

Pooled Procurement: Example of Tuberculosis and the Global Drug Facility

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4 May, 2022
Virtual Meeting

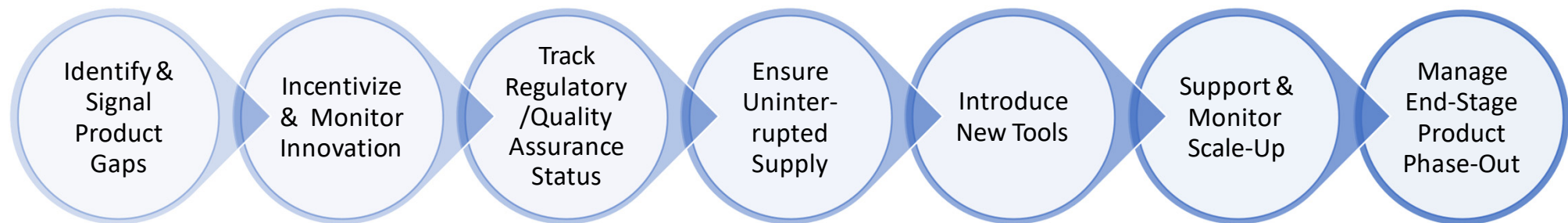
Global Drug Facility (GDF)

Overview

- Established in 2001 to create a market for quality-assured TB medicines
- UN enterprise within Stop TB Partnership; hosted by UNOPS;
- Largest procurer of TB medicines and diagnostics for the public sector:
 - One-stop-shop for TB diagnosis, prevention, and treatment: \$307 million to 123 countries in 2020
- ISO:9001 Certified

Operational Model: Integrated, Pooled Procurement Plus

- Bundled services: procurement along with technical assistance & capacity building; plus global TB stakeholder coordination; risk sharing with suppliers; innovative logistics
- End-to-End oversight of product life cycle with links to TB Programs & implementers

