

GDF: Connecting People, Programs, and Policies to TB Innovations

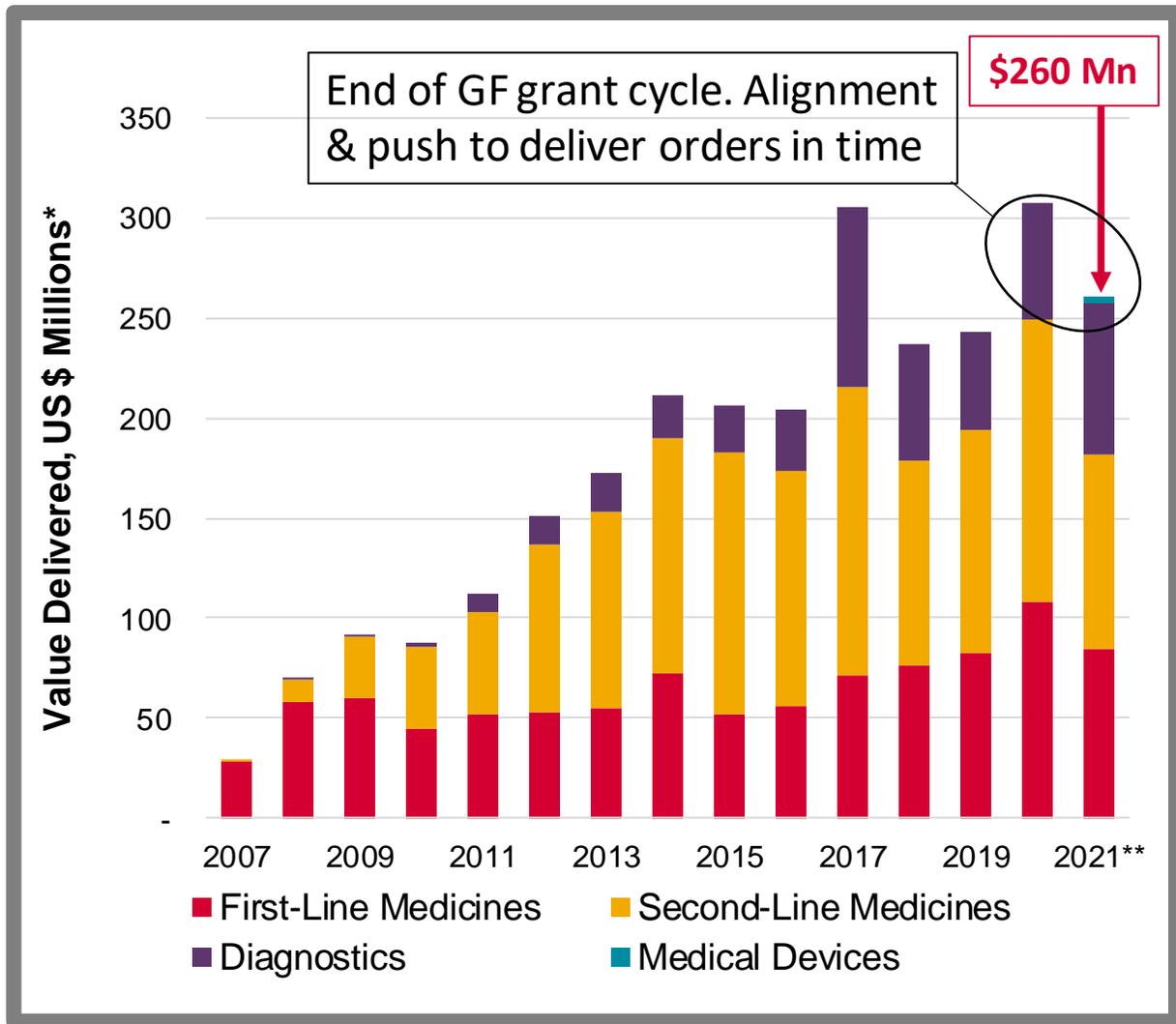
Dr Brenda Waning
Chief, Global Drug Facility, Stop TB Partnership

34th Meeting of the Stop TB Partnership Coordinating Board
29 September, 2021
Geneva - remote

