Promoting Access to TB Products
GDF's 2024 Updates

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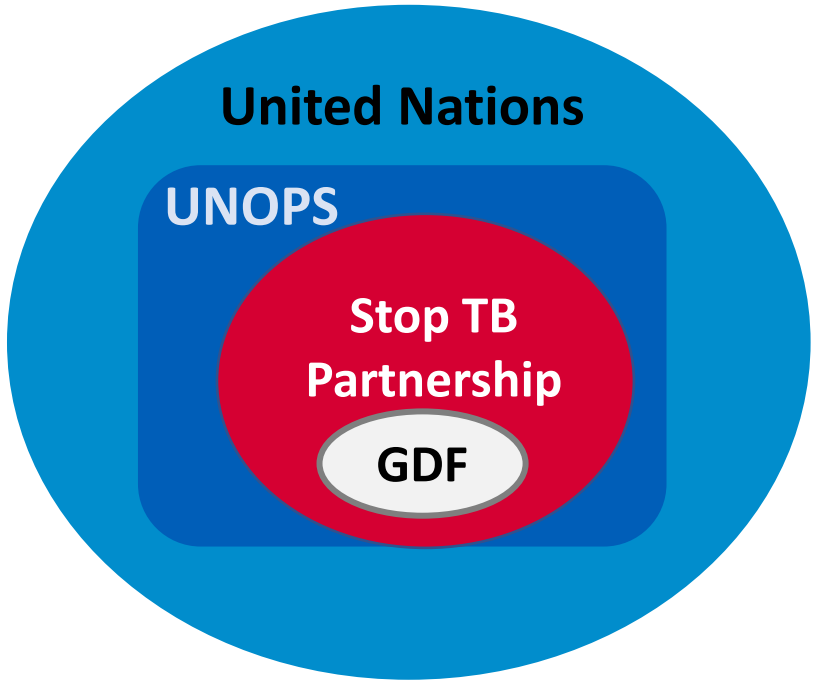
2024 Joint UNICEF, UNFPA, and WHO Meeting, Copenhagen, 2 – 6 December 2024

StopTB partnership and the Global Drug Facility (GDF)



- GDF was established in 2001
- Part of the United Nations (hosted by the United Nations Office for Project Services - UNOPS)
- Enterprise within the Stop TB Partnership
- Largely funded by USAID

USAID FROM THE AMERICAN PEOPLE

- GDF is ISO 9001:2015 certified

QS CERTIFIED SYSTEM ISO 9001

End-to-end approach along entire product lifecycle, coordinating TB market stakeholders

One-stop shop for TB products

All TB programmes are eligible to procure from GDF regardless of income classification or funding source in alignment with national rules and regulations (165 countries served since its inception in 2001). https://www.stoptb.org/facilitate-access-to-tb-drugs-diagnostics/global-drug-facility-gdf

GDF Mission and Strategic Framework, 2023-2028

MISSION	**Worldwide, equitable access to TB products**			
VISION	**Sustainable, viable global markets that deliver innovative, quality-assured, affordable TB products**			
STRATEGIC OBJECTIVES	① Drive **stewardship** of global TB markets	② Demonstrate best in class model for **global sourcing and supply**	③ Facilitate **country-led procurement** and supply solutions	④ **Incentivize and introduce** innovations
OPERATIONAL PRINCIPLES	**End-to-end product life-cycle management**	**Integrated procurement services maximizing efficiency & automation**	**Tailored solutions to address TB market challenges**	**Cost-effective, greener supply chains**

https://www.stoptb.org/2023-2028-operational-strategy

GDF Expansion into Antimicrobial Resistance (AMR)

- Strategic review revealed AMR to be an area where GDF could add value and have significant impact.
  - An expansion into medicines for AMR was then included as part of GDF's new 2023-2028 Strategy
- GDF to supply some AMR medicines when there is a value-add to leverage the GDF platform
- Progress to date:
  - May 2024, signed a partnership agreement with the Global Antibiotic Research & Development Partnership (GARDP) to support the introduction of new, priority antibiotics for AMR
    - GARDP is an AMR-focused product development partnership working with 70 partners across 16 countries to accelerate the development and access to treatments for drug-resistant infections. https://gardp.org
  - June 2024, Co-hosted with WHO, GARDP, and Unitaid the SECURE Operational Planning meeting
- Next steps: collaborate with partners to determine which medicines to include in a GDF AMR catalog, and support product road maps for introduction and scale-up in countries

https://www.stoptb.org/news/new-partnership-improve-access-new-antibiotics-low-and-middle-income-countries-boost-efforts

