

# Improving Access for Quality-Assured TB Medicines + Diagnostics



## Update on GDF Achievements & Strategic Framework Implementation

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GDI meeting  
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# What is the Global Drug Facility?

**An initiative of the Stop TB Partnership (2001), mainly funded by USAID and CIDA, with projects supported by UNITAID & Kuwait Fund, hosted in WHO and managed by the Stop TB Partnership**

An operating mechanism to support the Stop TB Strategy:

- **expanding access to quality-assured first (FLD) and second-line TB drugs (SLD) and diagnostics,**
- **contributing to the development of sustainable procurement and supply management for countries in need**

**GDF began supplying FLDs in 2001, and in 2006 added the supply of SLDs, pediatric TB medicines and diagnostics and is a major source for GeneXpert**



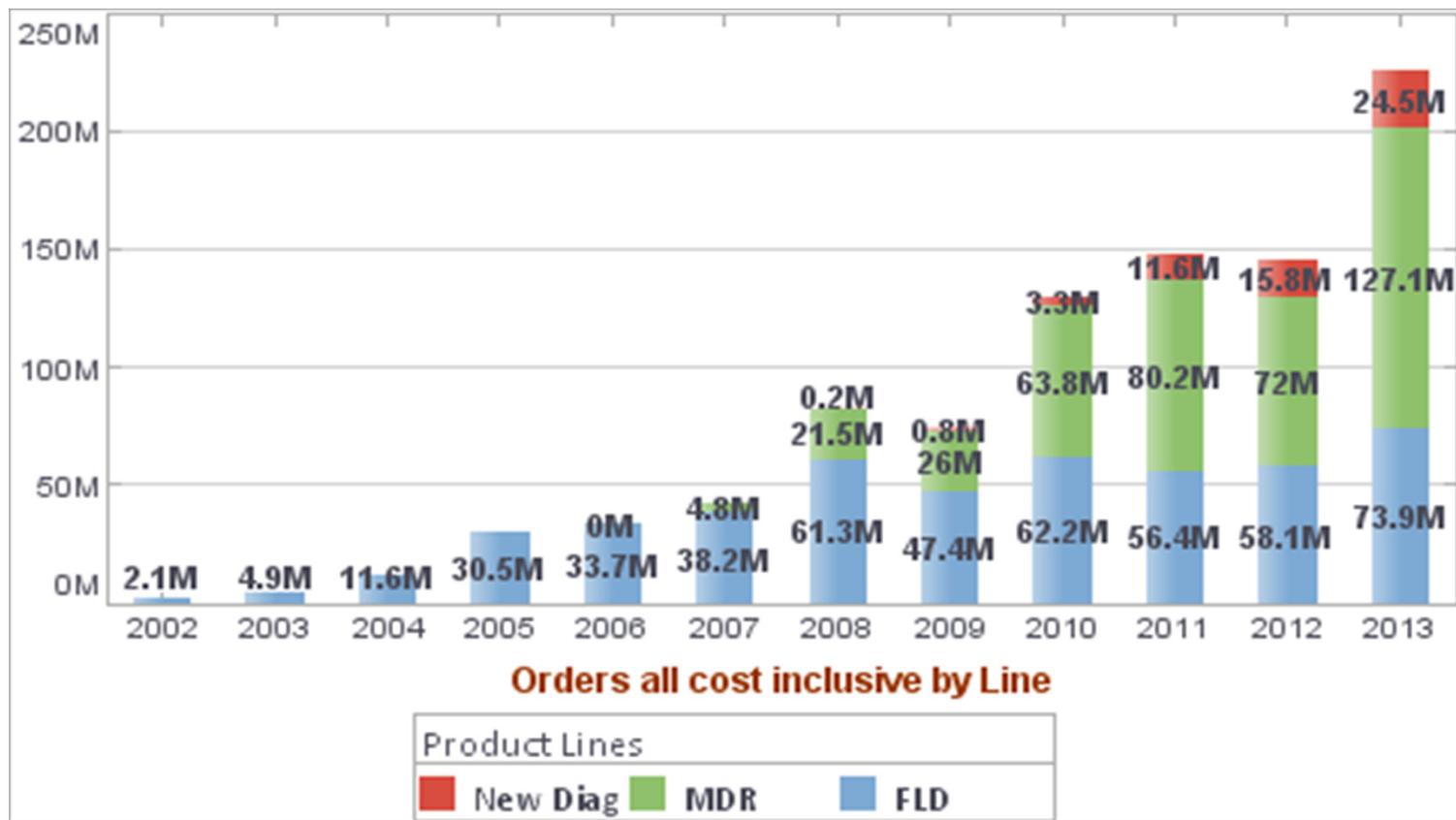
# Key GDF milestones to date

**A total of 128 different countries received the benefits from GDF procurement system and GDF multiple advantage**

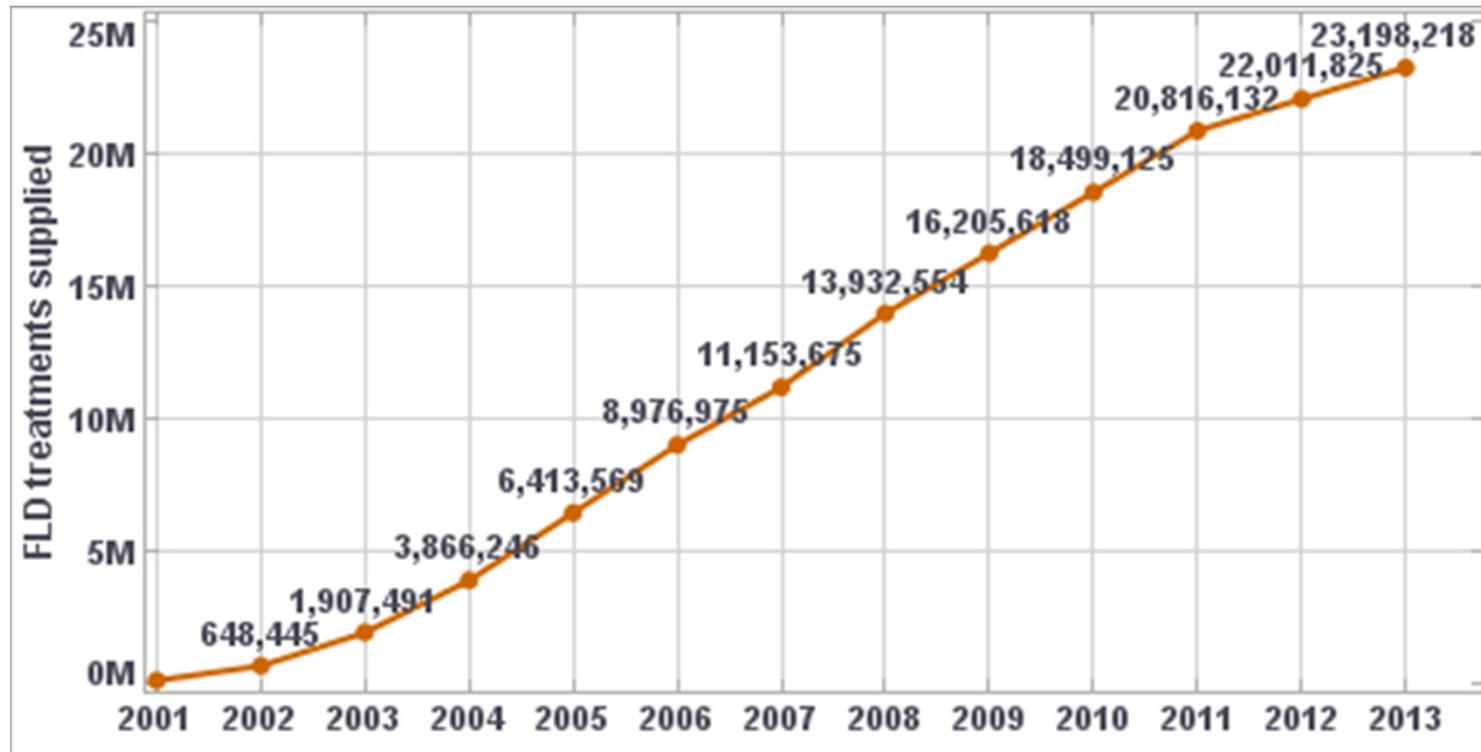
- ❖ > 23 Million FLDs patient treatments delivered
- ❖ > 116,000 SLDs patient treatments delivered (x2 comparing 2013 with 2012)
- ❖ > 1 billion USD of drugs and diagnostics procured since 2002 with a growing support from GDF to countries for diagnostics provision (TB REACH / Expand TB / TB Expert)
- ❖ +35% for TB products ordered value (146 M USD in 2012 to 225.5 M USD in 2013) and 3 new ITBs conducted for SLDs with further cost decrease achieved (up to -32%)



