

# Global Drug Facility's Products and Services for Accelerated Implementation of New WHO Policies

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Hanoi, Vietnam; April 2025

## • Outline of the Presentation

- GDF's pivotal role in the implementation of WHO TB Guidelines
- GDF product updates
- GDF services for accelerated WHO guidelines implementation
- Challenges & solutions to rapid uptake of new guidelines
- Take home message

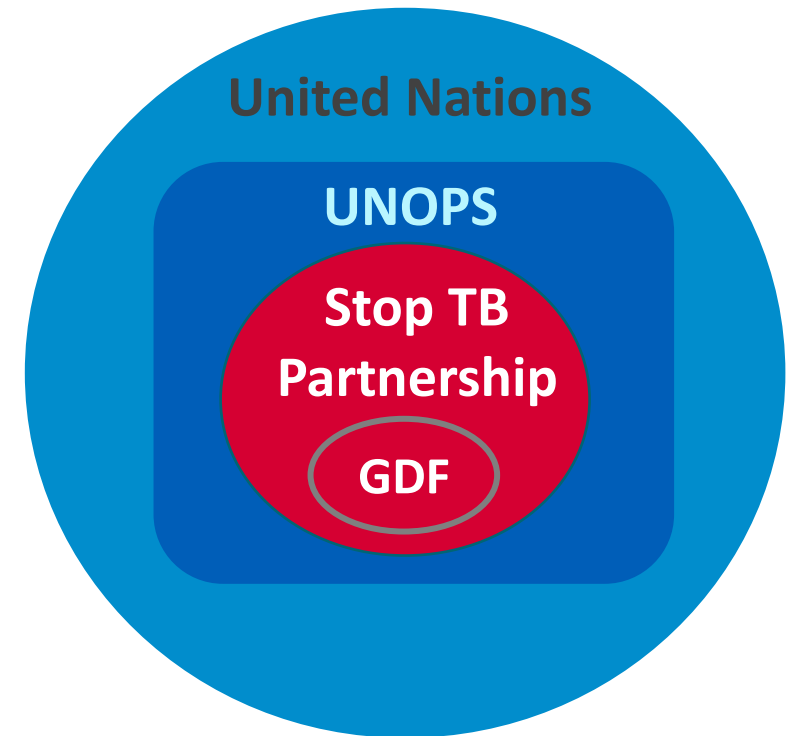
# Global Drug Facility

## VISION OF SUCCESS



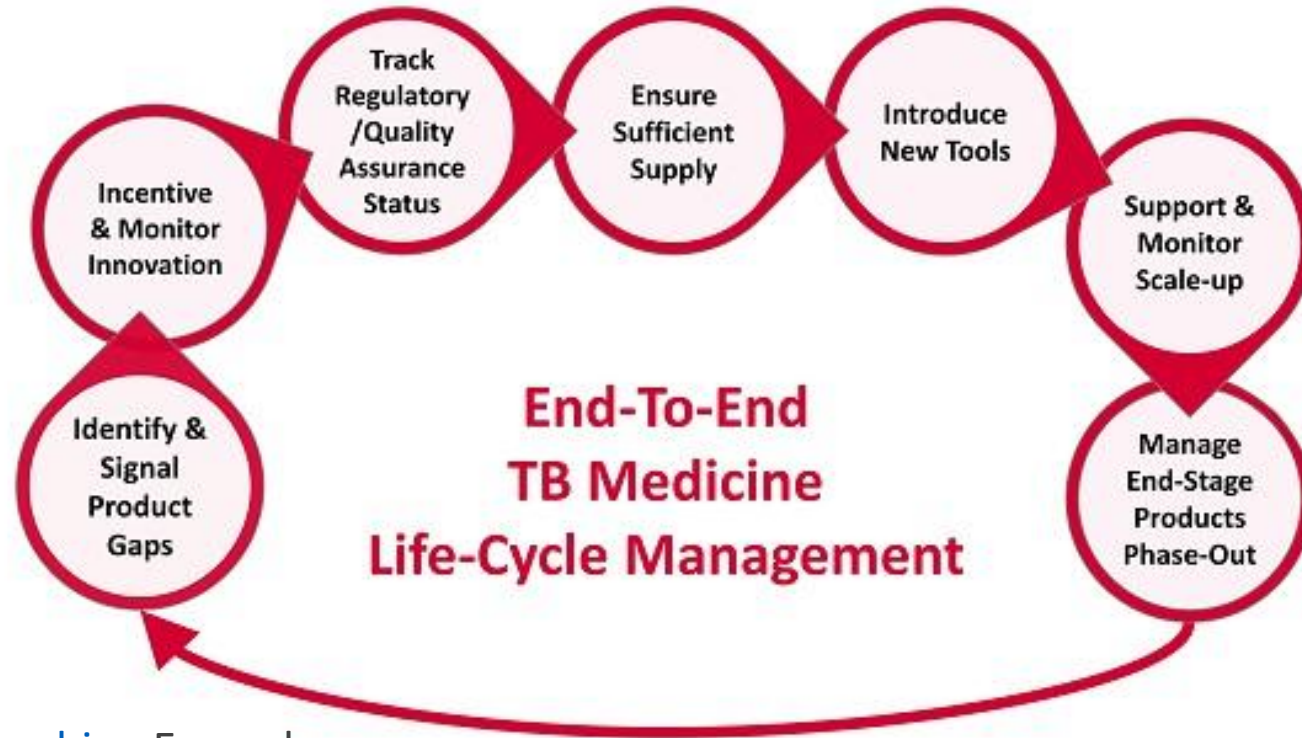
**Worldwide access to TB products through sustainable, viable global markets that deliver innovative, quality-assured, affordable TB products**

- UN enterprise within Stop TB Partnership hosted by UNOPS, funded largely by USAID
- Largest procurer of TB medicines and diagnostics
- Certified under the ISO 9001 Quality Management System
- Established in 2001 to create a market & promote access to quality-assured DS-TB medicines extended to products needed for screening, diagnosis, prevention, and treatment of all forms of TB for all groups of the population
- All countries can procure from GDF, regardless of whether funding is from donors or domestic sources
- No minimum order size required—countries can procure quantities smaller than standard batch sizes



# TB Procurement and Market-shaping Action Team (TPMAT)

- GDF established the TPMAT in 2016, to bring together national, regional, and global TB stakeholders to identify and address procurement and market-based challenges
- TPMAT manages the entire TB product lifecycle, from identifying priorities and developing formulations to introduction, scale-up, and phase-out.



