

The Global Drug Facility (GDF)

GDF, the Global mechanism to facilitate access to affordable quality assured TB medicines and diagnostics, including new tools

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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

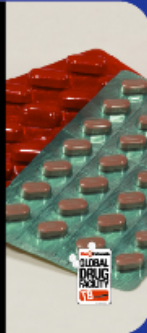
The Product List

http://www.stoptb.org/gdf/drugsupply/drugs_available.asp

1st and 2nd Line Anti-TB Drugs

RATIONAL USE

Providing an uninterrupted supply of GDF and Green Light Committee approved anti-TB drugs.



Paediatric Anti-TB Drugs

AN INCLUSIVE APPROACH

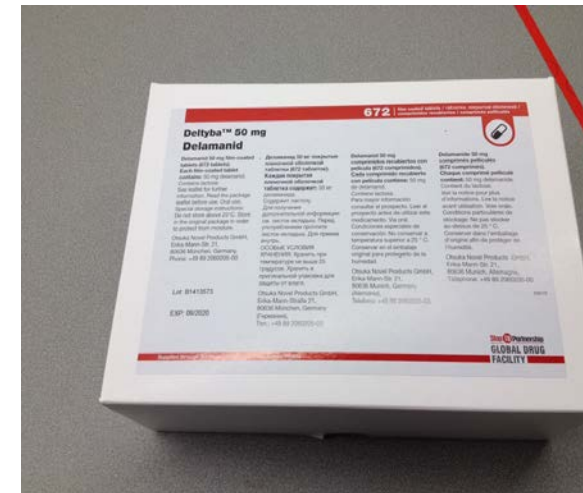
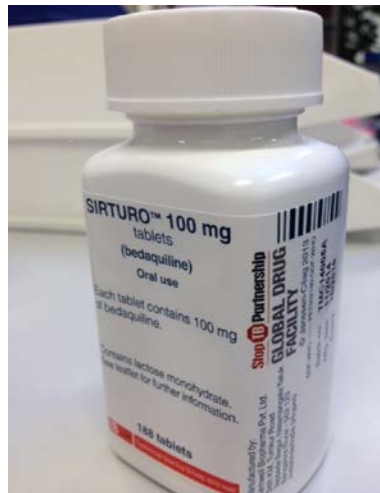
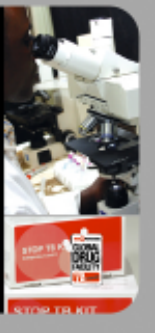
Supplying appropriate anti-TB drugs for children, who also have the right to be treated.



Diagnostic Kits

CASE-FINDING REDEFINED

Offering practical diagnostic tools for laboratories to improve case-finding.



