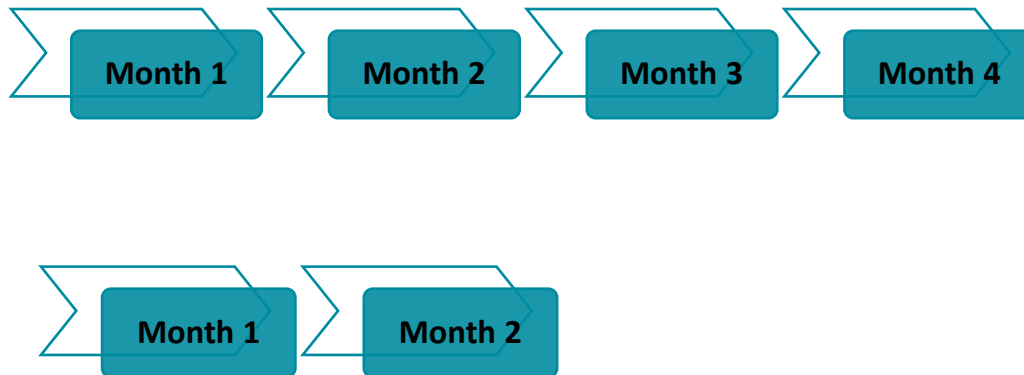
Countries Procuring via GDF by Funding Source 2007-2023*



GDF's management of urgent and emergency orders

In 2023, GDF expedited shipments of TB products to 123 countries where products were needed earlier than the standard six-months lead time.

GDF
Integrated
Pooled
Procurement
Approach



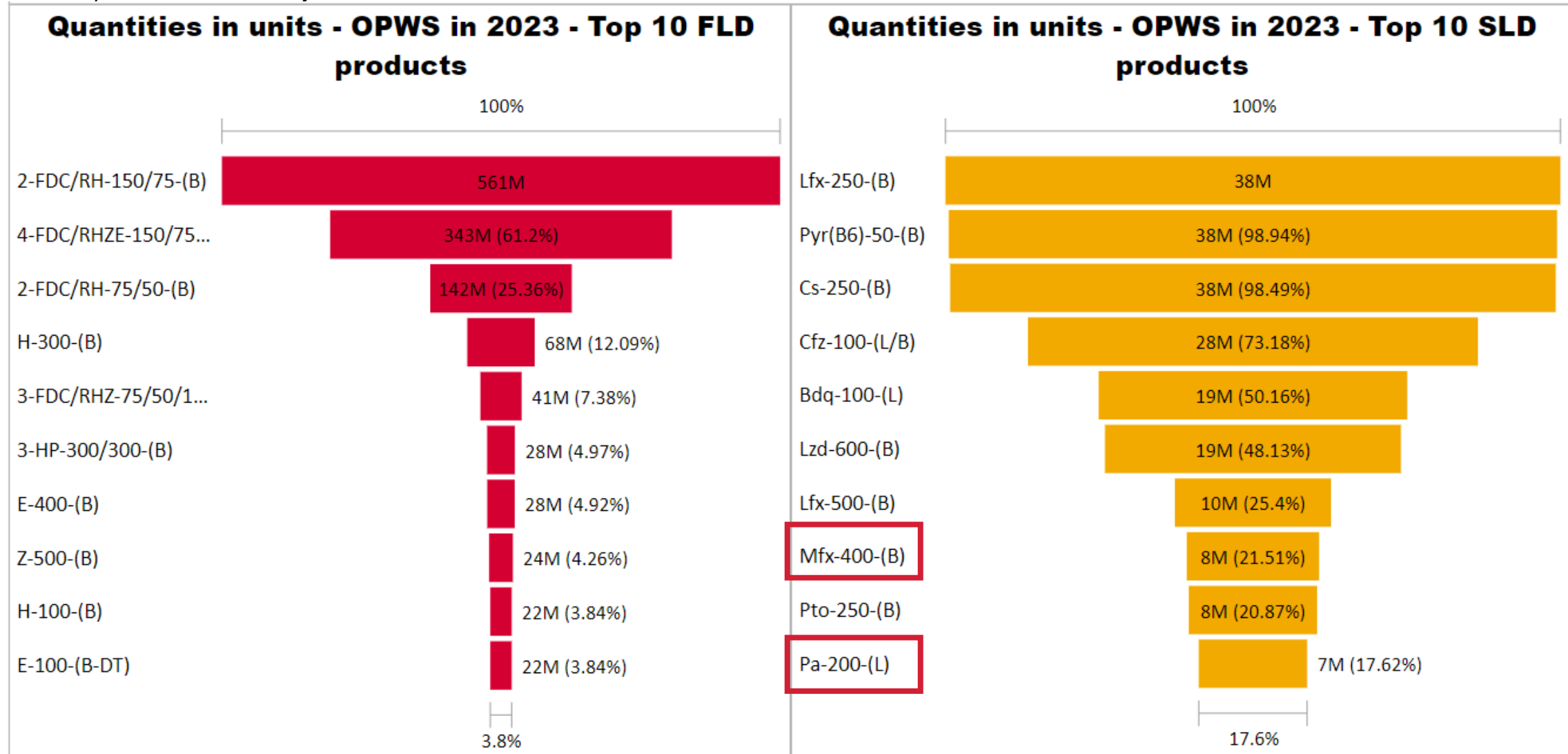
GDF Delivered Products to 114 Countries
within **2-4 Months for Urgent Orders***

GDF Delivered Products to 71 Countries
in **Less than 2 months for Emergency Orders***

* q1-3 2023

Top 10 Products Purchased by Countries via GDF in 2023

(in volume, as of 16/11/2023)



TB Medicines Gaps

TB Medicines for Which Additional Suppliers are Required

Product Type	INN/strength/form
Adult DR-TB	Pretomanid 200mg tablets
Pediatric DR-TB	Bedaquiline 20mg tablets or dispersible tablets (preferably scored) Clofazimine 50mg tablets or dispersible tablets Cycloserine 125mg capsules Delamanid 25mg tablets or dispersible tablets
TB Preventive Therapy (TPT)	Isoniazid 300mg/Rifapentine 300mg tablets (3HP) Rifapentine 300mg tablets

TB Medicines (New Formulation) for Which Suppliers are Required

Product Type	INN/strength/form
Pediatric LTBI	Rifapentine 150mg dispersible tablets (scored)

Watchlist:
-Study 31 FDC
-DLM 50mg
- 1HP (FDC)

As of 19/11/2023

How to become a GDF suppliers for TB medicines

Meet GDF
QA criteria

Contact GDF
at
gdf@stoptb.org
to access
GDF's CDP
Portal

Enter
required
product
information
in CDP
Portal for
GDF
approval

Compete in
a GDF public
tender and
be awarded

(multiple awards
possible with market
share allocation)

Complete
and sign a
long-term
agreement
(LTA)

with GDF's contracted
procurement agent

Product in
GDF catalog

How to become a GDF suppliers for TB Diagnostics

Meet GDF QA
criteria

Register with
the United
Nations Global
Marketplace
(UNGM)
<https://www.ungm.org/>

Compete in a
UNOPS/GDF
public tender
and be
awarded

(multiple awards possible
for some products)

Complete and
sign a long-
term
agreement
(LTA) with
UNOPS/GDF

Product in GDF
catalog

Thank You

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