[TB Medicines Dashboard | Stop TB Partnership](#) : Example

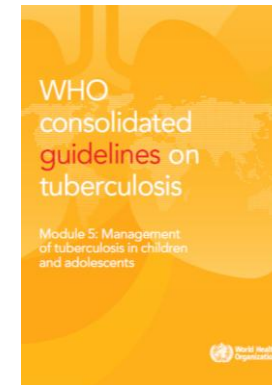
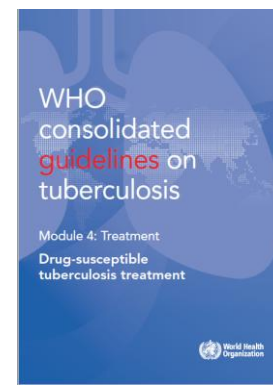
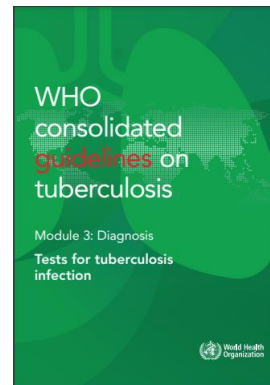
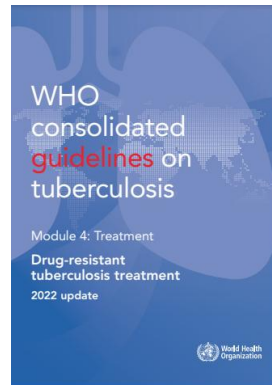
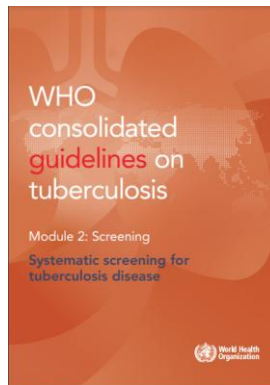
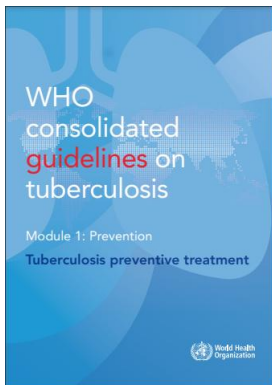
Medicine	Strength	GF Expert Review Panel EOI	WHO PQ EOI	GF List of Health Products	WHO Model EML
Bedaquiline	100mg tablet	✓ Added 2019	✓ Added 2018	✓ Added pre-2018	✓ Added 2015
	20mg dispersible tablet	✓ Added 2020	✓ Added 2019	✓ Added 2020	✓ Added 2021
Pretomanid	200mg tablet	✓ Added 2020	✓ Added 2020	✓ Added 2020	✓ Added 2023



**All WHO-recommended products available through GDF cover the whole cascade to prevent, screen, diagnose, and treat all forms of TB in all populations (children, adolescents and adults)**

- >500 Diagnostics, Medical Devices and other health products
- All WHO-recommended anti-TB medicines including child-friendly formulations

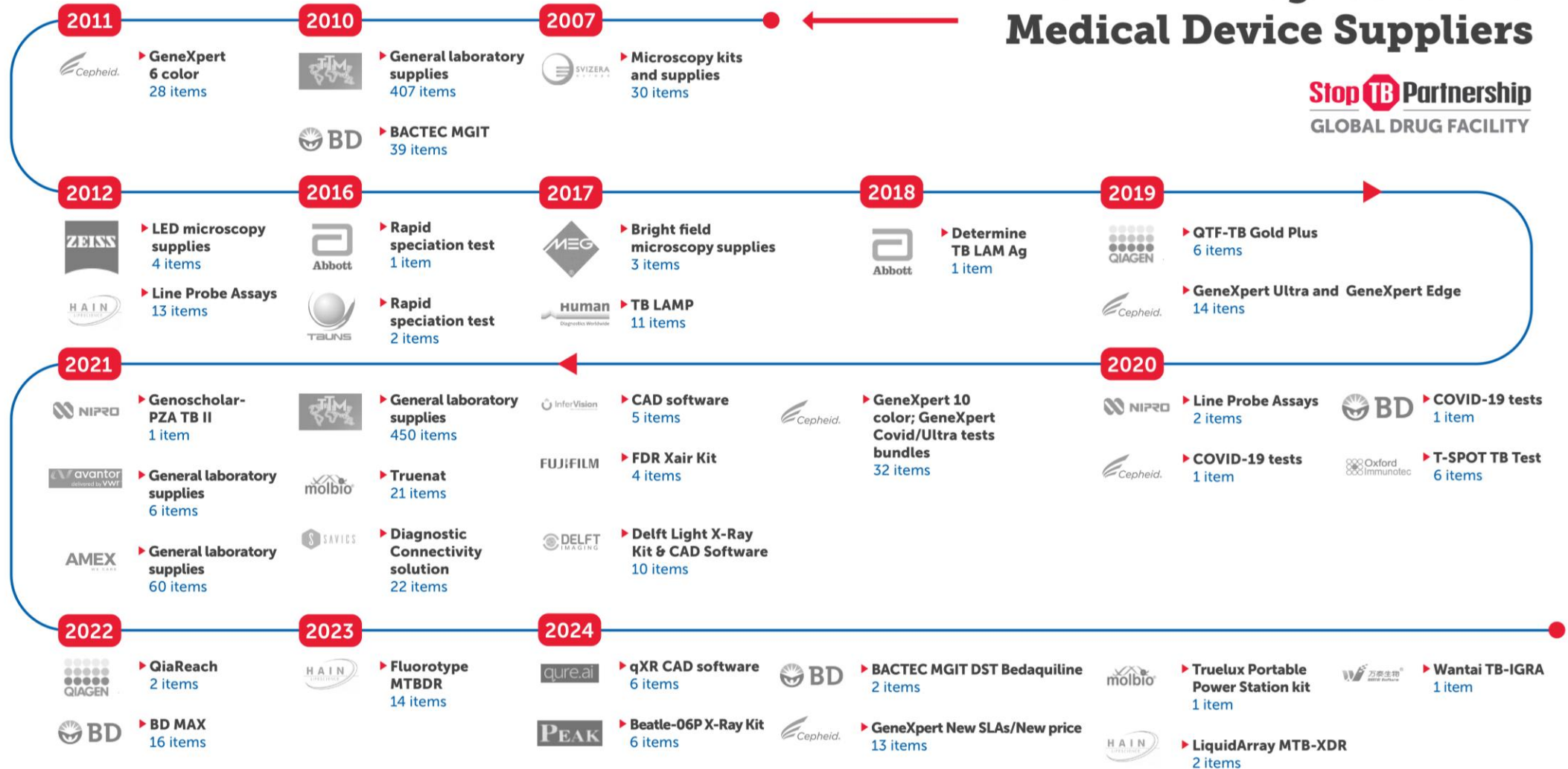
<https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog>