New Diagnostics

Tackling the problem in innovative way



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**

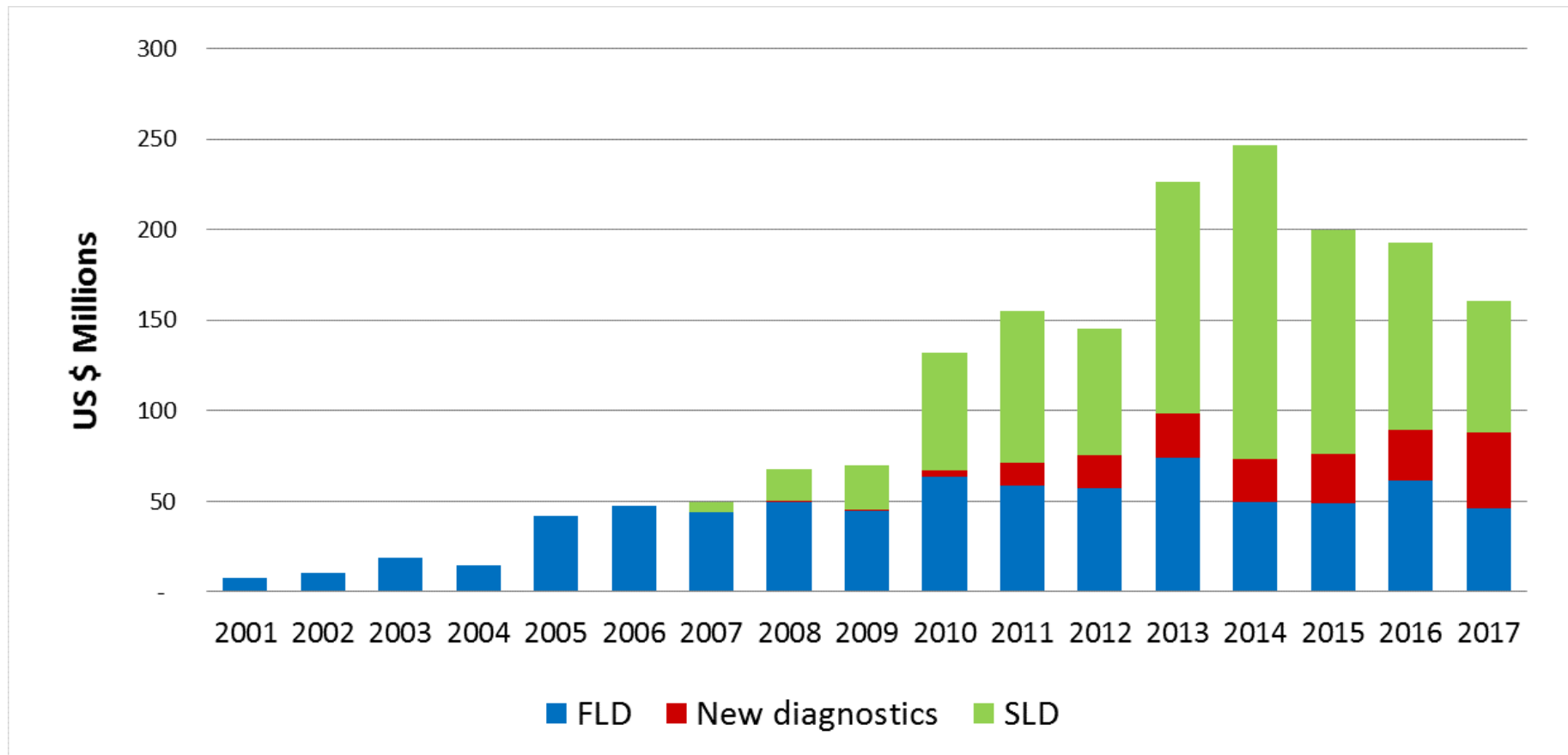
GDF Facts & Figures



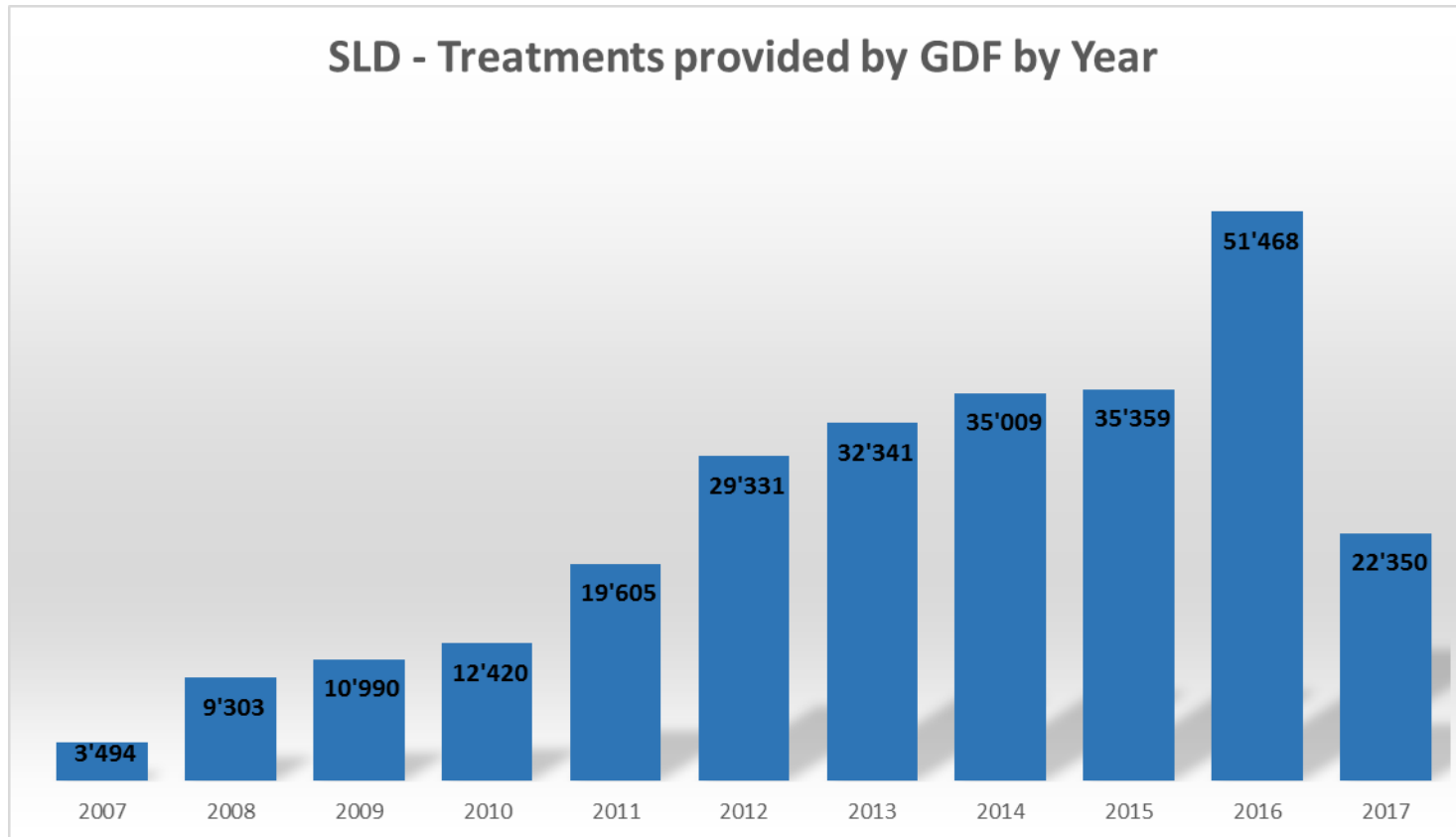
As of June 2017

- ❖ **138 countries** have benefited from GDF for the supply of TB medicines since its inception in 2001
 - **27,8 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
 - **261,670 of Second Line Medicines (SLDs)** patient treatments delivered since 2007
- ❖ and **US \$178 M of TB Diagnostics** delivered to **91 countries** since 2007
- ❖ Around **US \$1.78 billion** of TB products delivered to countries since 2001
- ❖ **27 GDF missions** conducted in 2016, **13 in Q1 2017** to support countries in estimating FLMs and SLMs needs and procurement planning for the introduction of new tools (new paediatric formulations, new MDR-TB regimen...)

Amount of GDF orders placed with suppliers per year (as of June 2017)