Stop TB Partnership
GLOBAL DRUG FACILITY

GDF PRODUCT CATALOG EVOLUTION

1. FLD - First Line Drugs
2. SLDs - Second Line Drugs
3. 3HP – rifapentine/isoniazid fixed dose combination

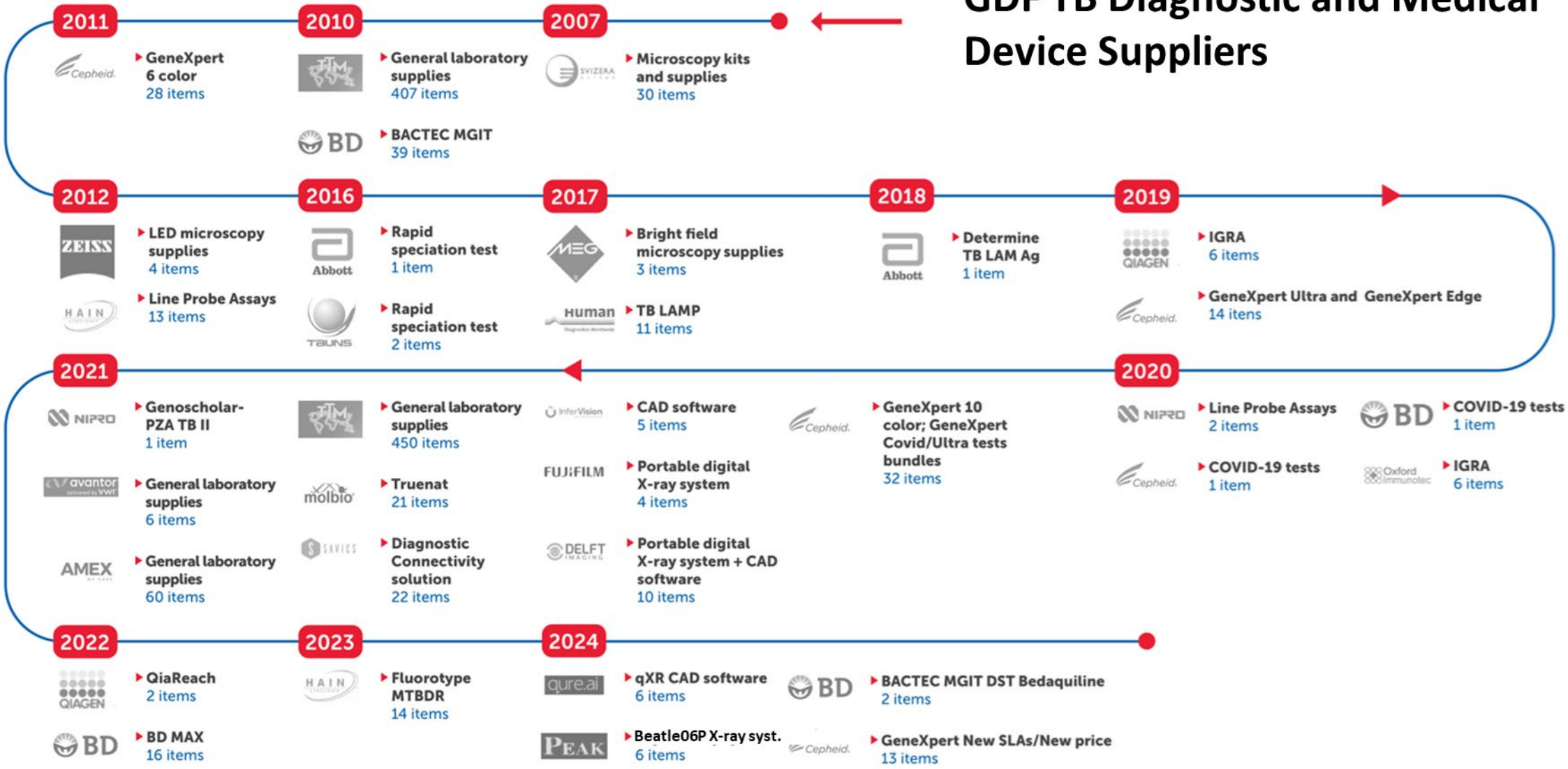
Child Friendly Formulations

- 3FDC - Rifampicin 75mg /Isoniazid 50mg/ Pyrazinamide 150mg
- 2FDC - Rifampicin 75mg/Isoniazid 50mg dispersible
- Isoniazid 100mg
- Cycloserine 125mg
- Ethambutol 100mg
- Ethionamide 125mg
- Levofloxacin 100mg
- Moxifloxacin 100mg
- Pyrazinamide 150mg
- Clofazimine 50mg
- Bedaquiline 20mg
- Delamanid 25mg
- Linezolid 150mg
- Rifapentine 150mg

TREAT & PREVENT

2001	FLDs[1]
2007	SLDs[2], FLD Paediatrics
2010	
2011	
2012	
2015	Bedaquiline (BDQ)
2016	Delamanid, New FLDs strength for Paediatrics
2017	
2018	Rifapentine 150mg, SLD Paediatrics
2019	Pretomanid
2020	3HP FDC[8], BDQ Paediatrics
2021	Delamanid Paediatrics
2022	Linezolid Paediatrics, Rifapentine 300mg
2023	Rifapentine Paediatric
2024	

GDF TB Diagnostic and Medical Device Suppliers



2024 New Products Introduction

Ultraportable Digital X-ray

FDR Xair Kit
(with safety accessories) (166

Product Code: 200

FDR Xair is a
X-ray Sys
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Peak Bea
(with safety act

Product Code: 20003

PeakBeatle06P Kit is an Ultraportable
System fully battery-powered capable of 20
exposures with fully charged batteries that can be used for TB screening and various other indications.

- 2024 GDF tender led to **price decreases up to 67%** for **ultraportable Digital X-ray kits** and **services** offered, leading to improved access and sustainable use
- Suppliers of **CAD/AI software** are encouraged to submit their dossier to the **WHO PQ Program for assessment**

https://www.who.int/news-room/articles-detail/call-for-expression-of-interest-by-manufacturers-of-software-for-computer-aided-detection-of-tuberculosis-(cad)-to-submit-products-for-who-expert-assessment

Computer-Aided Detection based on Artificial Intelligence (CAD/AI) software

InferRead DR Chest Software
Perpetual License (INDRCHESTPL) and 3 years License S&M (INDRCHEST3YL)

Product Code: 200001 and 200027

InferRead DR Chest Software is able to detect TB, for which it processes both antero-posterior (AP) and postero-anterior (PA) chest X-ray in less than 10 seconds. The output is a binary outcome for TB, continuous values for TB-probability and annotated images with rectangles indicating the areas identified as TB.

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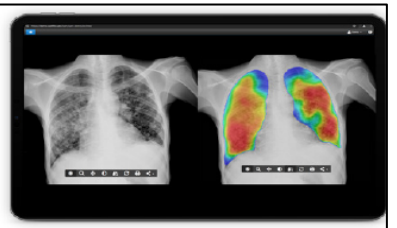
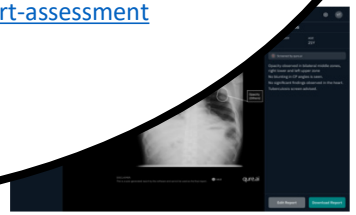


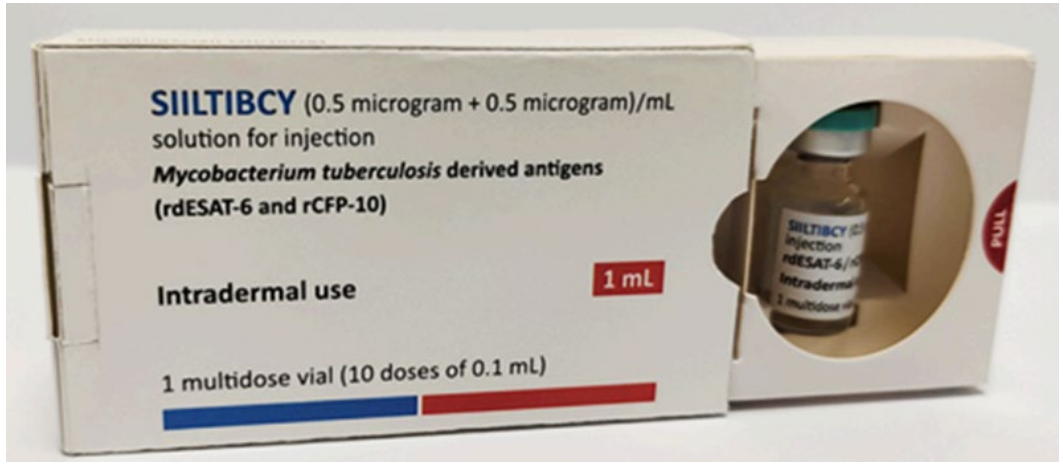


QXR AI SOFTWARE
Perpetual License (qXRPERP) and 3 years License S&M (qXRLICEN)

Product Code: 200036 and 200037

qXR AI is able to detect TB, for which it processes both antero-posterior (AP) and postero-anterior (PA) chest X-ray in less than 10 seconds. The output is a score ranging from 0-1 shown together with a heatmap and translated into a pre-set binary (positive / negative) score.