# Recent GDF Product Updates: DIAGNOSTICS

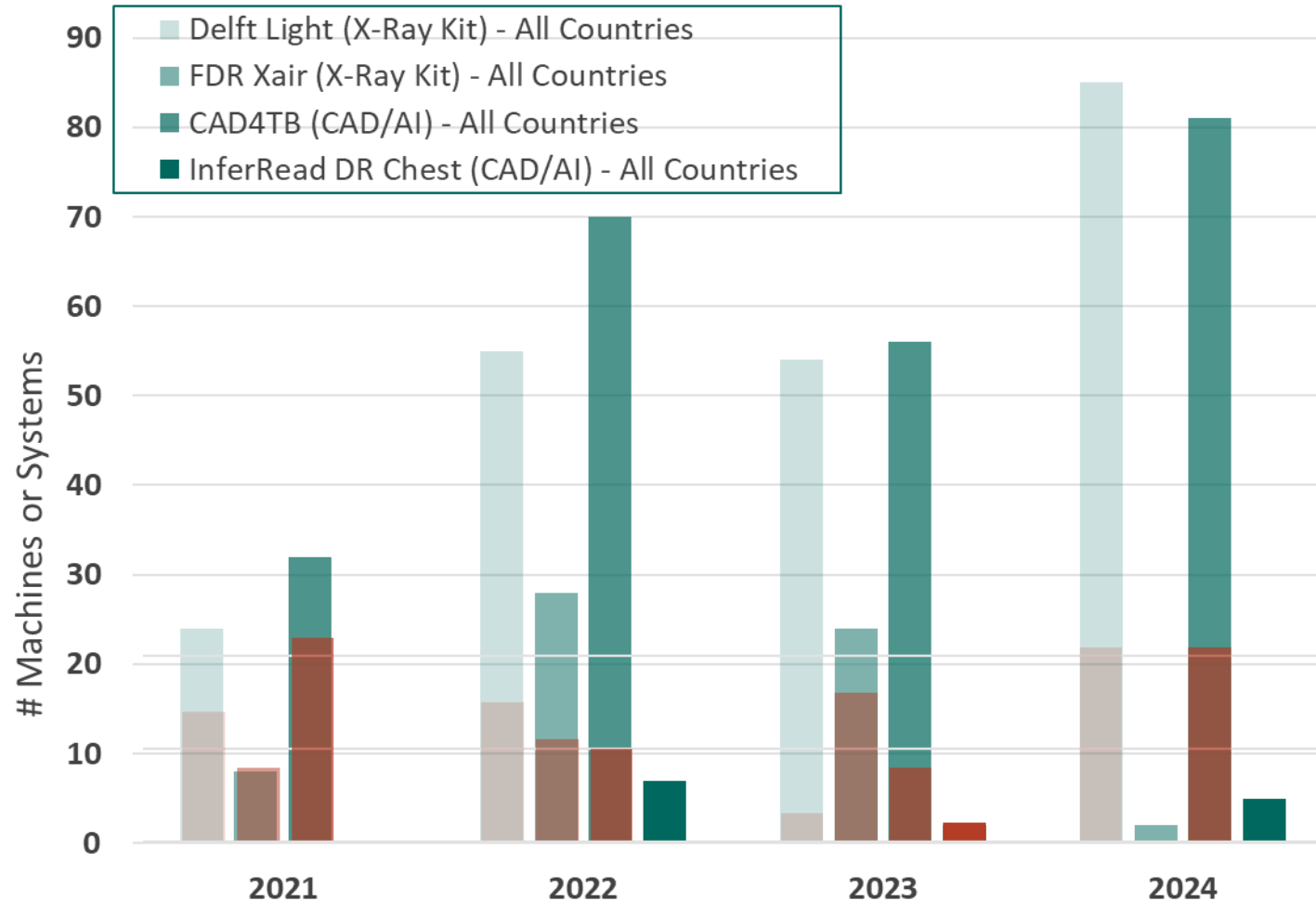
## GDF TB Diagnostic and Medical Device Suppliers

**Stop TB Partnership**  
GLOBAL DRUG FACILITY



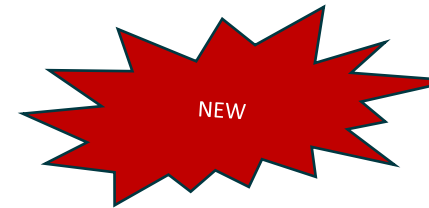
# Portable Digital X-Ray Kits and CAD/ AI Systems