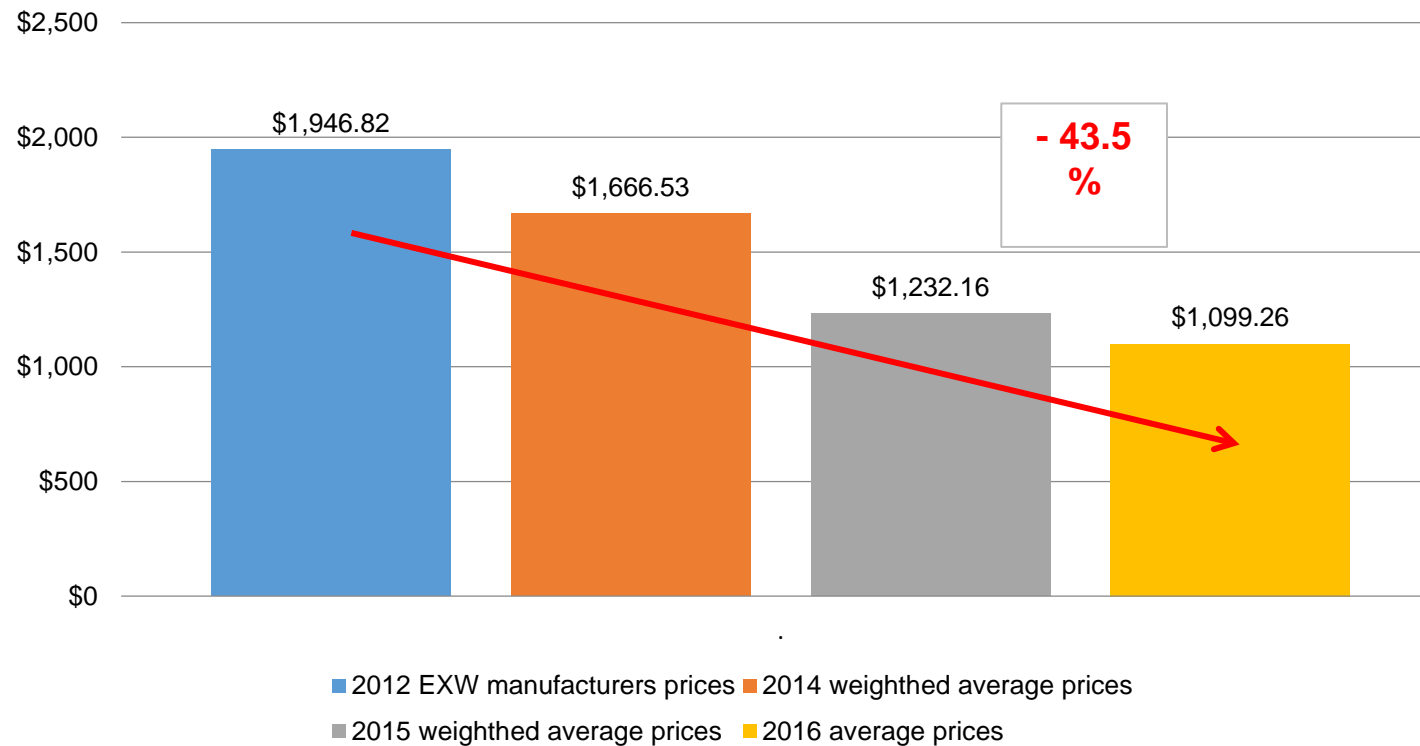


Number of SLD treatment delivered by GDF per year (as of June 2017)