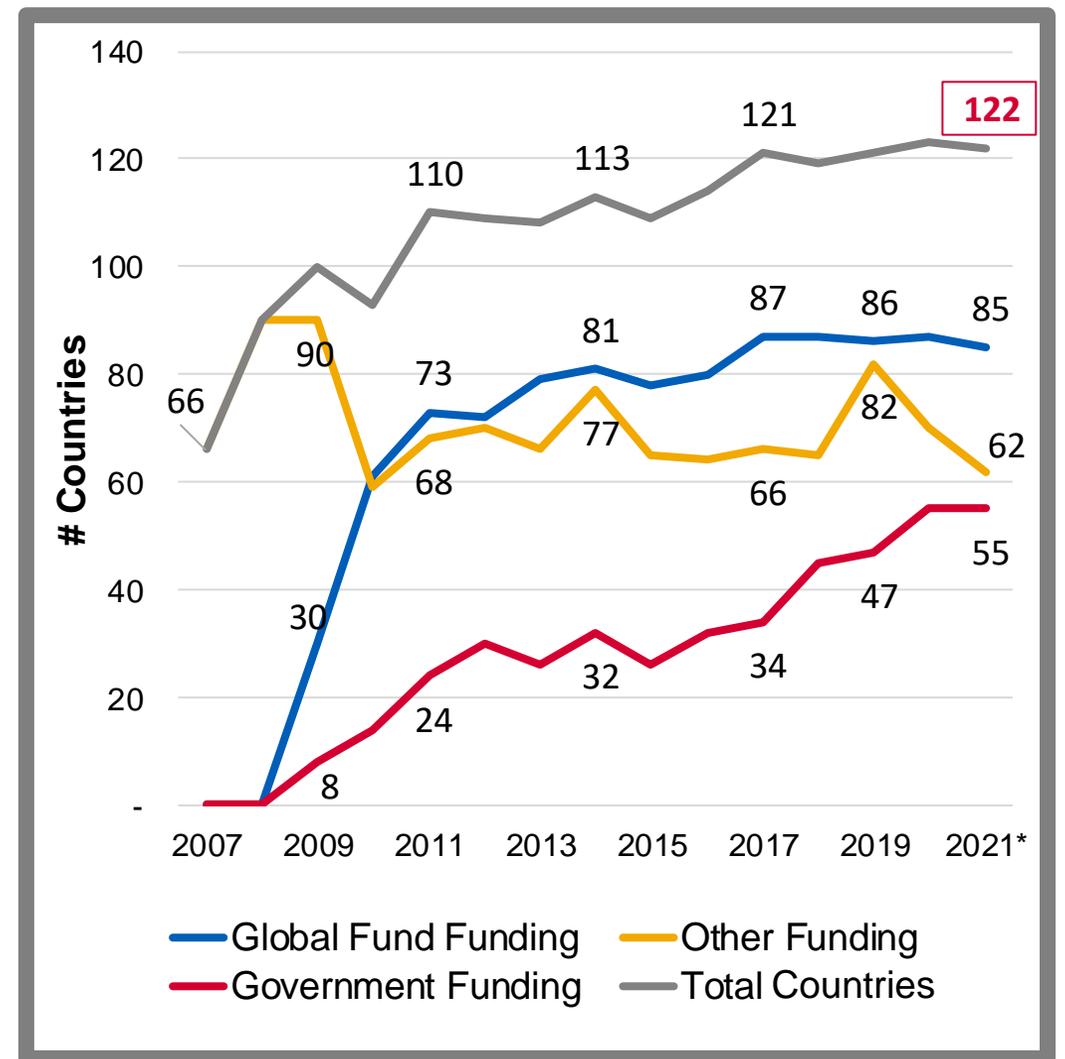
Session Overview

1. 2021 Key Highlights, Recent Product Launches & Introduction Update
2. New Tools on the Horizon: Opportunities & Challenges
3. Market Mapping and Partnering to Optimize Access & Incentivize Innovation