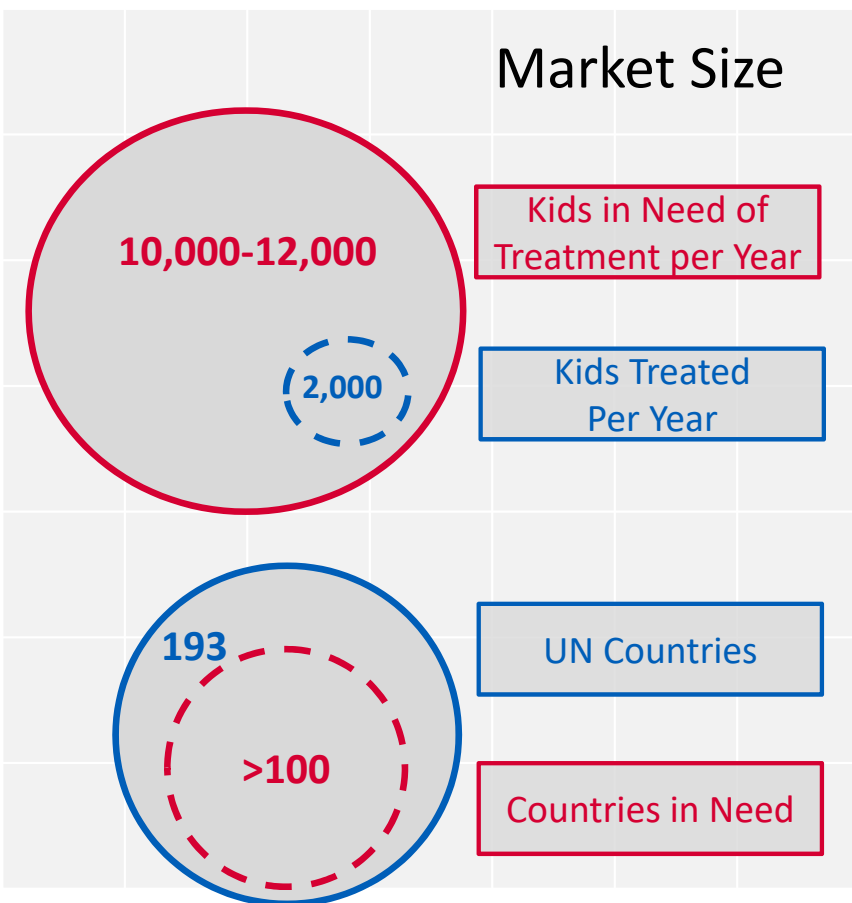


Tuberculosis (TB) Overview

- Centuries old disease.
- One of the top infectious disease killers in the world
 - Disease of low- and middle-income countries; 8 countries account for 2/3 global burden
 - 2 types: drug-sensitive and drug-resistant
- In 2020
 - 9.9 million people fell ill with TB
 - 5.5Mn men, 3.3Mn women, 1.1Mn children
 - 5.8 million people were diagnosed & treated for TB,
 - Leaving a gap of 4.1 million people undiagnosed
 - 150,000 people treated for DR-TB
 - 1.5 million people died of TB
 - TB is the #1 killer of people living with HIV (214,000 ppl in 2020)

Pediatric DR-TB Medicines (children under 5 yo): Failed Market

Market Size



WHO Recommended Treatment

- 11 medicines
- Many possible regimens
- 5-6 medicines per regimen, based upon resistance
- 12-month treatment

Production

- Made to order, No inventory
- Different batch sizes for each formulation
- Different lead times for each formulation

Orders

- Often for volumes <10 treatments per country per year

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

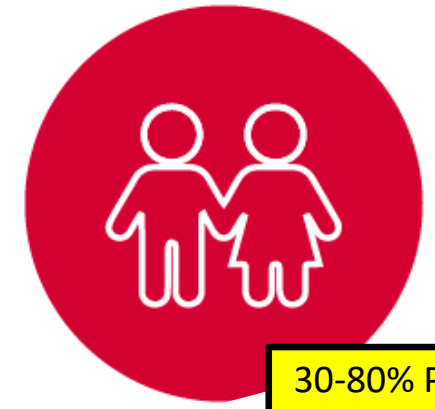
Cycloserine 125mg
Ethambutol 100mg
Ethionamide 125mg
Levofloxacin 100mg
Moxifloxacin 100mg
Pyrazinamide 150mg