Newly Added to GDF Catalog: SIILTIBCY™ skin test



Stop TB Partnership Global Drug Facility Info Sheet: SIILTIBCY
https://www.stoptb.org/sites/default/files/documents/SIILTIBCY%20GDF%20Info%20Sheet.pdf

SIILTIBCY™ skin test is classified as MEDICINE

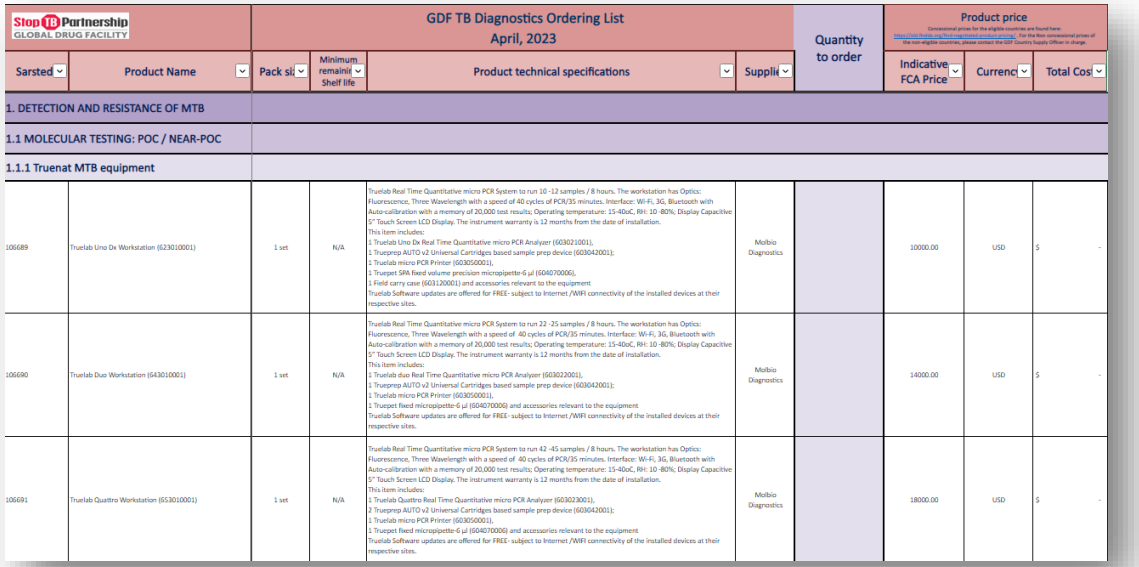
PRODUCT CODE	DESCRIPTION (PRODUCT, PACKAGING)	NUMBER OF UNITS PER PACK	PRICE OR PRICE RANGE (USD)	DRUG-SENSITIVE TB / DRUG-RESISTANT TB / MTB INFECTION
rdESAT-6/rCFP-10-0.5/0.5-(V)-1 (SIILTIBCY)	rdESAT-6/rCFP 0.5 µg/0.5 µg. Solution for injection intradermal, vial of 1ml. Each vial contains 10 doses/tests	1	15.00	Detection of Mtb infection

https://www.stoptb.org/news/breaking-news-only-150-detect-tb-infection-next-generation-siiltibcy-test

GDF Catalogues

GDF Medicines Catalog

GDF Diagnostics, Medical Devices and other Health Products Catalog



Stop TB Partnership GLOBAL DRUG FACILITY — GDF TB Diagnostics Ordering List, April, 2023

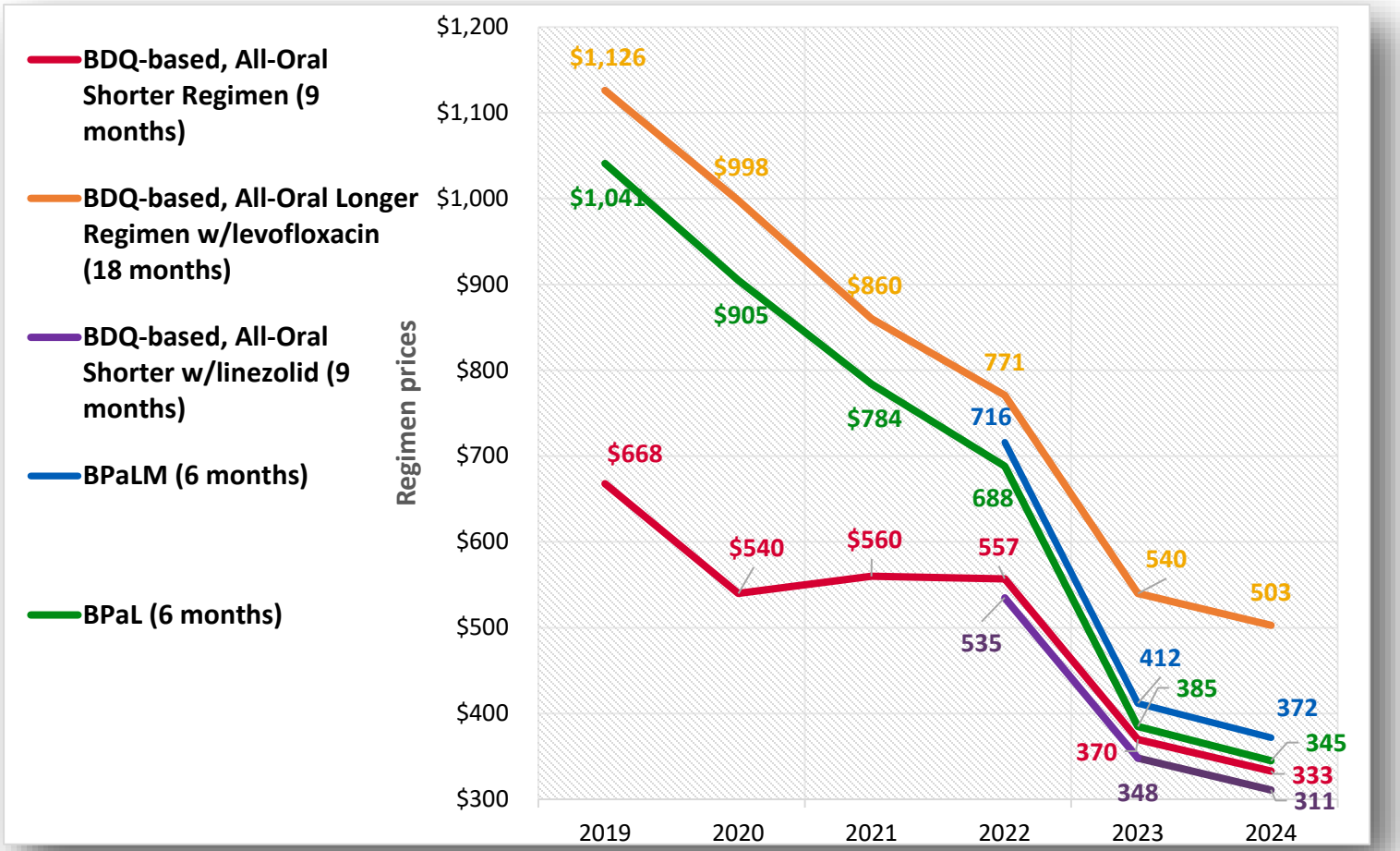
Sarsted	Product Name	Pack si	Minimum remainir Shelf life	Product technical specifications	Supplir	Quantity to order	Product price: Indicative FCA Price	Currenc	Total Cos
1. DETECTION AND RESISTANCE OF MTB									
1.1 MOLECULAR TESTING: POC / NEAR-POC									
1.1.1 Truenat MTB equipment									
106689	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: 15-40oC, 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 Analyzer (603021001), 1 Trueprep AUTO v2 Universal Cartridges based sample prep device (603042001); 1 Truelab micro PCR Printer (603050001), 1 Truepet SPA fixed volume precision micropipette-6 µl (604070006), 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: 15-40oC, 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 Analyzer (603022001), 1 Trueprep AUTO v2 Universal Cartridges based sample prep device (603042001); 1 Truelab micro PCR Printer (603050001), 1 Truepet fixed micropipette-6 µl (604070006) 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: 15-40oC, 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 Analyzer (603023001), 2 Trueprep AUTO v2 Universal Cartridges based sample prep device (603042001); 1 Truelab micro PCR Printer (603050001), 1 Truepet fixed micropipette-6 µl (604070006) 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	$ -