GDF 2021 Procurement Estimates: ~\$260Mn to 122 Countries



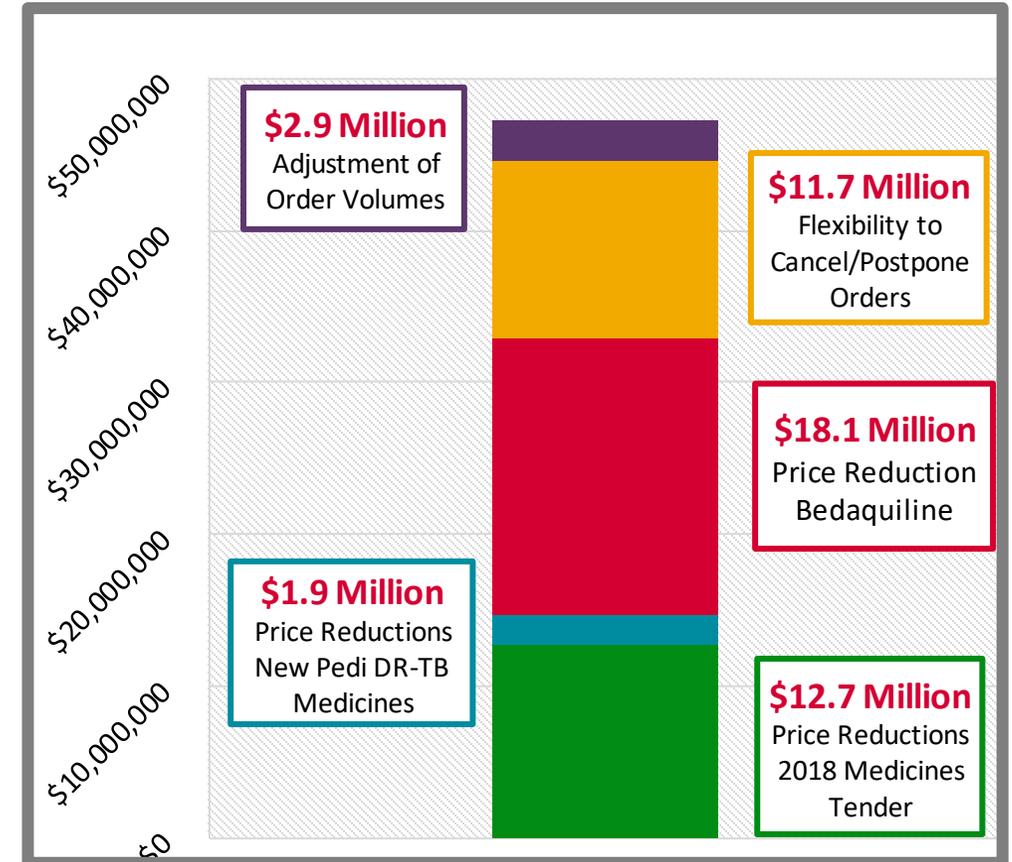
*Value includes product and shipping costs; **2021 projection as of Sep 2021