## Delivered by GDF – Globally



## ULTRAPORTABLE DIGITAL X-RAY SYSTEMS

- FDR Xair
- Delft Light X-RAY
- **Peak X-RAY**



## CAD-AI SOFTWARE

- InferRead DR Chest Software
- CAD4TB Software
- **QXR AI Software**

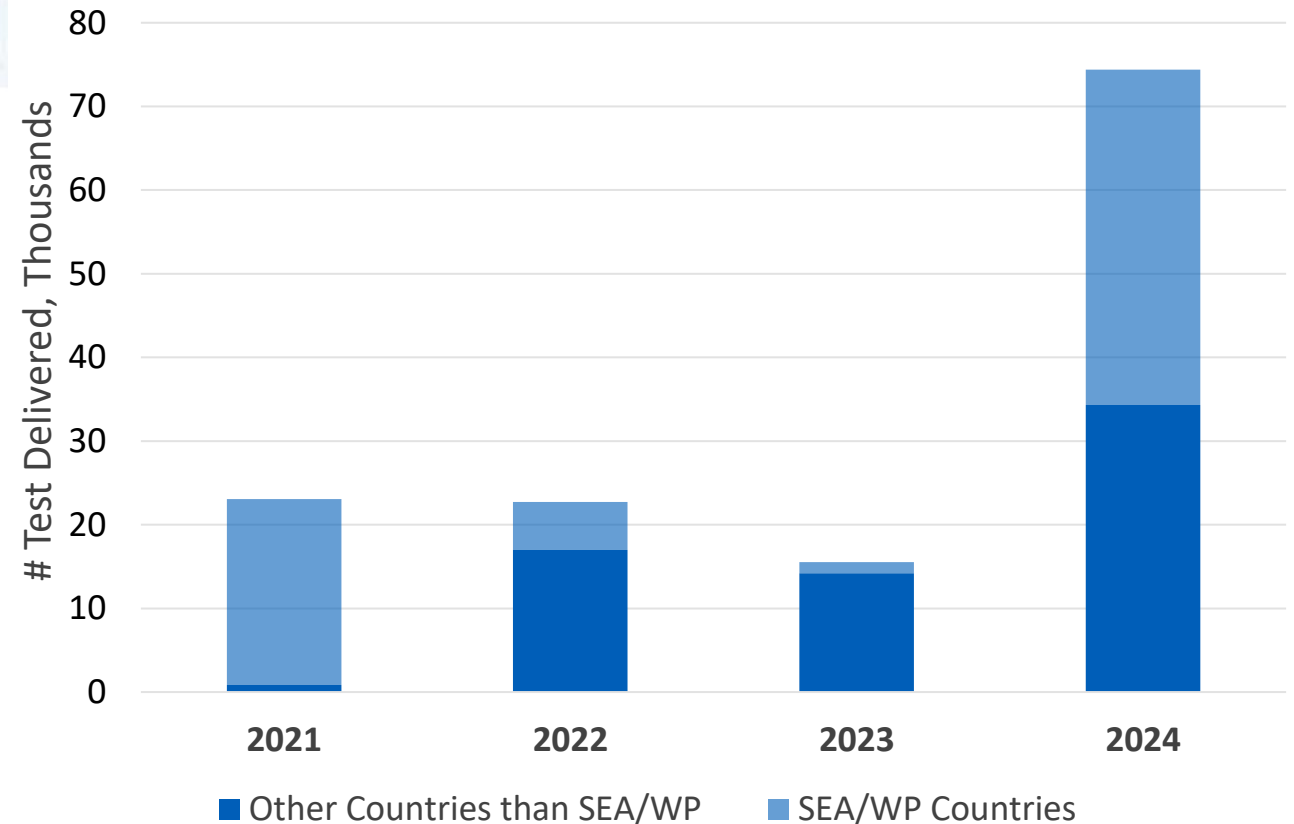
## Delivered by GDF – SEA/WP

- Delft Light (X-Ray Kit) - SEA/WP Countries
- FDR Xair (X-Ray Kit) - SEA/WP Countries
- CAD4TB (CAD/AI) - SEA/WP Countries
- InferRead DR Chest (CAD/AI) - SEA/WP Countries

# Interferon-Gamma Release Assays (IGRAs) available at GDF



Quantiferon-TB Gold Test Delivered by GDF



Standard E TB-Feron



WANTAI TB IGRA





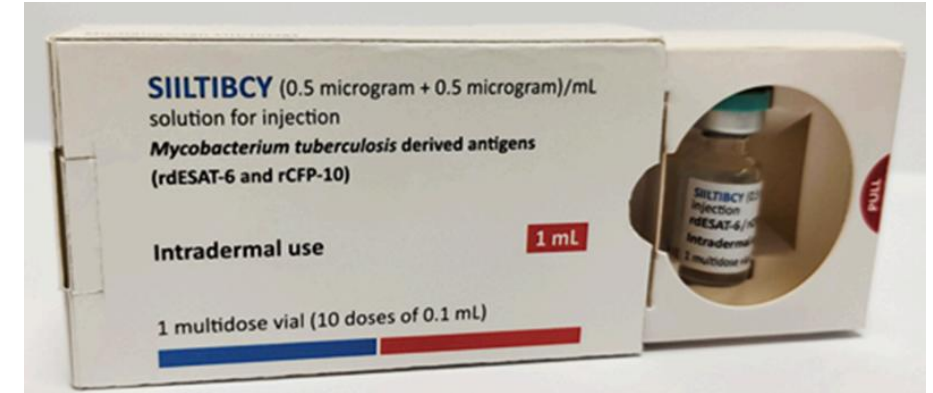
# Recently added to catalogue: SIILTIBCY™ skin test

<https://www.stoptb.org/sites/default/files/documents/SIILTIBCY%20GDF%20Info%20Sheet.pdf>

GDF played a critical role in facilitating the regulatory pathway and global availability of the SIILTIBCY skin test.

The SIILTIBCY skin test, marketed in India as Cy-Tb and manufactured by the Serum Institute of India Pvt. Ltd. (SIPL),

- Granted by European Commission Marketing Authorisation
- Approved by the Global Fund's Expert Review Panel (ERP)



With ERP approval, the test became eligible for procurement through GDF for purchase by any country at a price of \$1.50 per dose.

WHO Prequalification has opened an EOI for biotherapeutic and biosimilar products (biological product for diagnostic use). GDF is encouraging this and other WHO-recommended suppliers of TBSTs to submit under this pathway

# Targeted Next-Generation Sequencing (tNGS)

GDF is actively engaging with manufacturers to develop a procurement strategy aimed at making targeted next-generation sequencing (tNGS) accessible to national TB programs.

Although the tender process has not yet been launched, it is anticipated to commence in the third quarter of 2025.

# Rifampicin-Based TB Medicines for DS-TB Treatment: Update

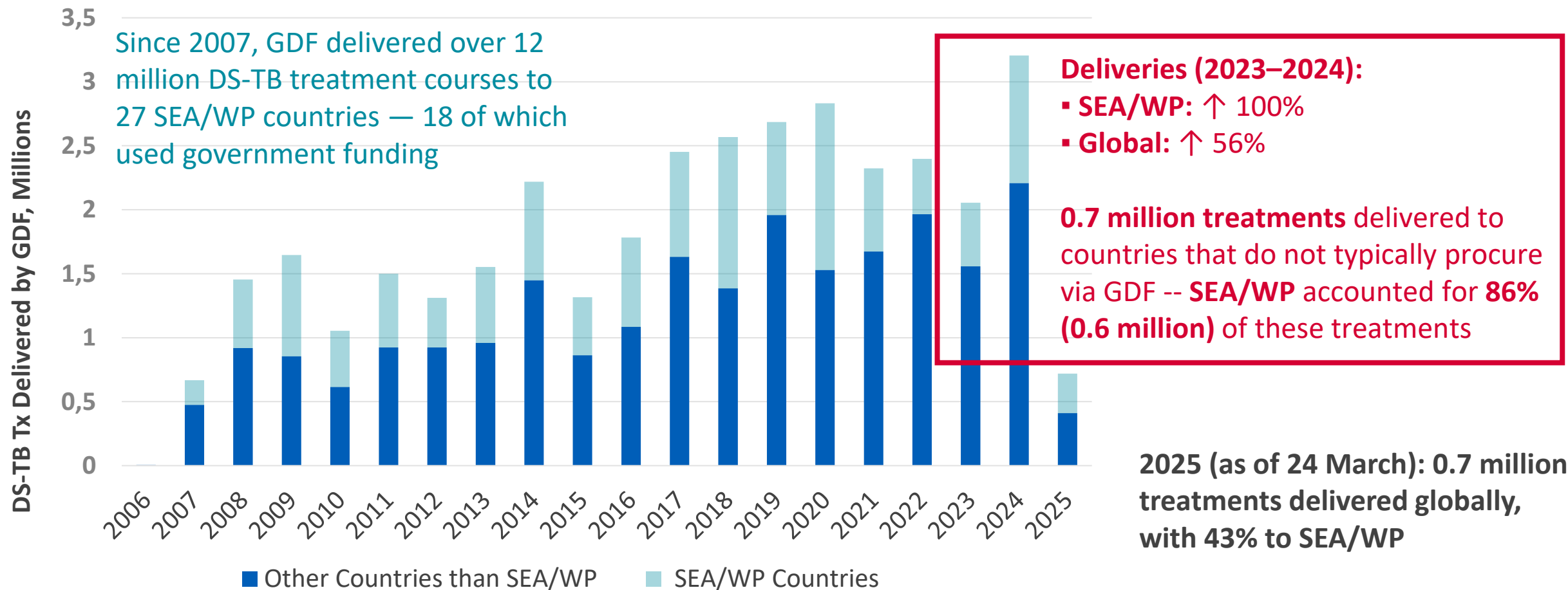
## Supply challenges:

- National tenders not requiring WHO PQ failed/delayed, led to FLD stockout risks
- Global API shortage in China created market shock
- GF-funded, non-GDF procurements also failed
- GDF got last-minute emergency orders (1–2 mo. Delivery for huge volumes)
- WHO PQ suppliers unprepared for sudden volume

## How GDF is resolving the crisis:

- Engages API and finished product suppliers to boost production capacity
- Works with WHO and GF to fast-track regulatory approvals
- Supports addition of new API sources to WHO PQP list
- Works with countries to share demand data to support planning and access
- Maintains global buffer stocks via the Strategic Rotating Stockpile
- Prioritizes products using a structured process to optimize supply and ensure equitable access based on risk and supplier capacity
- Monitored supply chain closely to manage disruptions
- Projects API stabilization by mid-2025; backlog cleared by Nov 2025

# 2024: Highest-Ever GDF Deliveries of DS-TB Treatments



Due to the ongoing shortage of rifampicin-based products, TB programs and PRs are encouraged to place orders as early as possible, but not later than indicated in the GDF [Procurement and Delivery Planning Guide](#).

# GDF Estimated Prices for Select DS-TB TB Treatment Regimens

Regimen type	Regimen composition	Age or weight band	Estimated Regimen Prices (USD) Jan 2025
Adult DS-TB	2HRZE/4RH (FDC)	35-<65kg	\$ 47
	2HPMZ/2HPM	35-<65kg	\$ 176
Pediatric DS-TB	2RHZ/4RH	12-<16kg	\$ 33
	2RHZ(E)/4RH	12-<16kg	\$ 68
	2RHZ/2RH	12-<16kg	\$ 23
	2RHZ(E)/2RH	12-<16kg	\$ 58

FDCs for HPMZ/HPM have been developed and are undergoing WHO PQ review

Estimated DS-TB Treatments Prices as of Jan 2025

<https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/buyers/plan-order>



# Scale-Up of 3HP FDC for TB Preventive Treatment

## USAID-Funded 3HP Catalytic Scaleup Project



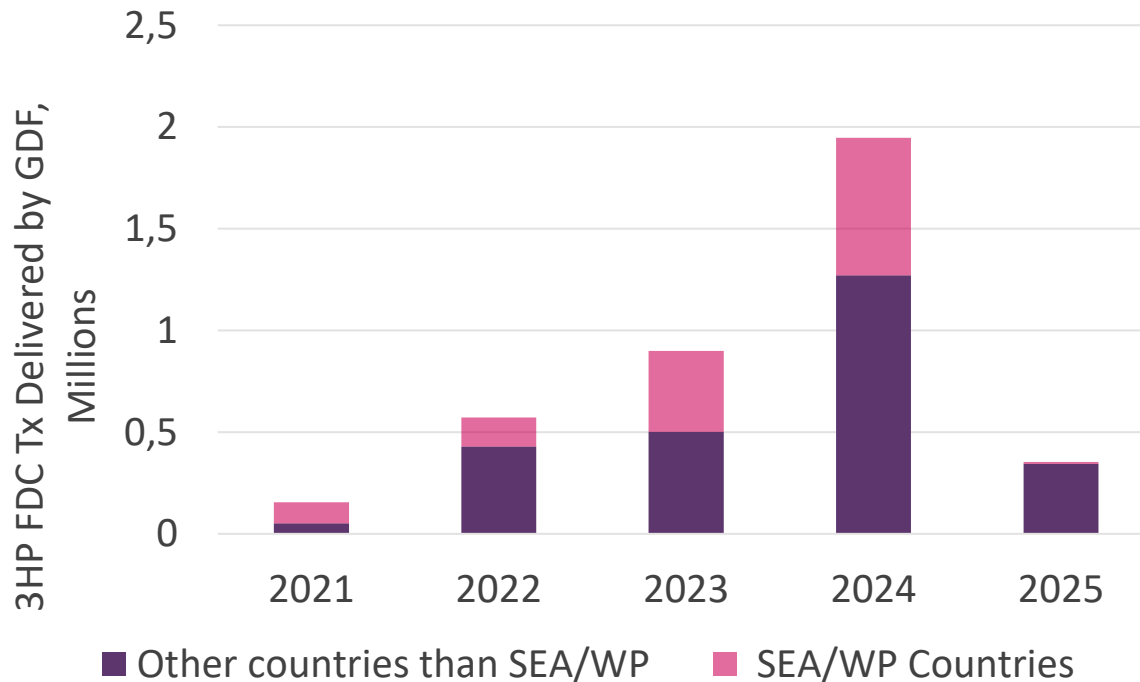
\$17 million  
in USAID  
catalytic  
funding for  
3HP FDC  
scaleup



30% 3HP  
FDC price  
reduction  
from \$14.25  
to \$9.99



USAID  
funded  
1.3 million  
treatment  
courses to  
11 countries



**Since 2021, 72 countries procured over 4M 3HP courses globally**

**19 SEA/WP countries accounted for 1.3M courses, of which, in 2024, 0.4M courses were granted to 3 countries via USAID-Funded 3HP Catalytic Project**

# 3HP TPT in Children: Rifapentine Tablet, Dispersible 150mg

## Rifapentine 150 mg dispersible tablets

WHO-prequalified

100 tablets per blister pack

USD 13.80 (available via GDF)

Shelf life - 24 months

TB402



WHO Product ID:	TB402
Status:	Prequalified
INN, dosage form and strength:	Rifapentine Tablet, Dispersible 150mg
Date of prequalification:	21 Nov, 2024
Basis of listing:	Prequalification - Full
Therapeutic area:	Tuberculosis
Type:	Finished Pharmaceutical Product
Dosage form:	Tablet, Dispersible
Applicant organization:	<b>Lupin Ltd.</b> Kalpataru Inspire, 3rd Floor, Off Western Express Highway, Santacruz (East) 📍 Mumbai, Maharashtra 400 055 India

### Packaging details and storage conditions:

Packaging Type:	Strip: Alu/Alu
Configuration:	10x10, 28x1
Shelf life (months):	24
Storage conditions:	Do not store above 30°C, protect from moisture
Packaging Type:	Blister: Alu/Alu
Configuration:	10x10, 12x10
Shelf life (months):	24
Storage conditions:	Do not store above 30°C, protect from moisture

### API Manufacturing Site(s)

[By Organization](#) [By Active Ingredient](#)

**Lupin Ltd.**  
T-142, M.I.D.C, Thane District 📍 Tarapur, Via Boisar, Maharashtra 401 506 India

Rifapentine

### FPP Manufacturing Site(s)

**Lupin Ltd.**  
A-28/1 MIDC Industrial Area, Chikalthana 📍 Chhatrapati Sambhajanagar, 431 210 India

GDF has delivered 45.6K\* child-friendly rifapentine 150mg treatment courses to 8 countries