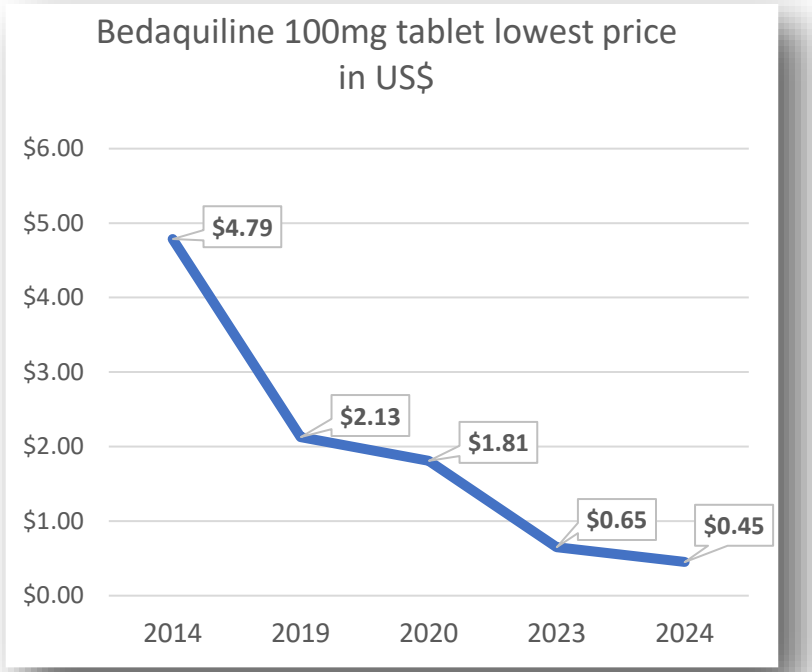
GDF Ordering List: help in planning and budgeting and contain detailed information on each available product

> 600 items

All are available online! [GDF Product Catalog | Stop TB Partnership]

Drug Resistant -TB Regimen Price Reductions



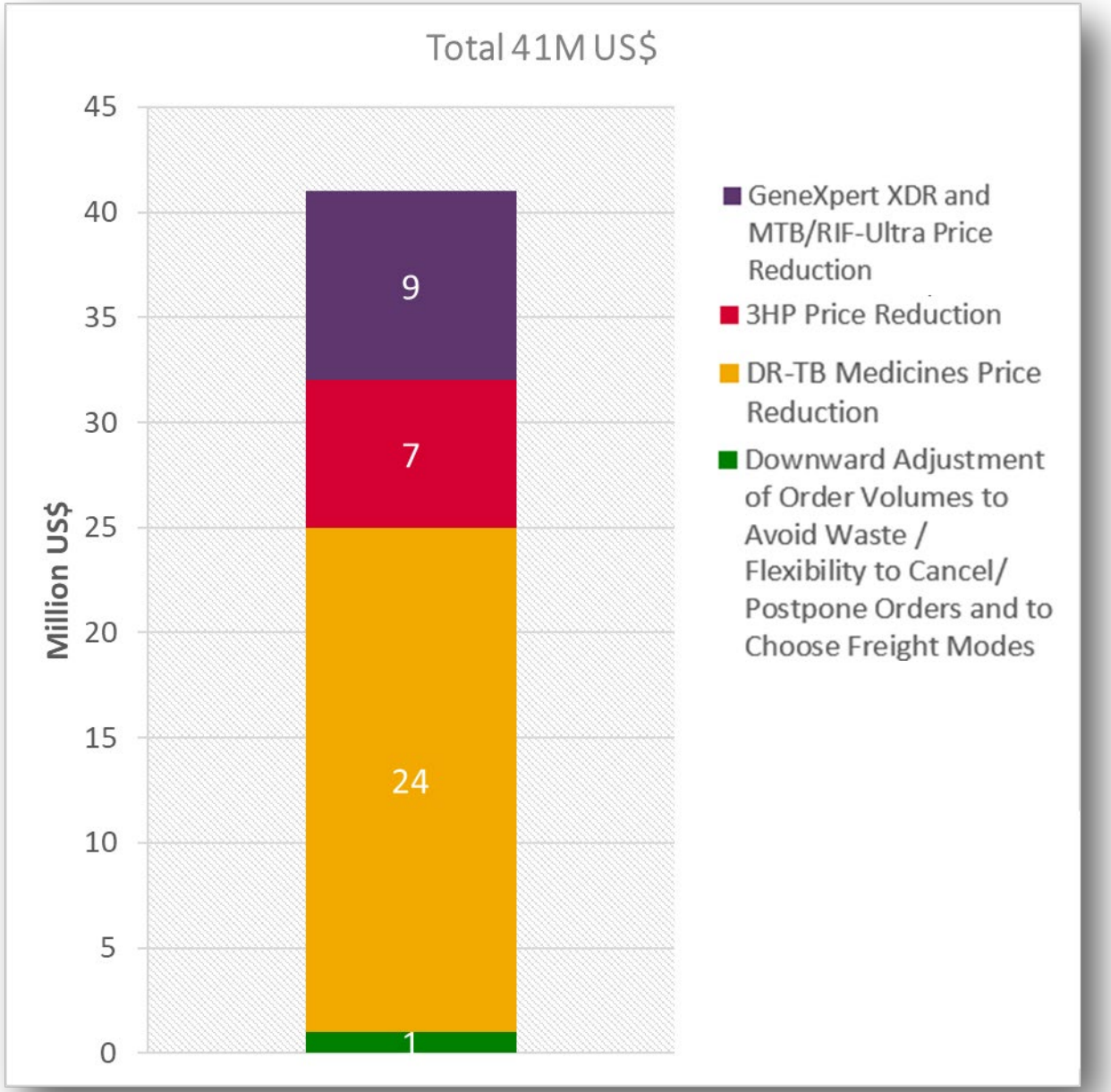


As of 22/11/2024

GDF Savings in 2024

GDF saved **US$ 41 million** as of 30 September 2024 equivalent to the cost of treating an additional **94,250 adults** with DR-TB using the newly-recommended **BPaLM regimen** or treating an extra **4 million** people with **3HP for TB prevention** or test additional **1.12 million of people** for TB with GeneXpert MTB/RIF Ultra.