*2021 projection as of Sep 2021

GDF 2020 Savings: 30% Higher than Projected in Nov 2020

\$36.4 Million 2020 Projected Savings → **\$47.2 Million 2020 Actual Savings***



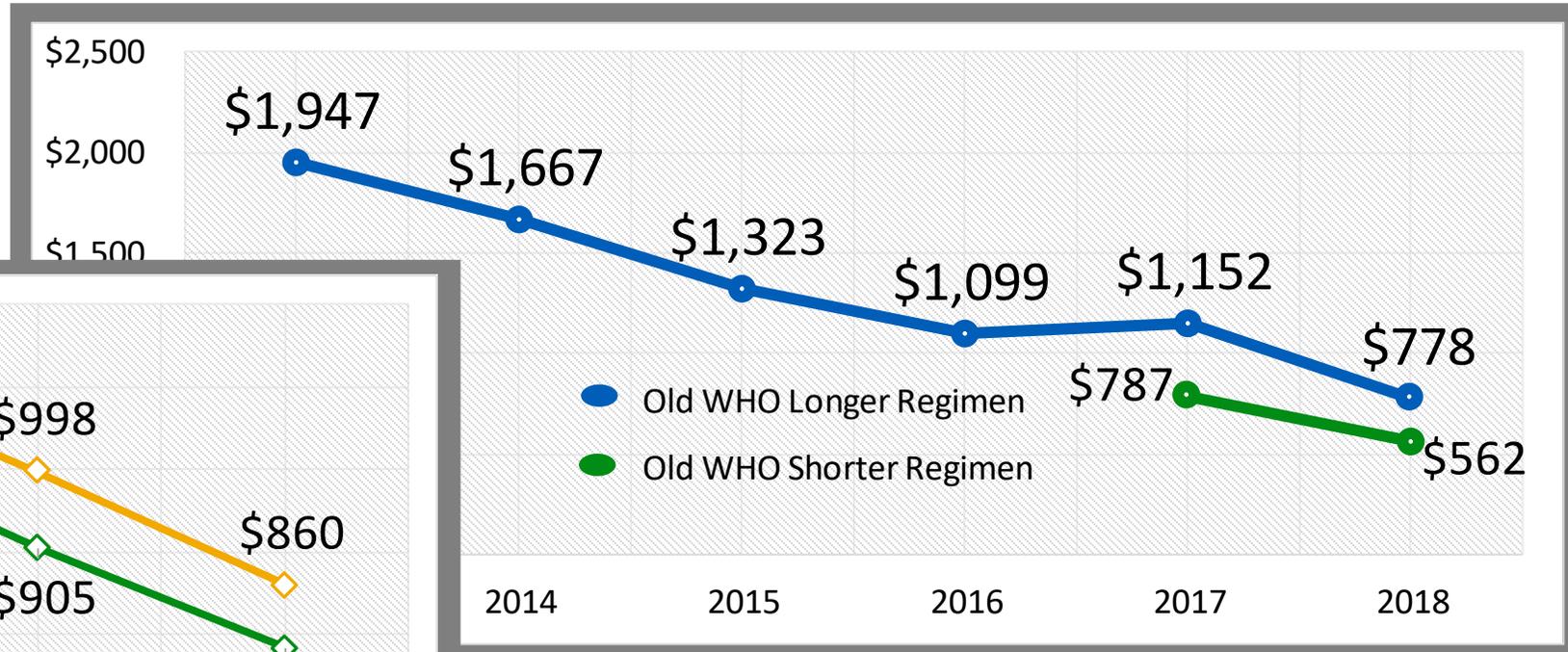
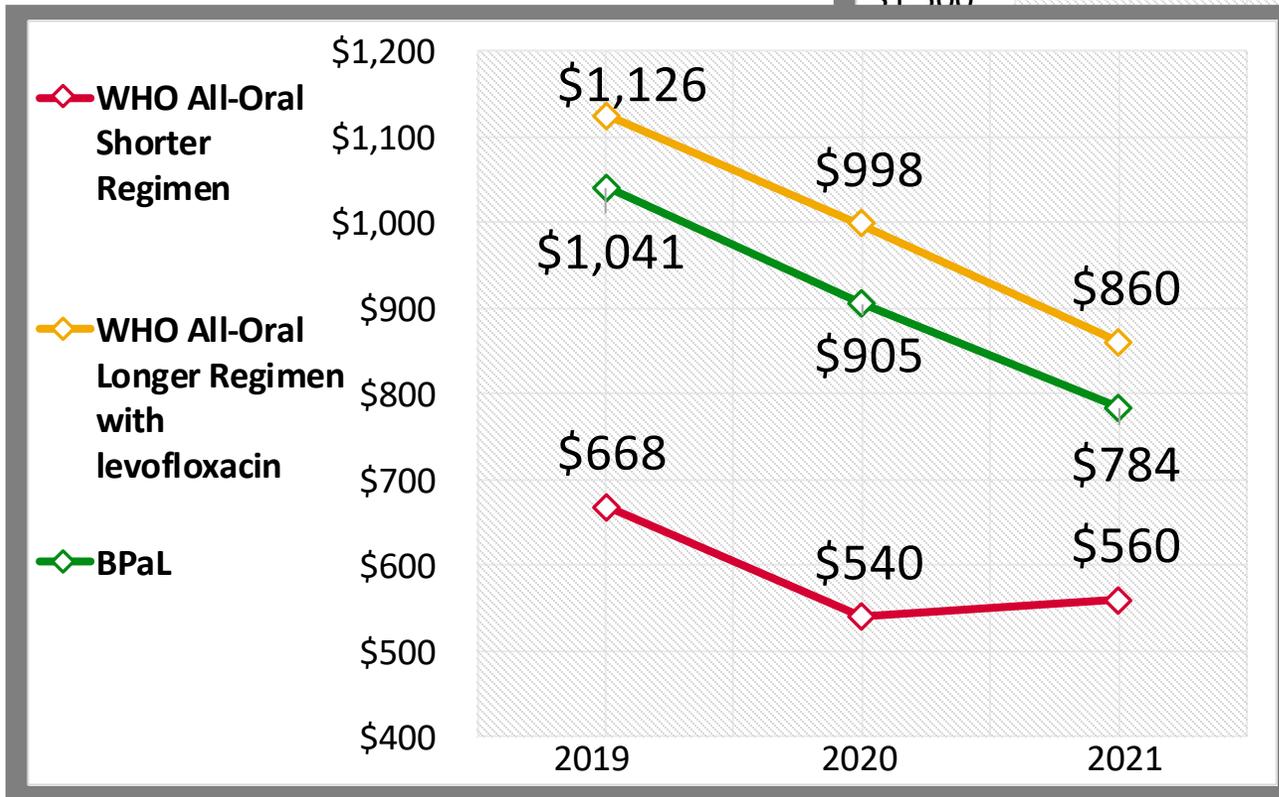
*Equivalent to: 15% of total sales; 1.1Mn DS-TB treatments