GDF continues to support procurement under the Early Market Access Vehicle (EMAV), launched by the Unitaid-funded IMPAACT4TB project to accelerate access to pediatric rifapentine tablets

- 23K courses have already reached 3 countries
- 28.4K additional courses are pending delivery to three more countries

*\*Number of treatment courses is estimated based on the 10–14.9 kg weight band*

<https://impaact4tb.org/press-release-child-friendly-rpt-short-course-tpt-and-early-market-access/>

# 300mg/300mg Rifapentine/Isoniazid FDC in Children

GDF collaborated with the WHO GTB Program to revise dosing guidance for the 300mg/300mg Rifapentine/Isoniazid FDC in individuals <50 kg in the updated [WHO operational handbook on Tuberculosis Module 1: Prevention – Tuberculosis Preventive Treatment](#)

- Optimal dosing for individuals below 15 kg remains a challenge with the current FDC.
- Monitoring for isoniazid toxicity is recommended for patients <50 kg on FDC, with pyridoxine supplementation as needed.
- Patient information leaflets will be updated to reflect new dosing recommendations.

**Dosing Table for Rifapentine/Isoniazid 300/300 FDC**

Weight Band (kg)	Total Dose (mg/mg)	Number of FDC Tablets
15 – <20	300 / 300	1
20 – <25	450 / 450	1.5
25 – <30	600 / 600	2
30 – <35	750 / 750	2.5
35 – <40	900 / 900	3
40 – <45	900 / 900	3
45 – <50	900 / 900	3
>50	900 / 900	3

# GDF Estimated Prices for Select TPT Regimen

Regimen type	Regimen composition	Age or weight band	Estimated Regimen Prices (USD) Jan 2025
Adult TPT	3HP FDC	> 50kg	\$ 10
	3HP (Rpt300+H300)	> 50kg	\$ 12
	1HP (Rpt300+H300)	> 50kg	\$ 18
	6Lfx	12-<49.9kg	\$ 8
Pediatric TPT	3RH	12-<15.9kg	\$ 19
	3HP (H100+Rpt150)	12-<14.9kg	\$ 6
	6Lfx (Lfx100 dt)	10-<14.9kg	\$ 42

## Rifapentine-Based TB Preventive Products

**3HP 300/300** – 2 manufacturers, 36-month shelf life

**Rifapentine 300mg** – 2 manufacturers, 36-month shelf life

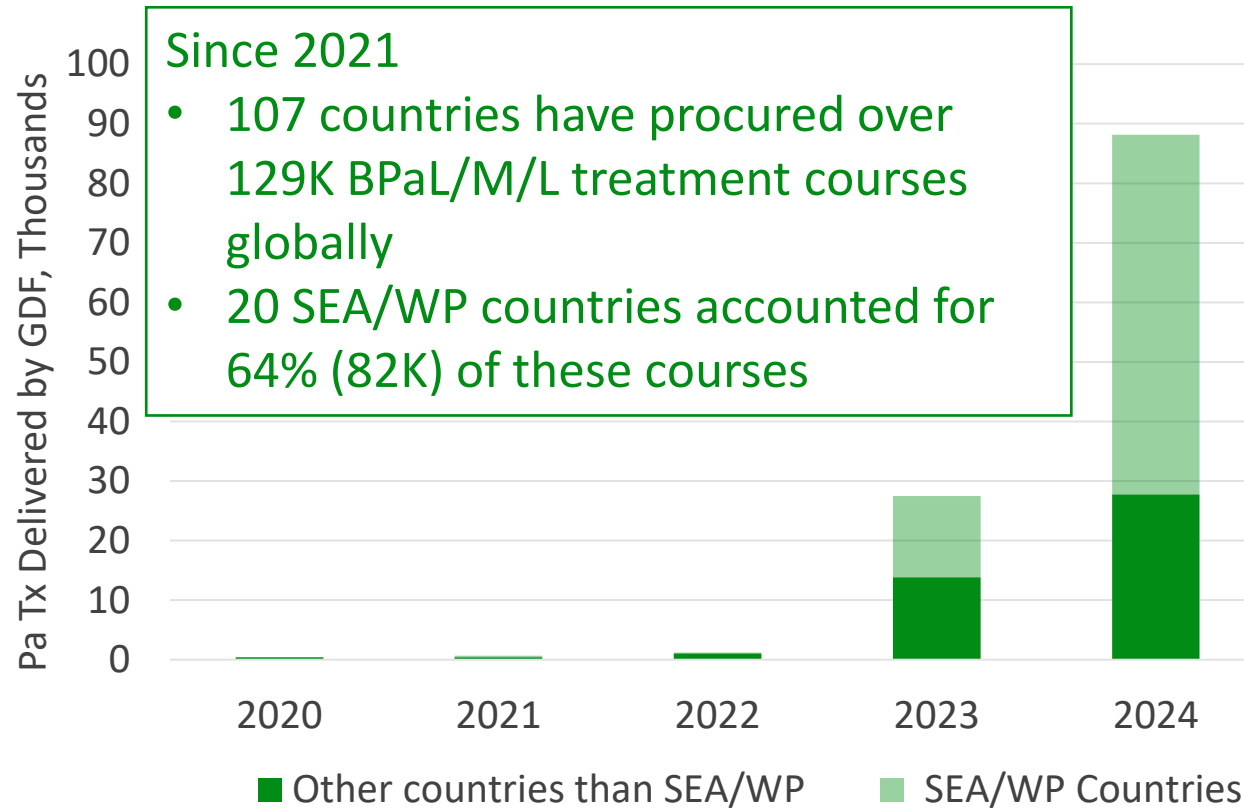
**Rifapentine 150mg** – 1 manufacturer, 36-month shelf life

**Rifapentine 150mg DT** – 1 manufacturer, 24-month shelf life

<https://www.stoptb.org/what-we-do/facilitate-access-tb-drugs-diagnostics/global-drug-facility-gdf/buyers/plan-order>