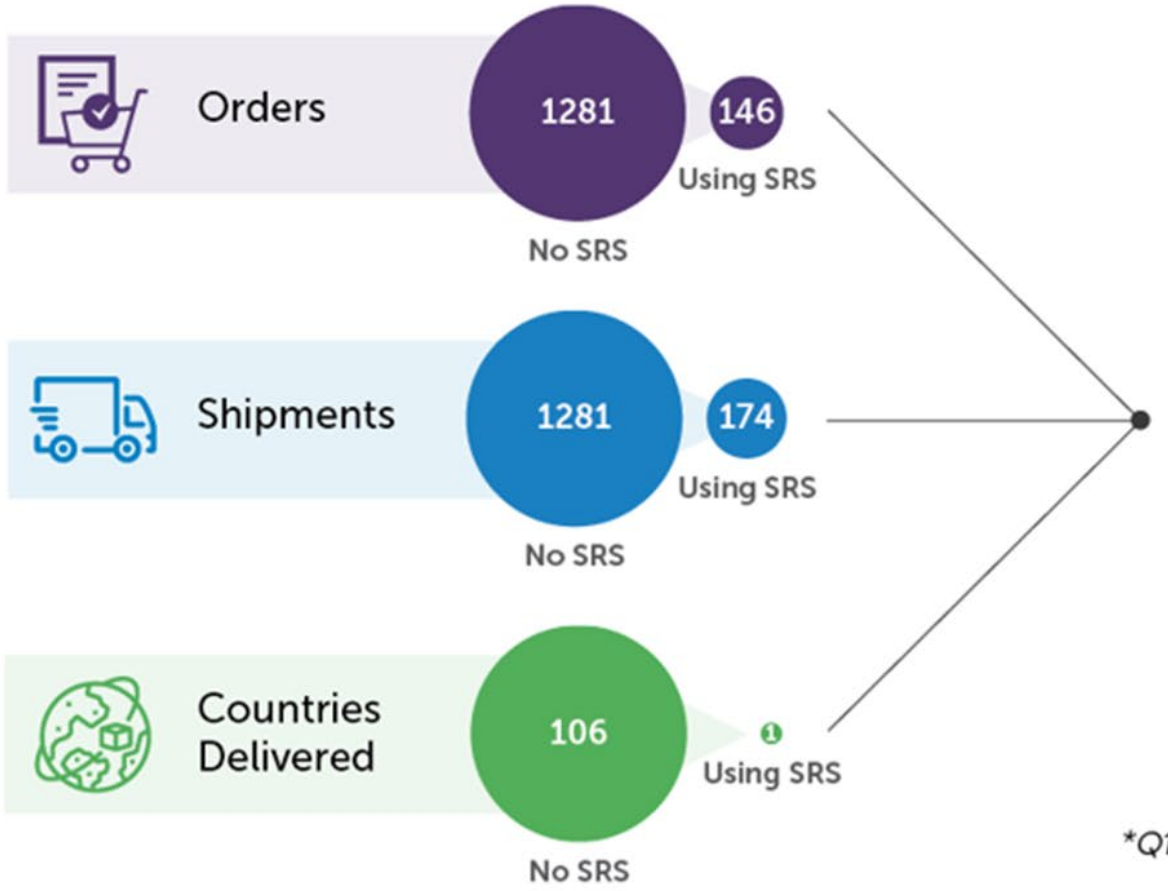
These savings are the results of GDF strategic procurement and collaboration with Donors (USAID and Global Fund)



GDF Strategic Rotating Stockpile

Benefits to suppliers must be passed to patients

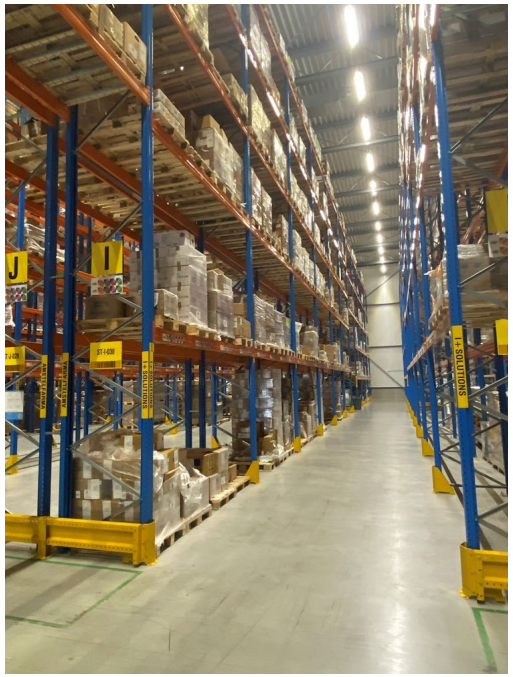
2024*: Fewer orders and shipments decreased suppliers' transaction costs:



GDF requests suppliers to pass on the reduced transaction costs to the prices of TB medicines