DR-TB Regimen Price Reductions

Past WHO-Recommended Regimens

Current WHO-Recommended Regimens

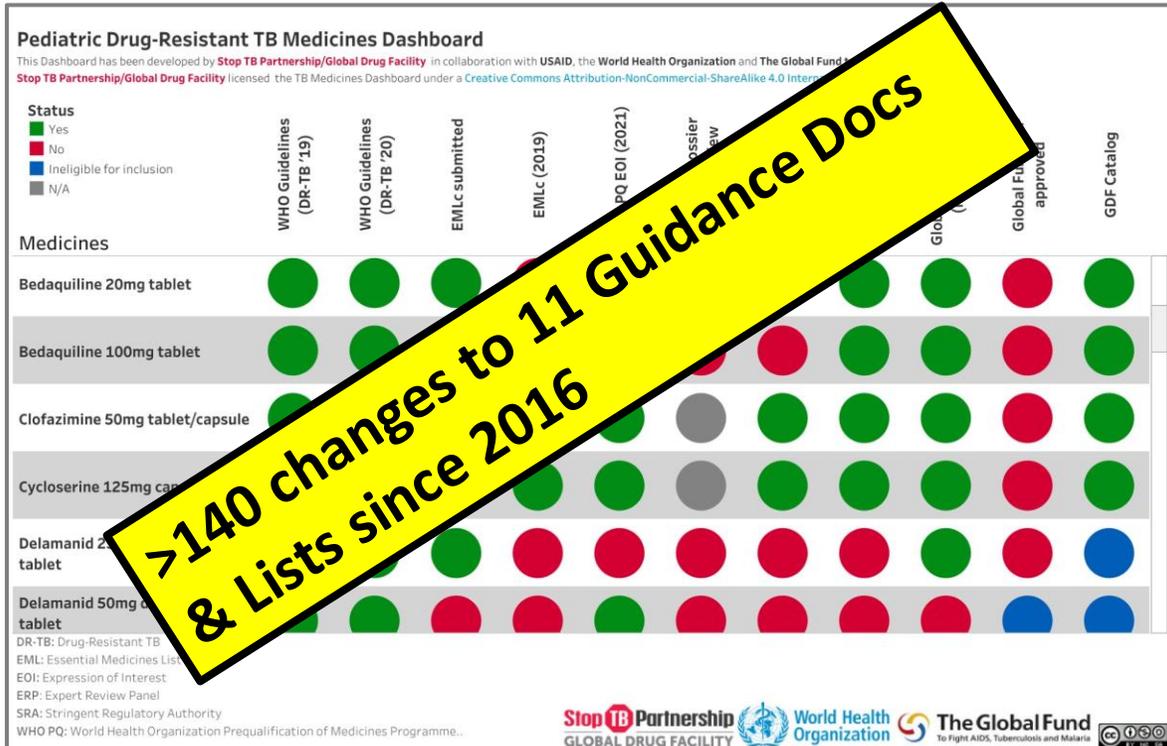


- **25% decrease in BPaL regimen** since end-2019 approval
- **16-24% decrease** new WHO all-oral regimens since 2019
- Price decreases despite stagnant demand/volumes

TB Procurement and Market-Shaping Action Team (TPMAT)

Stakeholder Coordination & Alignment, Product Mapping & Prioritization

WHO-GDF-Global Fund TB Medicines Dashboard



Recommendations Currently Under Review:

- 20 Changes to 2021 WHO Model Essential Medicines List
- 4 Changes to GF Round 24 ERP Expression of Interest

TPMAT recommendations to Global Fund Expert Review Panel's EOI Round 23

TB Procurement and Market-Shaping Action Team Fund's (GF) Expert Review Panel

Paediatric Friendly Formulations

Medicine formulation	TPMAT Recommendation
Bedaquiline 20mg tablet	Add to EOI
Clofazimine 50mg dispersible tablets	Remain in EOI
Cycloserine 125mg capsule	Remain in EOI
Delamanid 25mg tablet or dispersible tablet	Remain in EOI

TUBERCULOSIS PROCUREMENT AND MARKET-SHAPING ACTION TEAM (TPMAT)
SUMMARY MEETING REPORT OF THE SIXTH GENERAL MEETING
 19 February 2021
 Meeting Held Virtually

Background and Introduction

Content of Presentation: TPMAT Overview & Progress Update; Meeting Objectives and Agenda

1. TPMAT Overview & Progress Update Presenter: Brenda Waning (GDF)

TPMAT Overview

The Global Drug Facility (GDF) opened the meeting by providing an overview of TPMAT and summarizing recent TPMAT progress. The TB Procurement and Market-Shaping Action Team (TPMAT) – established in July 2016- is the key global forum that brings together stakeholders to address common market-shaping and procurement challenges related to ultra-fragile TB commodity markets. It serves as an umbrella for all TB stakeholders to align on issues and coordinate activities towards common goals of expediting and optimizing access to quality-assured TB products for people living with TB, irrespective of procurement modalities or funding source. The TPMAT is comprised of procurers, donors, implementers, international organizations, non-governmental organizations, regulators, WHO, civil society, and National TB Programs. Its current members can be found in [Annex 2](#).