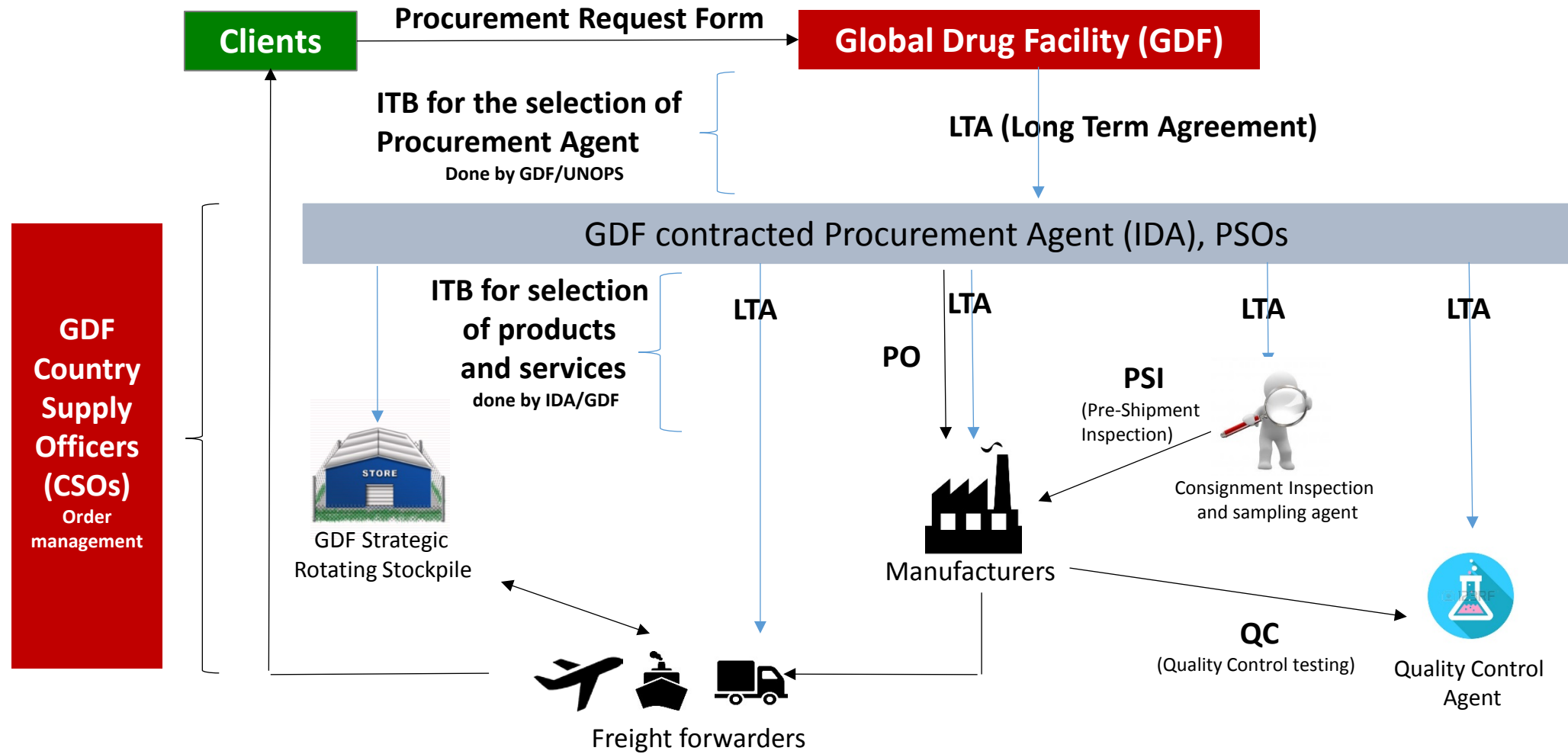
Cost of treatment regimens is dynamic

2012/2016 Regimen costs:
Mid regimen 8 Z Km Lfx Eto Cs / 12 Z Lfx Eto Cs



- ✓ The **Global Fund (GF)** 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**

GDF operational model for procurement and supply of anti-TB medicines



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
3. **ERP:** Expert Panel Review, hosted by WHO. More information on ERP:
http://apps.who.int/prequal/info_press/pq_news_27April2012_ERP.htm
ERP-approved products are listed online at
www.theglobalfund.org/en/procurement/quality/pharmaceutical/#Lists

GDF Procurement principles:

- Derived from ultimate objective of procurement to **add value to GDF and its partners** in fulfilling their goals and objectives
- Includes concepts such as maintaining the best **image and reputation** of the organization and **promoting public good**

- Trade off between price and performance/quality providing the **greatest overall benefit**
 - **Price** = life cycle cost, not just purchase price
 - **Quality** = required performance, reliability, social and environmental considerations



- Free from favouritism, **impartial**, honest and applies visibility and openness in all transactions
- **Ethical** behavior
- **All information** on policies, procedures, opportunities and processes are clearly defined and made **widely known**

- Fostering **competition** as a driver for best value for money
- Achieved through: **sufficient number of prospective bidders** which are independent and compete under same conditions

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

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. **Registered** in every country
5. Produced and delivered with the shortest possible **lead time**
6. By a **supplier** with 100% **performance**
7. With **Minimum Order Quantity** (MOQ) of 1



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

GDF Tender process for medicines

On behalf of GDF, the GDF contracted procurement agent (PA) invites eligible suppliers to submit a bid for the medicines described in the Invitation to Bid (ITB)

Information publicly available on GDF and IDA websites:
http://stoptb.org/gdf/drugsupply/procurement_notice.asp

| Activity | Responsible |
|---|-------------|
| 1. ITB Launch/web-publishing | GDF/PA |
| 2. Request for information/clarification on ITB | Bidders |
| 3. Responses to requests for information/clarification on ITB | GDF/PA |
| 4. Preparation and electronic submission of Technical and Financial Bids according to the terms and conditions stated in the ITB document | Bidders |
| 5. Opening and screening of Technical Bids to check the eligibility of the Bidders and products offered | GDF/PA |
| 6. Public opening of Financial Bids of eligible bidders | GDF/PA |
| 7. Evaluation of Technical and Financial Bids of eligible bidders/products | GDF/PA |
| 8. Adjudication and market share allocation per awarded bidders | GDF/PA |
| 9. Notification of Awards to all bidders | GDF/PA |

Schedule of GDF tenders

- For **FLMs**: every 1-2 years for a contract period from 1st January to 31 December
- For **SLMs**: each year for a contract period from 1st April to 31 March

The frequency of tenders and period of contract for FLMs and SLMs are under review by GDF/PA

Suppliers will be informed as soon as a new decision will be made

Market share allocation*

- 100%/0% for primary-sole supplier/auxiliary supplier
- 55%/45%/0% for primary/secondary/auxiliary supplier(s)
- 50%/30%/20%/0% for primary/secondary/tertiary/auxiliary supplier(s)

*allocation is indicative only, and the actual allocation might deviate due to importation requirements, client preferences, registration status and other factors as deemed necessary by GDF or its clients.

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 guideline**

- 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)

GDF Quality assurance policy

Goal of GDF QA Policy

- To guarantee the Safety, Efficacy and Quality of the Finished Pharmaceutical Products (FPP) procured through GDF
- The products procured through GDF are:
 - ✓ Recommended for use by WHO
 - ✓ WHO prequalified or SRA approved
 - ✓ ERP approved in absence of WHO prequalified or SRA approved products
 - ✓ Authorized for use by NMRA of recipient countries
 - ✓ Monitored through a Product Quality Monitoring Programme

GDF QA policy

- Quality standard requirements during procurement process
- Quality monitoring program in place



GDF Quality Monitoring Program for medicines

1 PSI

- ▶ **Product & shipment documentation visual inspection**
- ▶ **Product specification review**
(including packaging, labelling, Artwork, remaining shelf life, storage condition...)