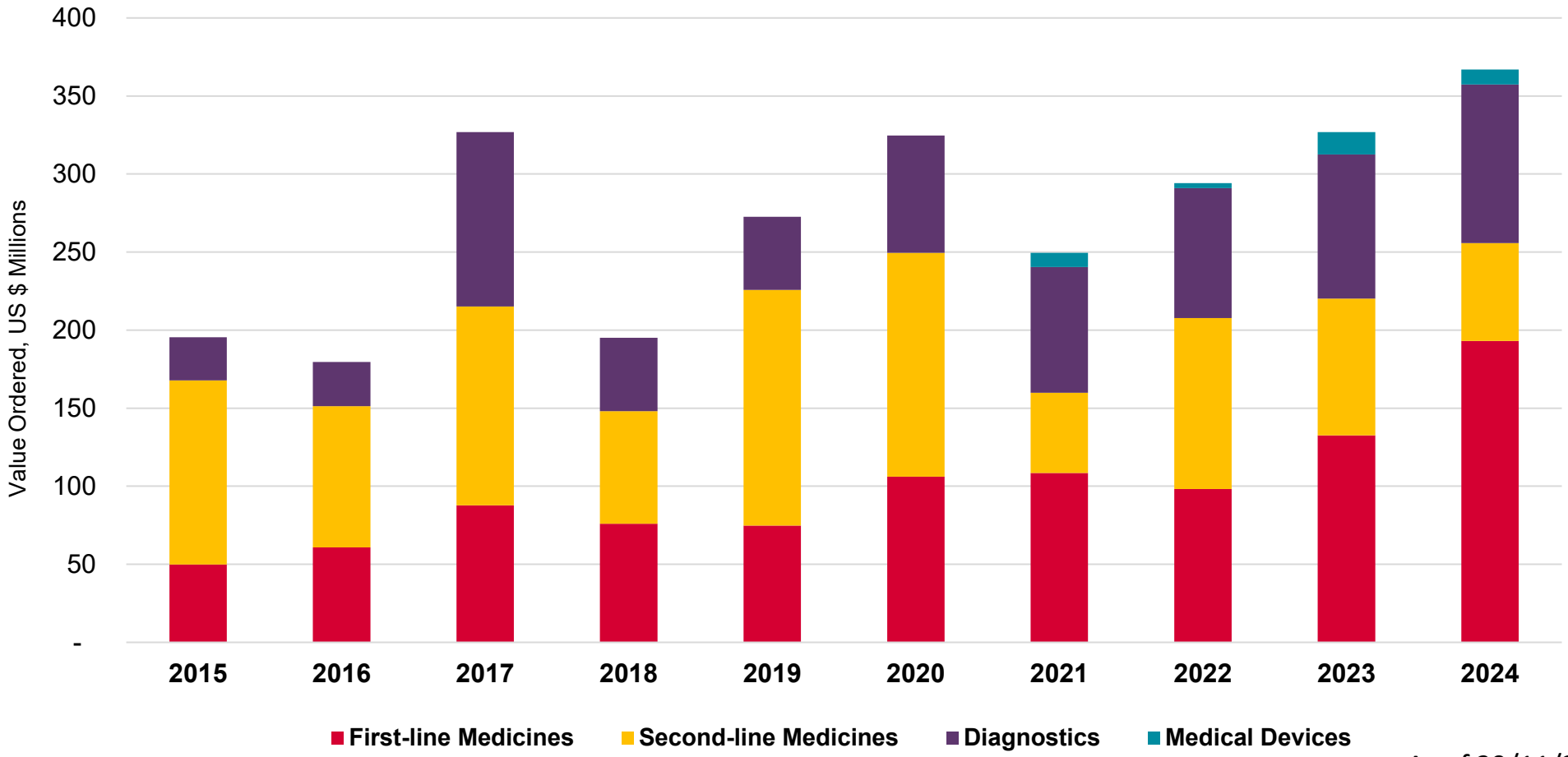
*Q1 to Q3 2024 (01/01 to 30/09)

Suppliers awarded as primary suppliers in GDF tenders are prioritized for inclusion in the GDF Strategic Rotating Stockpile



2024 GDF New Record - US$ 367 Million of TB Products Procured

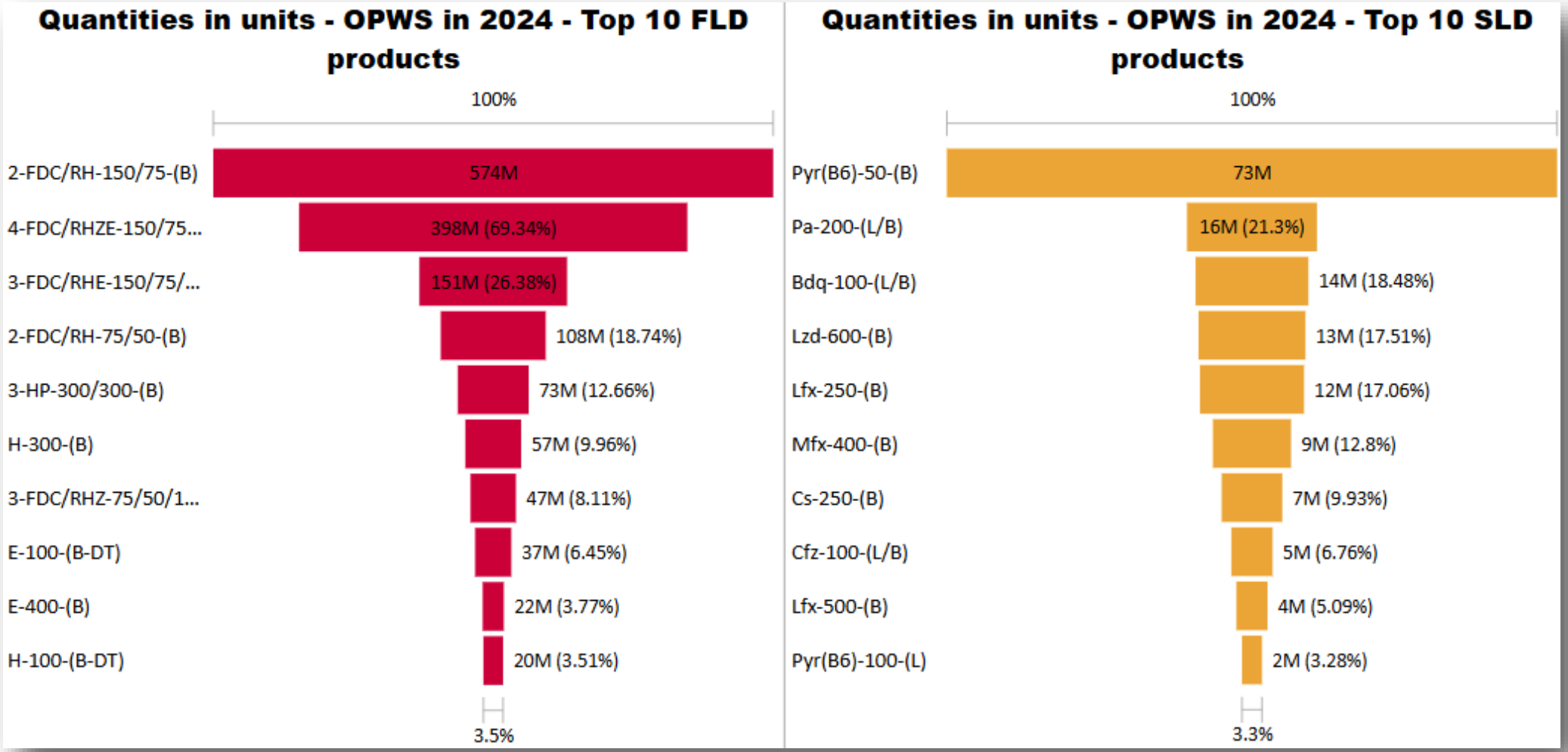
Value of GDF purchase orders placed with suppliers per category of products per calendar year