*Last updated January 2025*

# Pretomanid-Based Regimens for DR-TB Treatment



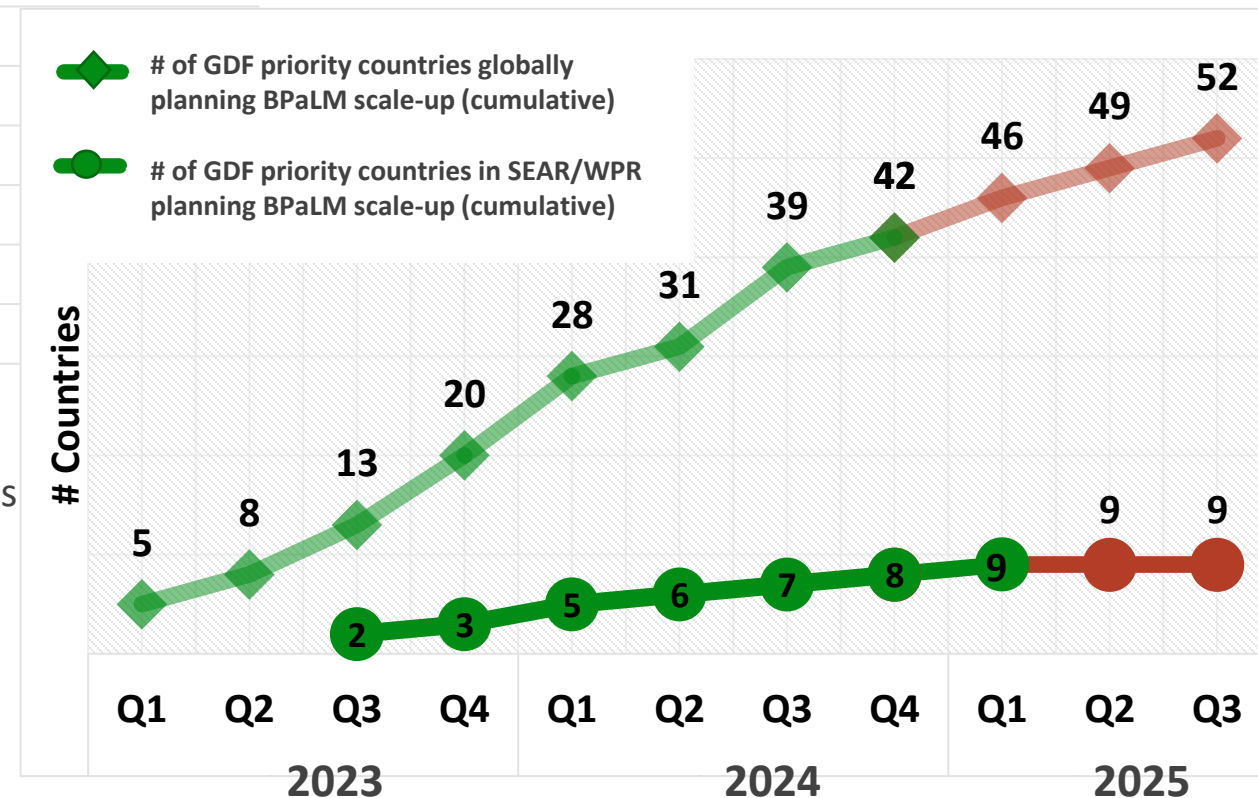
SEAR/WPR: 9/9 priority countries have started BPaLM scale-up.

GDF has been helping all 9 countries in transition planning and implementation.

Globally:

42/52 GDF priority countries have started BPaLM

10/52 countries expected to start by the end of 2025





# Registration requirements in SEA/WP priority countries

Of the 9 priority countries in SEA/WPR, 4 have registered Pretomanid in their national drug regulatory authority.

Pretomanid registration	Country	Medicine registration requirement
Registered	India	waiver possible
	Indonesia	waiver possible
	Papua New Guinea	<b>Mandatory</b>
	Philippines	<b>Mandatory</b>
Not registered	Bangladesh	waiver possible
	Cambodia	waiver possible
	Myanmar	waiver possible
	Nepal	waiver possible
	Vietnam	waiver possible

# GDF Estimated Prices for Select DR-TB Treatment Regimens

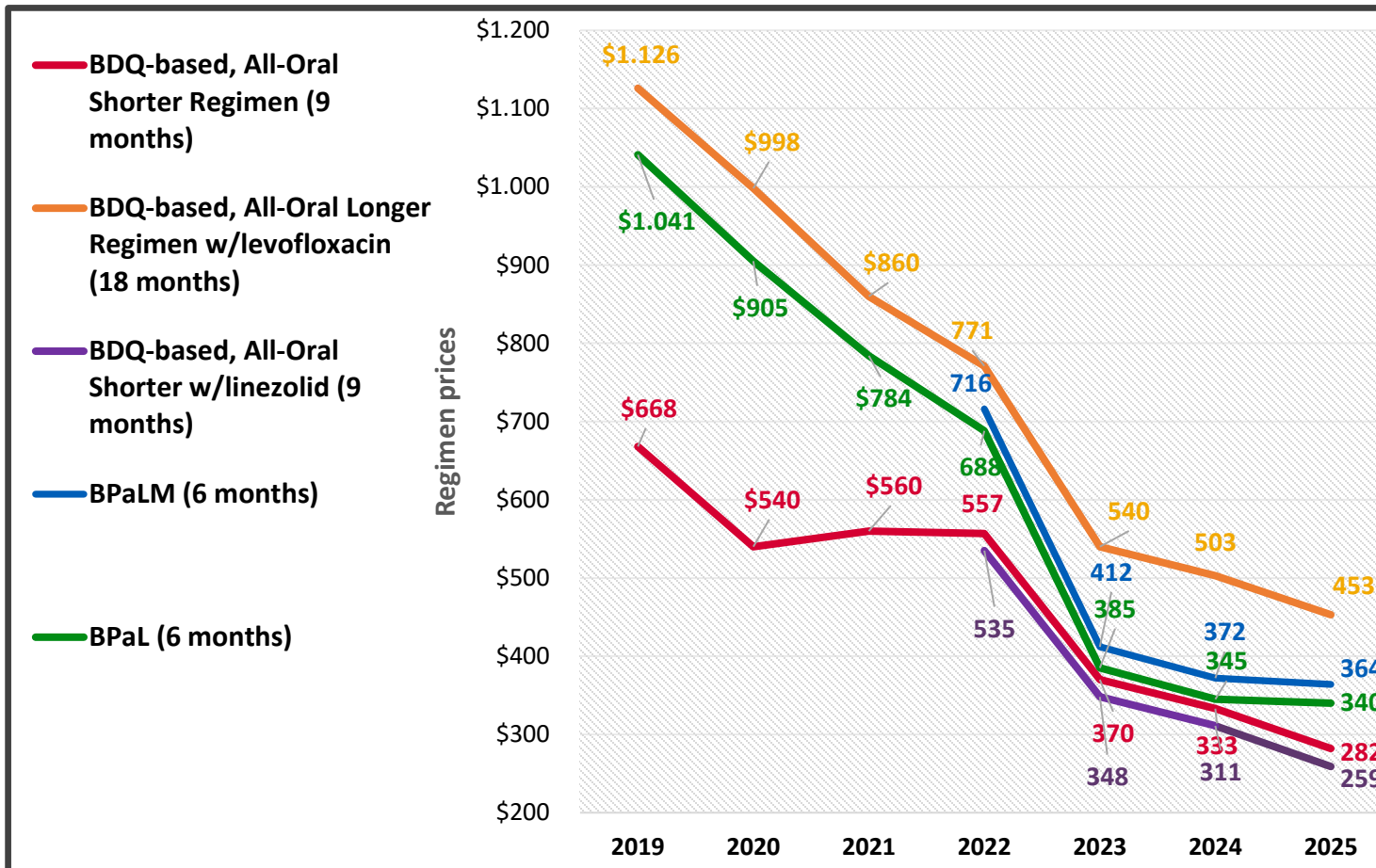
Regimen type	Regimen composition	Age or weight band	Estimated Lowest Regimen Prices (USD), Jan 2025
Adult DR-TB	6 BPaLM	>= 14 yrs old	\$ 364
	6 BPaL	>= 14 yrs old	\$ 340
	6 Bdq Dlm Lzd Lfx (BEAT-TB/ BDLL)	> 50kg	\$ 926
	6 Bdq Dlm Lzd Cfz (BEAT-TB/BDLC)	> 50kg	\$ 981
	6 Bdq Dlm Lzd Lfx Cfz (BEAT-TB/BDLLC)	> 50kg	\$ 998
	9 Bdq Lzd Mfx Z (endTB/BLMZ)	55-70kg	\$ 209
	9 Bdq Lzd Lfx Cfz Z (endTB/BLLfxCZ)	55-70kg	\$ 318
	9 Bdq Dlm Lzd Lfx Z (endTB/BDLLfxZ)	55-70kg	\$ 1,500
Pedia DR-TB	6 Bdq Dlm Lzd Lfx (BEAT-TB/BDLL)	10-<16kg	\$ 786
	6 Bdq Dlm Lzd Cfz (BEAT-TB/BDLC)	10-<16kg	\$ 816
	6 Bdq Dlm Lzd Lfx Cfz (BEAT-TB/BDLLC)	10-<16kg	\$ 854
	9 Bdq Lzd Mfx Z (endTB/BLMZ)	10-<16kg	\$ 444