3 CoA review

- ▶ **Standard:** CoA review of all shipped batches
- ▶ **Critical:** of all products at initial procurement including compliance with specifications

2 Sampling

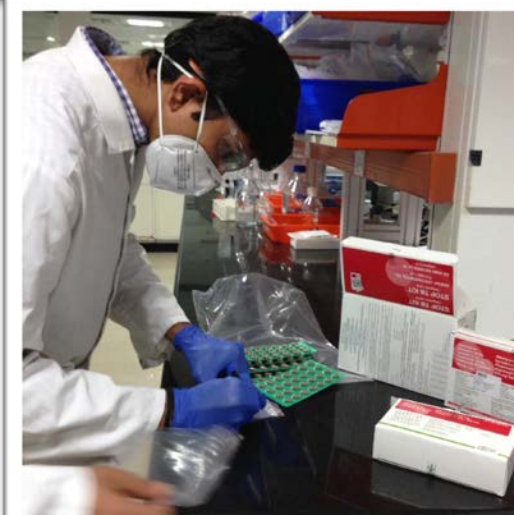
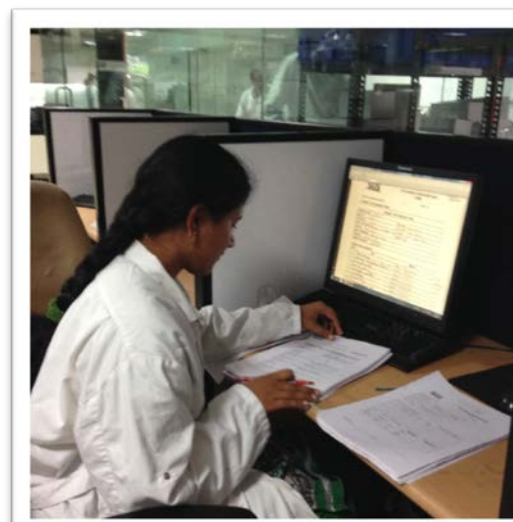
- ▶ **ERP/WHO PQP products:**
randomized sampling of product batches
- ▶ **SRA products:** ad hoc

4 Lab testing

- ▶ **Testing** for compliance with in-house specifications or pharmacopeia monograph/s (US, BP, IP, EU, Nationals)
- ▶ **Stringent OoS investigations**

GDF Quality monitoring programme: 2016 figures

| | 2016 |
|----------------------|------|
| Total number of PO | 2139 |
| PSI | 679 |
| Sampling | 144 |
| CoA review | 3098 |
| Testing | 283 |
| Critical CoA reviews | 26 |



Overall results in 2016

- **No** recall
- **No** QC quality failure
- PSI: reduction of deviations
- CoA review: 1.6% follow up required

CONCLUSION

GDF Services (1):

GDF offers to countries a package of services that includes:

- ✓ Access to **GDF negotiated prices** leading to savings for diagnosing and treating more people
- ✓ Access to **quality assured** TB products (GDF Quality Assurance Policy, Pre-shipment Inspection & Quality control services)
- ✓ Access to **new TB tools (BDQ, DLM, new diagnostics)** and **GDF country support** to facilitate their introduction/uptake (Procurement and Supply Management (PSM) transition plan)
- ✓ Access to **Shortened delivery lead time** : Currently 4-6 months BUT in 2017, anticipated significant decrease of GDF delivery lead time thanks to the **new GDF Strategic Rotating stockpile (SRS)**, leading to more order flexibility (frequent ordering possible)

GDF services (2):

- ✓ Assurance of **Supply availability of TB products** matching country demand, preventing global shortages (Sourcing, Market intelligence, strategic procurement, supplier engagement, forecasts and production plans)
- ✓ Provision of a **Quality supply service** ensuring timely delivery of TB medicines to countries through its contracted procurement agent and through in-house procurement and supply for diagnostics, with the support of dedicated GDF Country Supply Officers (CSOs)
- ✓ Access to the **GDF ordering tracking tool** (OMS) ensuring management and traceability of orders to country teams
- ✓ 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