Clofazimine 50mg
Isoniazid 100mg

Bedaquiline 20mg

Delamanid 25mg
Linezolid 150mg

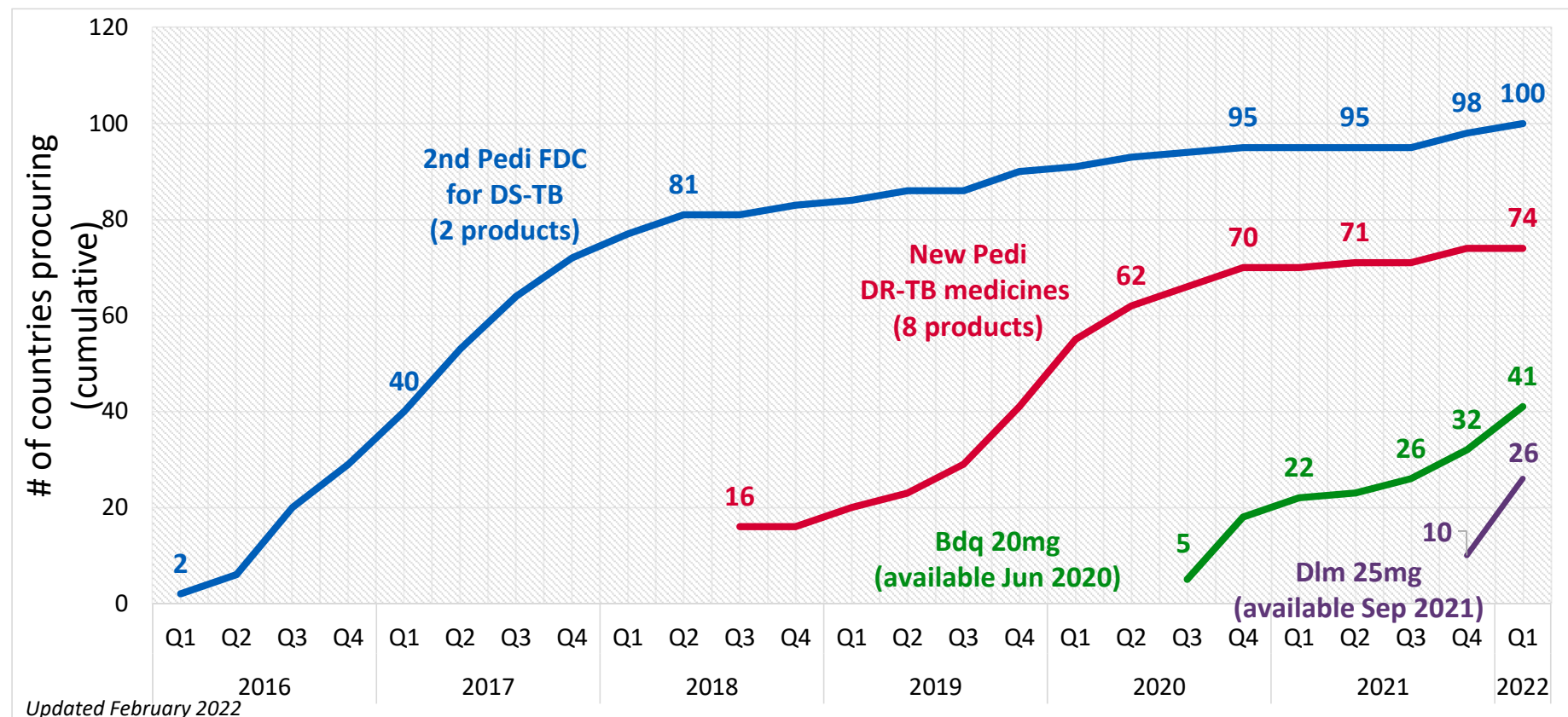
All 11 WHO-Recommended
DR-TB Medicines
Now Available & Accessible
Despite Market Size of
<1,000 Treatments/Year



30-80% Price
Reductions

*Blue indicates 2 suppliers

GDF Launch Pad – Expediting Introduction of New Child-friendly TB Formulations



Updated February 2022

Finding the Win-Win-Wins for Clients and Suppliers

Role and value of pooled procurement depends upon the size and nature of the national and global market at the formulation level

- GDF Model has evolved to changing market & needs
 - Available to all countries and types of clients, regardless of funding source
 - Pre-payment mechanism for domestic procurement
 - GDF-Specific packaging in 4 languages
 - Consolidated shipments of 5-6 medicine orders needed for a regimen into 1 shipment
 - Apply international QA standards
 - Registration support, including waivers when relevant
 - Joint demand review and production planning
 - Strategic Rotating Stockpile (SRS):
 - Decreases # supplier POs & shipments from >160 to 12 per year; from >13 to 1 per month
 - Facilitates expedited introduction of new products & regimens; Protects against stockouts

Finding the Win-Win-Wins for Clients and Suppliers (2)

- GDF Model (continued)
 - Promotion of rational use
 - Catalog displays medicines by WHO-recommended indications
 - Validation of orders against quantification: medicines, regimens
 - Adverse Drug Event Reporting
 - Technical assistance on procurement & supply planning
 - Expedite new product introduction and scale-up
 - Support transition to new WHO recommendations
 - National Early Warning Systems to identify and address stockout risks
 - Supply to clinical research studies
 - Guidance to suppliers on research & market trends
 - Market stewardship: partner coordination, global policy, etc.



Challenges

- TB market is very small, with no opportunity to leverage innovation and sales from HICs.
- Current procurement systems were successful because donors had stipulations that supported creation of a homogenous market that was as consolidated as possible
 - International quality assurance standards: consolidation around ~10 global suppliers
 - Compliance with WHO treatment guidelines: consolidation around what drugs are used
 - Use of appropriately adapted formulations (pedi, FDC): consolidation around which formulations used
- Now a shift from donor to domestic funding and procurement
 - Many levers used for consolidating donor funding markets are gone
 - Markets likely to dramatically fragment: increase in suppliers, # medicines used, types of formulations used, varying standards of quality
 - How to strike a balance to ensure ongoing access & innovation, but comply with national regs & directives

Thank you

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