**All DR-TB medicines have child-friendly formulations (except Pa) – so all these regimens for kids can be implemented with child-friendly formulations**

# DR-TB Regimen Price Reductions and Supply Information

Since 2019, BPaL regimen price dropped over 65% and Bdq-based regimens over 60%, mainly due to Bdq price reduction. Prices may update soon after Pa tender. No DR-TB medicine supply issues expected.

DR-TB Treatment Regimens Prices, 2019-2025



DR-TB medicines supply information

Medicines	# of manufacturers	Shelf life
Bdq 100mg	3	30, 36 months
Pa 200mg	2	36, 48 months
Lzd 600mg	3	48, 60 months
Mfx 400mg	3	48, 60 months
Lfx 250mg	4	36, 48, 60 months
Dlm 50mg	2	36, 60 months
Cfz	3	36, 48 months

January 2025

# GDF Services for Accelerated WHO Guidelines Implementation



**9 GDF Regional Advisors support 51 countries globally (9 in SEA/WP) on all aspects of TB PSM, including uptake of new TB regimens:**

- Conduct ~25 key quantification and planning exercises per country annually to support transition planning and development of costed supply plans
- Lead PSM in TA missions and Joint Program Reviews
- Provide input into Global Fund proposals and reprogramming plans



**The Flexible Procurement Fund (FPF)** helps countries facing administrative constraints by bridging payments until domestic funds are available.



**The Strategic Rotating Stockpile (SRS)** reduces delivery lead time, mitigating stockout risks and ensuring timely access to essential products.



**Product consolidation** at the Procurement Agent's warehouse supports clients and suppliers by delivering full treatment regimens, reducing costs and administrative burden, and improving production planning.



**Product prioritization** in short supply ensures equitable access despite supply challenges.

# Addressing PSM Barriers to Rapid Uptake of New TB Guidelines

Challenges	Solutions
<b>Policy &amp; Regulatory Barriers</b> Slow policy adoption & regulatory approval	Streamline policy adaptation; Develop implementation plans; Coordinate with regulatory and in-country partners to allow to procure and implement new TB tools
<b>Procurement &amp; Supply Management</b> Complex quantification, nonadherence to PSM transition plans, weak systems, rigid system for write-off	Strengthen supply chain & procurement planning; Develop scenarios for PSM transition; Advocate for patient-centered and more effective treatment regimens; <b>Early engagement of GDF in transition planning</b>
<b>Funding Constraints</b> Limited domestic/international financing	Promote sustainable, innovative financing models; Costed PSM plan can be used to mobilize funding
<b>Health System &amp; Infrastructure</b> Limited capacity & training Limited or lack of data on patient's data by regimen, age category, assumptions on projected patients per regimen Distribution issues leading to delayed transition	Build national capacity and systems; Train/orient TB health personnel to expedite roll out of new tools; Expedite update/revision of info system; Improve health system resilience



# QuanTB Tool and Data Sharing



- [QuanTB Tool](#) - serves as the premier solution for TB medicines quantification, forecasting, and supply planning.
- When used regularly, it functions as an essential early warning system for TB programs.
- The QuanTB tool helps countries improve accuracy in quantification, forecasting, and supply planning, reducing the risk of stockouts and wastage.
- GDF supports countries in development and updating quantification files, serving as costed PSM transition and supply plans – essential for new regimens scale up
- 50+ participants from 14 SEA/WP countries participated in the Regional Quantification Workshop organized by GDF in Hanoi, Vietnam, in October 2024, aimed at enhancing skills in TB medicine quantification and supply planning.
- **Countries are requested to share quantification data regularly, as this is essential** for GDF to create accurate global forecasts, optimize procurement, prevent supply chain disruptions, shape the global market, ensure access to medicines at lower prices, advocate for funding, build resilient TB medicine supply systems, and support the rollout of new regimens.

# Take home message

- All WHO-recommended TB products are available through GDF, thanks to its End-to-End Market Management approach and its added-value services ensure equitable access to quality-assured, affordable TB products—regardless of funding source and order size.
- There are no global supply issues for any products except of rifampicin-based medicines for DS-TB treatment. Due to ongoing global shortages of rifampicin-based products, countries should place orders as early as possible, and no later than the timelines outlined in the GDF Procurement and Delivery Planning Guide.
- Collaborative implementation planning is crucial when introducing new regimens. Countries should proactively engage in activities like guideline development, procurement and supply management, information systems, diagnostics, and training to ensure alignment. Early engagement with GDF is key to developing data-driven transition plans that consider funding implications, lead times, and projected patient enrollment.
- Effective procurement and supply planning and timely stock replenishment are critical for the smooth scale-up of new treatment regimens. GDF encourages programs to regularly update quantification files using QuanTB, regardless of funding source.
- Regular sharing of quantification data with GDF is strongly encouraged, as it supports better procurement planning, helps prevent supply disruptions, informs market-shaping efforts, reduces prices, and accelerates the adoption of new TB regimens.

# Thank you!

## Acknowledgements:

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