As of 29/11/2024

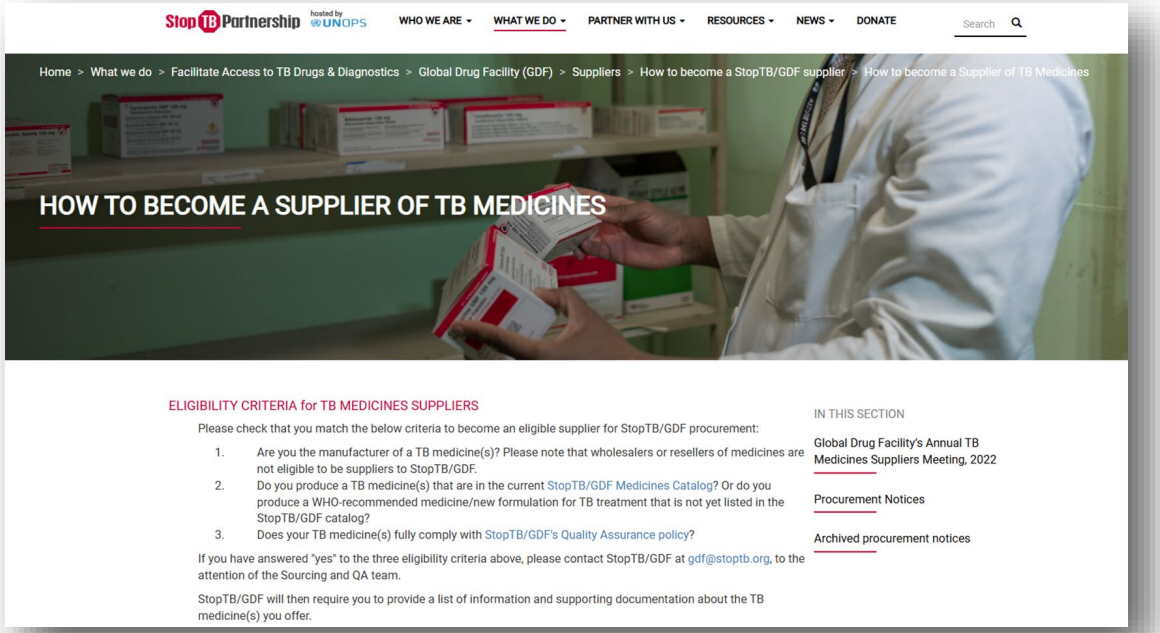
2024 GDF Top 10 TB-Selling Medicines (in volume)

Quantities (in tablets, capsules) procured by countries via GDF



As of 21/11/2024

Become a GDF Supplier

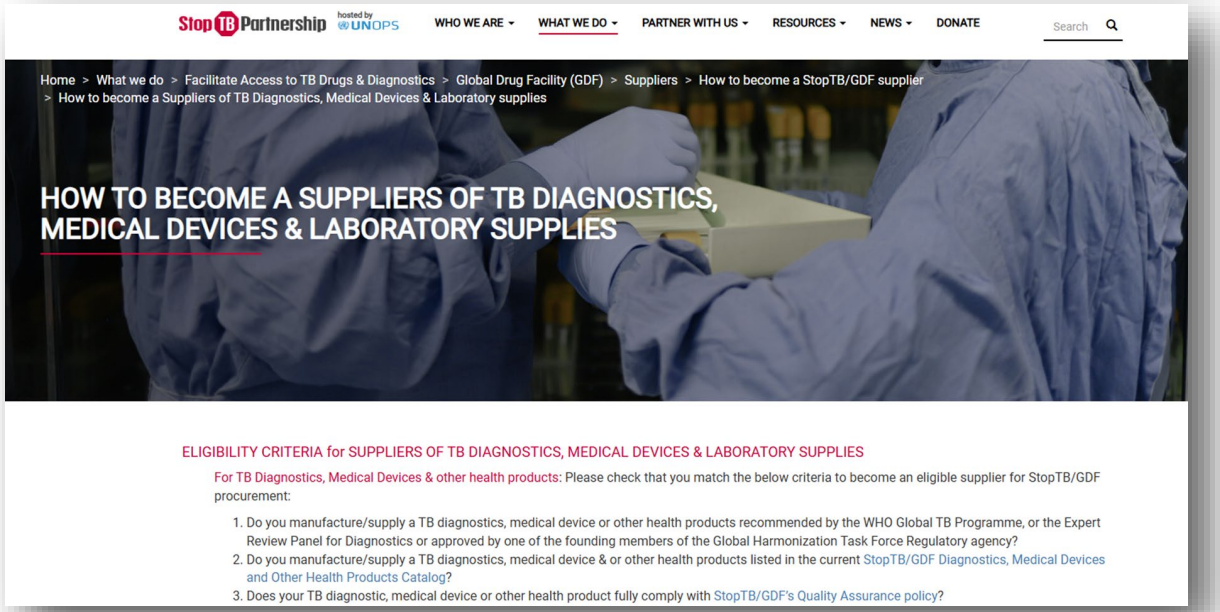


For TB Medicines

https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/suppliers/how-become-stoptbgdf-supplier/medicines

For TB diagnostics, Medical devices and laboratory supplies

https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/suppliers/how-become-stoptbgdf-supplier/suppliers-tb-diagnostics-medical-devices-laborato

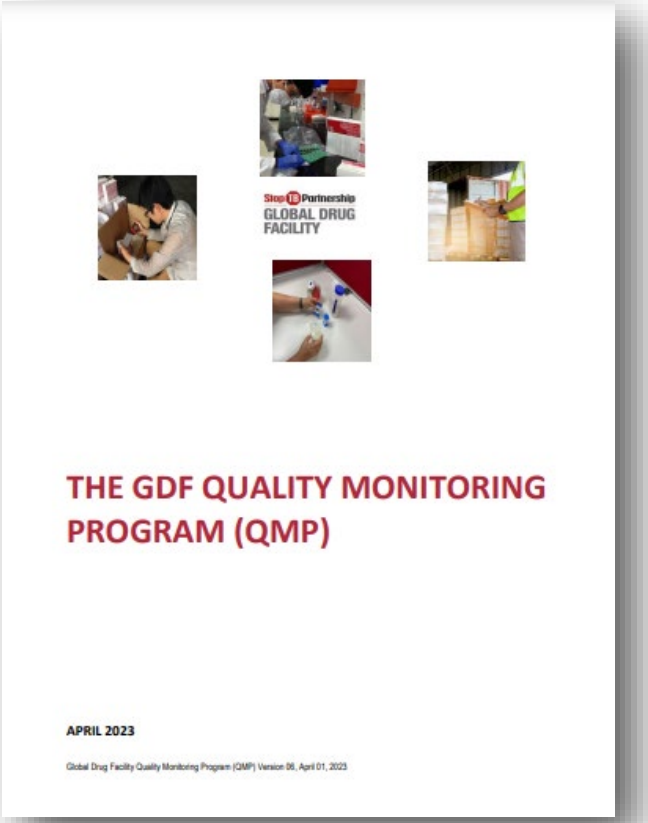


GDF Quality Assurance (QA) Policy and GDF Quality Monitoring Program (QMP)

Only suppliers with TB products meeting the GDF quality assurance policy (QA) are eligible to become GDF suppliers