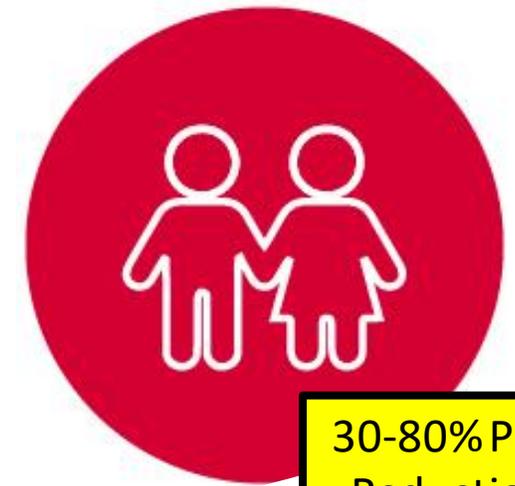
Children less than 5 years of age: two quality-assured suppliers commercially available.

<http://www.stoptb.org/gdf/medicinesdashboard/>

<http://www.stoptb.org/gdf/tpmat/>

Recent Product Launches: Child-Friendly, DR-TB Formulations* (final)

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



**30-80% Price
Reductions**

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



Clofazimine 50mg
Isoniazid 100mg



Bedaquiline 20mg



**New:
Sep-2021**

Delamanid 25mg

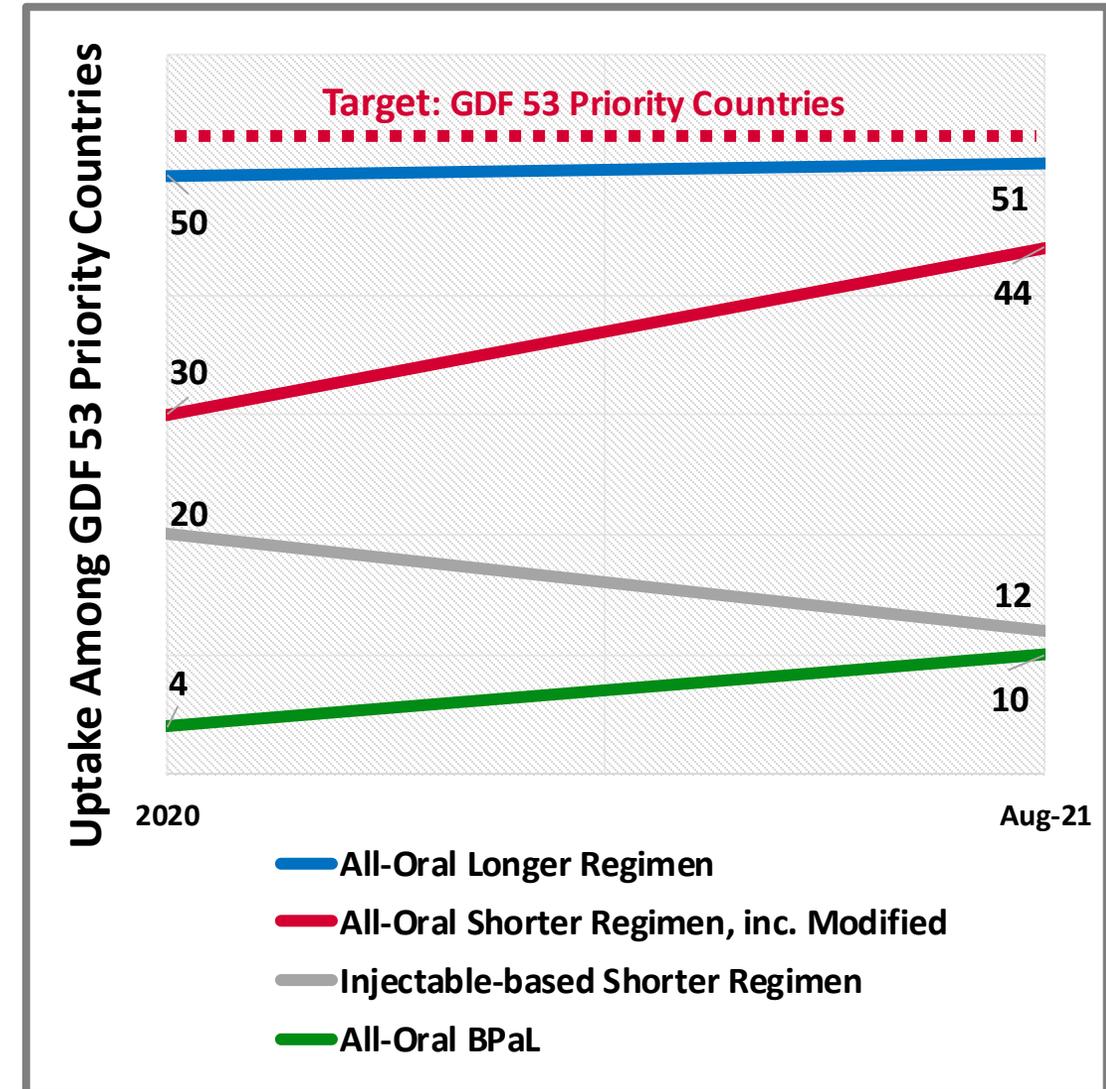
In process:
Linezolid 150mg



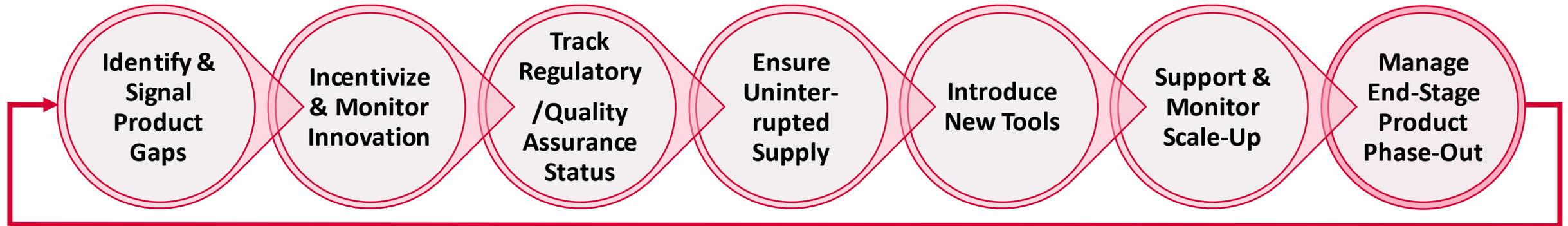
*Blue indicates 2 suppliers

Introduction of New TB Medicines & Regimens (Jun 2021)

Phase	New TB Medicines and Regimens	GDF Board KPI Progress (# Countries Introduced/ # Priority Countries)	# Countries Procuring from GDF
1	Paediatric FDCs (DS-TB)	25/25	99
	Bedaquiline 100mg	25/25	112
	Delamanid 50mg	26/26	88
2-3	Paediatric DR-TB formulations	51/53	75
3	All-oral, longer regimens for DR-TB	51/53	N/A
	All-oral, BDQ-based shorter regimens for DR-TB, inc. Modified	44/53	N/A



GDF and TB Procurement & Market-Shaping Action Team (TPMAT)



Approach to Life-Cycle Management is end-to-end:

- Historically, product-specific approach used
- Even new regimen introduction involved substituting one medicine with another
- But new research is generating many new drugs and treatment options, leading to frequent changes in WHO guidelines
 - Drugs no longer used for DS-TB or DR-TB; now see overlap in use of drugs for both types of TB
 - Multiple regimens, each have different impact on demand for a particular drug
 - Shorter regimens ultimately result in even smaller global market
- **Innovation is most welcome!** But, increasingly challenging to manage market to optimize access

