GDF:
Global mechanism to facilitate access to affordable quality assured TB medicines and diagnostics

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GDF is an initiative of the Stop TB Partnership (2001), mainly funded by USAID, hosted by UNOPS and managed by the Stop TB Partnership Secretariat

GDF is a mechanism to support the Stop TB Operational Strategy 2016-2020
Goal 3:
Facilitate world-wide, equitable access to TB medicines and diagnostics, including new tools, across public and private sectors

GDF began supplying First Line Medicines (FLMs) in 2001, and in 2007 added the supply of Second Line Medicines (SLMs), pediatric TB medicines and in 2010 new diagnostics (key source of GeneXpert). Bedaquiline in 2014 and Delamanid in 2016
GDF Strategy

Strategic Objective 1 – Apply Market Intelligence

- Improved market coordination

Strategic Objective 2 - Strengthen Procurement & Global Supply system

- Shorter lead times, better forecasts, & improved production planning

Strategic Objective 3 - Facilitate the uptake of new TB tools

- Expedited uptake of new TB regimens, medicines, and formulations
GDF Services:

GDF offers a full package of services to client countries that includes:

✓ Uninterrupted access to quality assured TB products at the lowest possible sustainable price

✓ A Flexible Procurement Fund (FPF)- bridge funding to support countries to procure on their own

✓ Country support to facilitate introduction and uptake of new tools (medicines and diagnostics)

✓ A new GDF Strategic Rotating stockpile (SRS), that smooths production cycles and improves lead time for deliveries to countries (more frequent ordering)

✓ Access to technical assistance and capacity building on quantification and TB products management, including early warning system and order planning, for decreasing risk of stock-outs, overstocks and expiries
The Product List

http://www.stoptb.org/gdf/drugsupply/drugs_available.asp
GDF Facts & Figures

As of 1 September 2017

- **138 countries** have benefited from GDF for the supply of TB medicines since its inception in 2001
  - 28.2 M of First Line Medicines (FLMs) adult patient treatments delivered to countries since 2001
  - 1.8 M of FLMs pediatric patient treatments delivered since 2007
  - 272.641 of Second Line Medicines (SLDs) patient treatments delivered since 2007
  - US $208 M of TB Diagnostics delivered to 96 countries since 2007

- Around **US $1.87 billion** of TB products delivered to countries since 2001

- **27 GDF missions** conducted in 2016, **16 as of Q3 2017** to support countries in estimating FLMs and SLMs needs and procurement planning for the introduction of new tools (new pediatric formulations, new MDR-TB regimen)
Amount of GDF orders placed with suppliers per year
(as of September 2017)
Procurement today and tomorrow

✓ The **Global Fund** is the biggest donor to countries for procurement and supply of TB products

✓ Countries have to procure **SLMs through GDF** when using GF Funds

✓ For FLMs and TB diagnostics, countries can procure through GDF or not

✓ **Future:** Several countries are transitioning from the GF to domestic funds. GDF is now working to set a system that will allow countries to continue to procure quality assured TB products through GDF using domestic funds

✓ Need to promote the importance of the quality of medicines (resistance risk)
How GDF helps to get products to market sooner: Central Role in New Paediatric FDC implementation

Donor-funded development of new, appropriately dosed paediatric formulations
GDF Tender Process
Eligible TB medicine suppliers for GDF tenders

Eligible suppliers are those who are in compliance with GDF's Quality Assurance policy

WHO-PQ ¹, or Approved by a Stringent Regulatory Authority (SRA) = ICH members, observers and associates ²

If products meeting these criteria are not available on the market:

ERP authorized products ³

1. WHO Prequalification of Medicines Programme (PQP): www.who.int/prequal
2. SRAs: Listed in each organization’s QA policy

ERP-approved products are listed online at www.theglobalfund.org/en/procurement/quality/pharmaceutical/#Lists
GDF procurement strategy

1. Ensuring the **lowest possible sustainable price** of quality assured TB medicines through competitive, fair and transparent biddings
2. Ensuring reliable supplies through **performant suppliers**
3. Maintaining **sufficient suppliers in the market** by understanding and supporting supplier’s interest as far as possible and by encouraging new suppliers to enter in the market
4. Ensuring **supply security and flexibility** through improved GDF forecasts, improved supplier engagement and production capacity and decreased guaranteed production lead time
5. Limitation of risk of expiries and write off by encouraging suppliers to **extend product shelf life and storage condition** (zone IV)
6. Reducing supply chain risks by encouraging suppliers to **register** their products in countries
GDF TB Diagnostics procurement
GDF TB Diagnostics

Since 2008, GDF has provided direct access to the entire range of WHO-endorsed TB diagnostics and other quality-assured laboratory consumables, reaching all levels of laboratories in more than 96 countries.

Current categories of products in the GDF catalogue

**Conventional culture and DST**
- Solid and liquid culture and DST
- MTB identification from culture

**Molecular Testing**
- Line Probe Assays (LPA), including second-line LPA for triaging patients onto shorter MDR-TB regimen
- Xpert MTB/RIF assay (cartridge-based automated nucleic acid amplification assay)

**Microscopy**
- LED/light microscopes and kits
- Sputum containers

**Biosafety; waste management**
Value of goods shipped (ex-works) under GDF orders:
TB diagnostics and lab supplies

Orders pending shipment in remainder of 2017
Having become the largest procurer of TB diagnostics globally, GDF is now:

• Building capacity to guide countries on adoption and use of new diagnostics in line with WHO recommendations and targets of the End TB Strategy

• Developing tools to guide countries in quantification of diagnostics and other laboratory consumables for accurate country forecasts

• Leading efforts to negotiate better terms of service and prices for countries, using its leverage in collaboration with other major procurers

• Continuing to expand its catalogue of products in line with newly WHO-recommended diagnostics and other quality-assured products to meet country needs
Changing TB medicines landscape
Shift to Shorter regimens (STR) 
and what it means in terms of supply needs

• Change in the composition of regimen: out- and in-coming medicines
• Change in pill-count and duration: good for patients, smaller market for suppliers
• Change in price: good for programs, smaller profit for suppliers

Standard:  8 Km Lfx Cs Eto Z / 12 Lfx Cs Eto Z ($1000 – 1100, GDF), 20 months
STR:  4 Km-Mfx-Pto-Cfz-Z-E-H_{highdose} / 5 Mfx-Cfz-Z-E ($700-800, GDF), 9 months duration
GDF TB medicines portfolio in 2017 and future demand

- **Portfolio**
  - FLMs: 12 Manufacturers for 31 products
  - SLMs: 24 manufacturers for 34 products

- **Current and future demand due to single source or new WHO guidelines**
  - Clofazimine API and FPP
  - Kanamycin API
  - Gatifloxacin
  - Rifapentine
  - Bedaquiline
  - Delamanid
  - Medicines for pediatric DR-TB (small current demand)
  - LTBI FDCs:
    - Isoniazid/Rifapentine 150mg/150mg (dispersible)
    - Isoniazid/Rifapentine 300mg/300mg (coated tablet or capsules)
Ideal TB medicine / supplier

1. Quality assured (according to GDF quality assurance policy)
2. Lowest possible sustainable price
3. Longest shelf life (5 years when possible)
4. Registration in every country
5. Produced and delivered with the shortest lead time
6. By a supplier with 100% performance
7. With No Minimum Order Quantity

For each product, GDF has to find the best balance considering GDF procurement principle and strategy to ensure an uninterrupted supply of quality assured TB medicines worldwide at the lowest possible sustainable price while simultaneously maintaining a sustainable and competitive market.
Thank You