GDF QA Policy

GDF Quality Monitoring Program



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

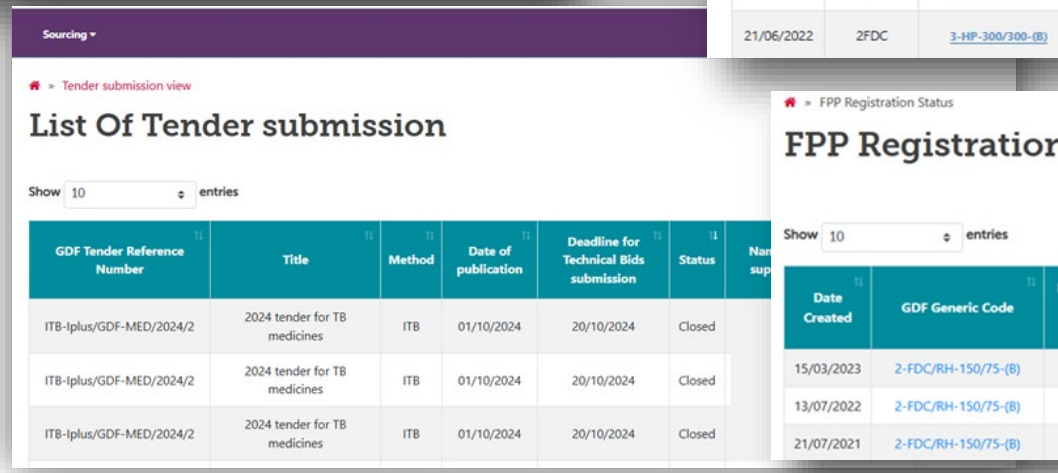
QA Requirements for TB Products for GDF Procurement Eligibility

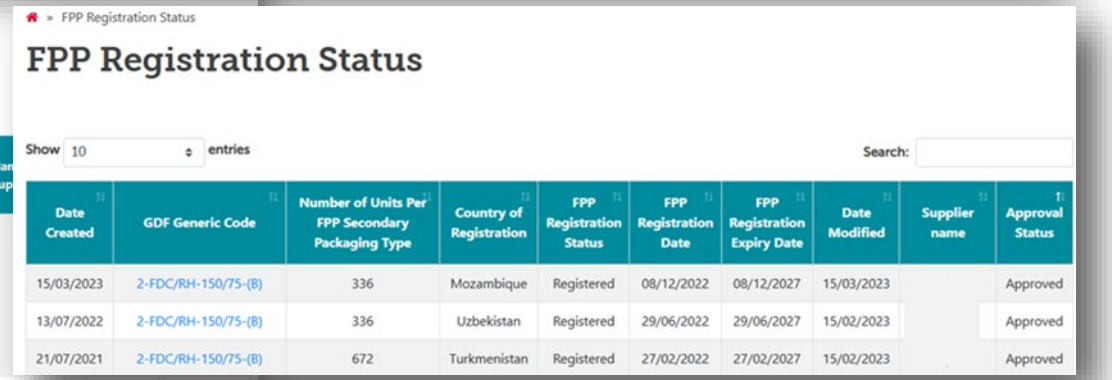
Category of TB products	QA requirements
TB medicines	• Prequalified by WHO PQ programme, OR • Authorized for use by a Stringent Regulatory Authority (SRA), OR • Recommended by the WHO-coordinated Expert Review Panel for medicines (ERP).
Medical devices, IVDs, Medical software	• Recommendation by the WHO Global TB Programme, OR • Regulatory approval/marketing authorization by former GHTF/IMDRF founding member for applicable risk classification, OR • Prequalified by WHO PQ programme, OR • Recommended by the WHO-coordinated Expert Review Panel for Diagnostics (ERPD), AND • Declaration of Conformity in accordance with IMDRF and/or ISO 17050, AND • Compliance with the quality requirements/specifications against test methods set for them
General laboratory supplies	• Declaration of Conformity in accordance with IMDRF and/or ISO 17050, AND • Compliance with the quality requirements/specifications against test methods set for them
New emergency products	• In the case of new products where no other quality-assured products exist, GDF may accept products approved under Emergency Use Listing by WHO or SRA

GDF's Digital Transformation for Strategic Procurement

Suppliers are required to submit information about TB medicines to the CDP Portal for review and approval by the GDF

All suppliers with TB medicines approved by the GDF can participate in GDF tenders via the CDP Portal.





TB Medicines Gaps

As of 21/11/2024

TB Medicines for Which Additional Suppliers are Required

Product Type	INN/strength/form
Adult DR-TB	Pretomanid 200mg tablets Delamanid 50mg tablets Clofazimine 100mg tablets functionally scored
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 Medicines (New Formulation) for Which Suppliers are Required

Product Type	INN/strength/form
Adult DS-TB	3-FDC rifapentine 300mg/isoniazid 75mg/moxifloxacin 100mb tablets 4-FDC rifapentine 300mg/isoniazid 150mg/pyrazinamid 400mg/moxifloxacin 100mg tablets

December 2024

2024 GDF Tenders

Category of products	ITB number	Status	Contract duration
Ultraportable Digital X-Ray Kit, and Computer-Aided Detection using Artificial Intelligence (CAD/AI) software for Tuberculosis (TB)	RFP/2024/49478	Closed	31/07/2027
Delamanid 50mg tablets and 25mg dispersible	ITB-Iplus/GDF-MED/2024/1	Closed	31/12/2025
Interferon Gamma Release Assay (IGRA) for the detection of latent TB infection	ITB/2024/52841	Closed 03/09/2024	For 3 years
TB medicines (44 TB medicines)	ITB-Iplus/GDF-MED/2024/2	Closed	31/12/2025
Infection Prevention Supplies	RFP/2024/54109	Closed 02/12/2024	For 3 years
Bedaquiline 100mg et 20mg tablets, rifapentine /isoniazid 300mg/300mg tablets, rifapentine 300mg tablets and 150mg dispersible tablets	ITB-Iplus/GDF-MED/2024/3	Open Deadline 9/12/2024	31/12/2025

For TB medicines: https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/suppliers/procurement-notices
For diagnostics: https://www.ungm.org/Public/Notice

Q1 2025 GDF Tenders

Category of products	Timelines
General laboratory supplies (around 230 items)*	Q1 2025
Pretomanid 200mg tablets**	Q1 2025

If you are a supplier of TB products that meet GDF's quality standards, deliver on time, and offer competitive and sustainable prices, please participate in GDF tenders.

If selected, you will be included in the **GDF catalog** and gain access to the **global TB market** to support us in the fight against TB, the **top infectious killer disease**.

* For diagnostics: https://www.ungm.org/Public/Notice. Contract for 3 years with an option to renew the LTA for two additional periods of one (1) year each, under the same terms and conditions for a maximum total of five (5) years

** For TB medicines: https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/suppliers/procurement-notices Contract with Initial term of 1 year with possibility of extension up to 12 months at a time under the same terms and conditions. Total duration of the Initial Term and all Extended Terms cannot exceed three years.

Summary – Take Home Points

- GDF is the largest supplier of affordable, quality-assured TB products to countries (165 countries served since its inception in 2001).
- GDF added value is the End-to-end approach along entire product lifecycle, coordinating TB market stakeholders.
- GDF expansion into medicines for AMR area could have significant impact.
- Partnership approach between GDF and suppliers is the approach of choice for access to TB products
- Suppliers interested to develop TB medicines are invited to contact GDF
- Suppliers of TB products that meet GDF's quality standards are invited to participate in GDF tenders

Thank You

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