TB Regimen Evolution- New Tool Horizon Scanning

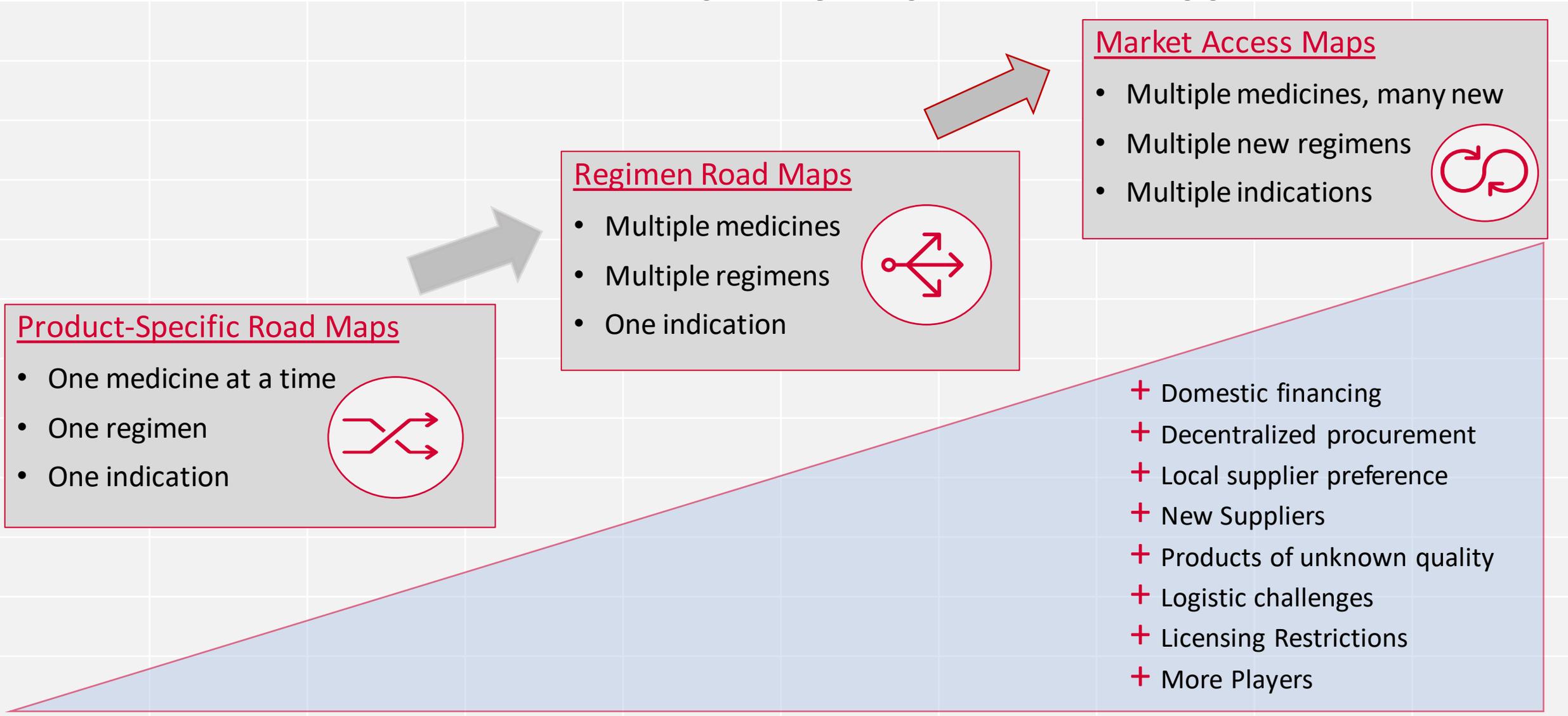
		2017	2021	>2022
Drug-Sensitive TB	Regimens	1 Rifampicin-based regimen	New Rifapentine-Based Regimen	New drugs & many new regimens
	Duration	6 months	4 months	< 4 months
	Overlap w/DR-TB	None	Starting to overlap	Increased overlap
	FDC Available	Yes	No	No
	Market	Consolidated	Potential to Fragment	Increased Fragmentation

		2010-2015	2016-2019	>2022
Drug-Resistant TB	Regimens	Many injectable-based regimens	Move towards all-oral regimens	New drugs & many new regimens
	Duration	18-24 months	9-20 months	< 6 months
	FDC Available	No	No	No
	Market	Fragmented	Fragmented	Increased Fragmentation

Goal: Pan-TB Regimen(s)

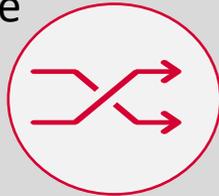
- ✓ Same treatment for DS-TB & DR-TB
- ✓ Likely to include new & newer drugs
- ✓ Market consolidation
- ✓ Safer
- ✓ Shorter
- ✓ FDC
- ✓ Pediatric formulation available early
- ✓ Quality Assured
- ✓ Multiple Suppliers
- ✓ Affordable

Treatment Evolution & Market Complexity Require Shift in Approach



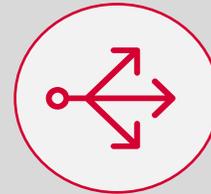
Product-Specific Road Maps

- One medicine at a time
- One regimen
- One indication



Regimen Road Maps

- Multiple medicines
- Multiple regimens
- One indication



Market Access Maps

- Multiple medicines, many new
- Multiple new regimens
- Multiple indications



- + Domestic financing
- + Decentralized procurement
- + Local supplier preference
- + New Suppliers
- + Products of unknown quality
- + Logistic challenges
- + Licensing Restrictions
- + More Players

Summary

- Lots of progress in 2021, despite COVID impacts. Big push to support GF PRs with end-of-grant spending, new concept notes
- Dramatic surge in TB treatment research resulting in frequent WHO guideline changes
- Results are encouraging and welcomed as treatment becomes safer, shorter, easier to tolerate
- But numerous, competing regimens and other factors make it more challenging to manage/consolidate market to achieve access goals
- GDF and TPMAT will need to expand/alter approach to mapping and managing markets to keep suppliers engaged, minimize losses, and promote access to optimal, affordable, quality-assured treatments

Thank You

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- USAID and the Government of Japan for financial & technical support