# GDF order placed value all inclusive – By Product Line 2001-2013



# Total Patient Treatments Supplied 2001-2013 First Line Drugs



Live Report Jan 2014

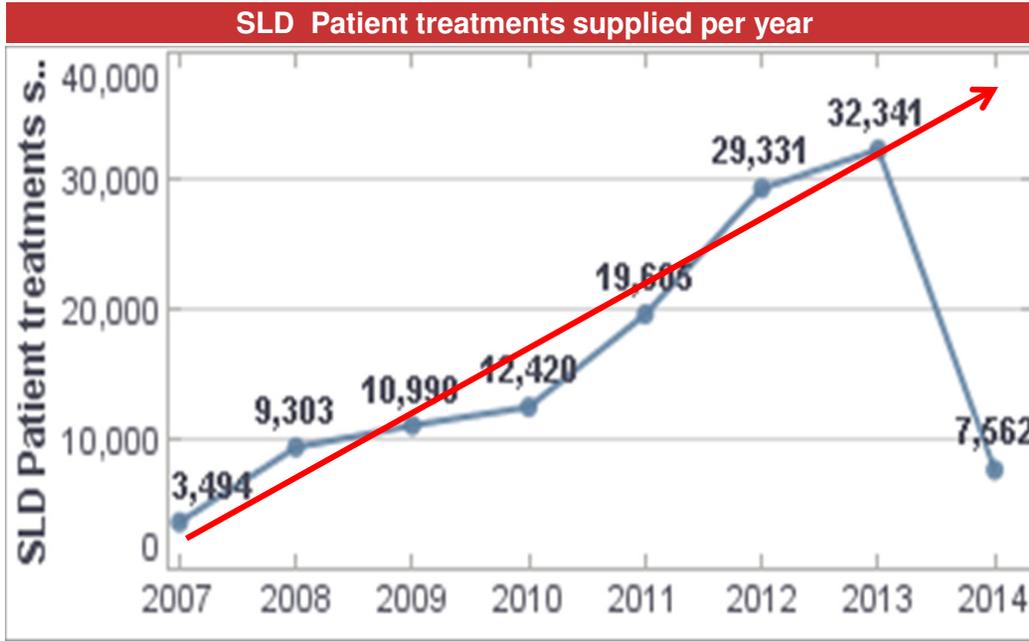
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Stop TB Partnership  
GLOBAL DRUG  
FACILITY

# Total Patient Treatments Supplied 2001 - 2013 Second Line Drugs / Market share around 35%

6 months IP until 2012, 8 months thereafter

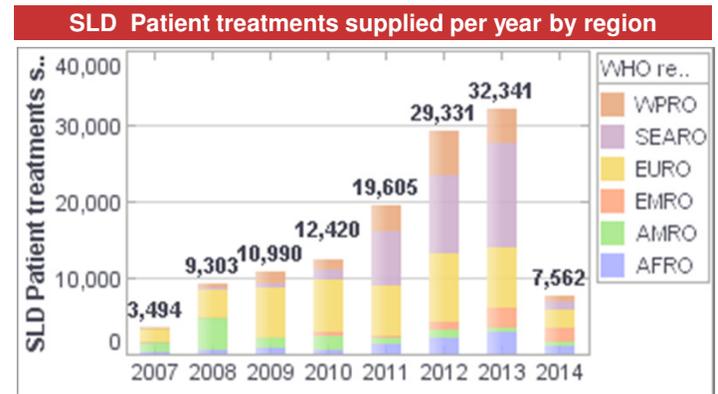
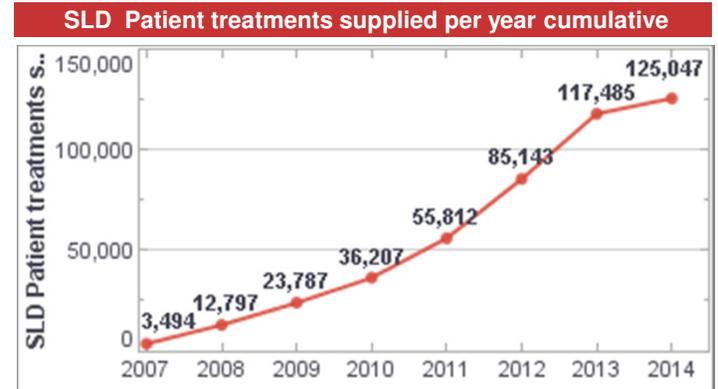


Note : 2014 data till April 23 ,2014

2013/14 values are boosted by India orders.

Live Report April 23 2014

[http://gva1swamphion/sree/Reports?op=vs&path=/WHO\\_HQ\\_Reports/G1/PROD/INT/Shared/MDR+Patient+treatments+supplied+-+method+Injectable+standard+180-240dose+Rev+3.0&userid=GDF\\_ro&password=gdfread1](http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/MDR+Patient+treatments+supplied+-+method+Injectable+standard+180-240dose+Rev+3.0&userid=GDF_ro&password=gdfread1)



# Second & Third-line drugs portfolio: 2014 update

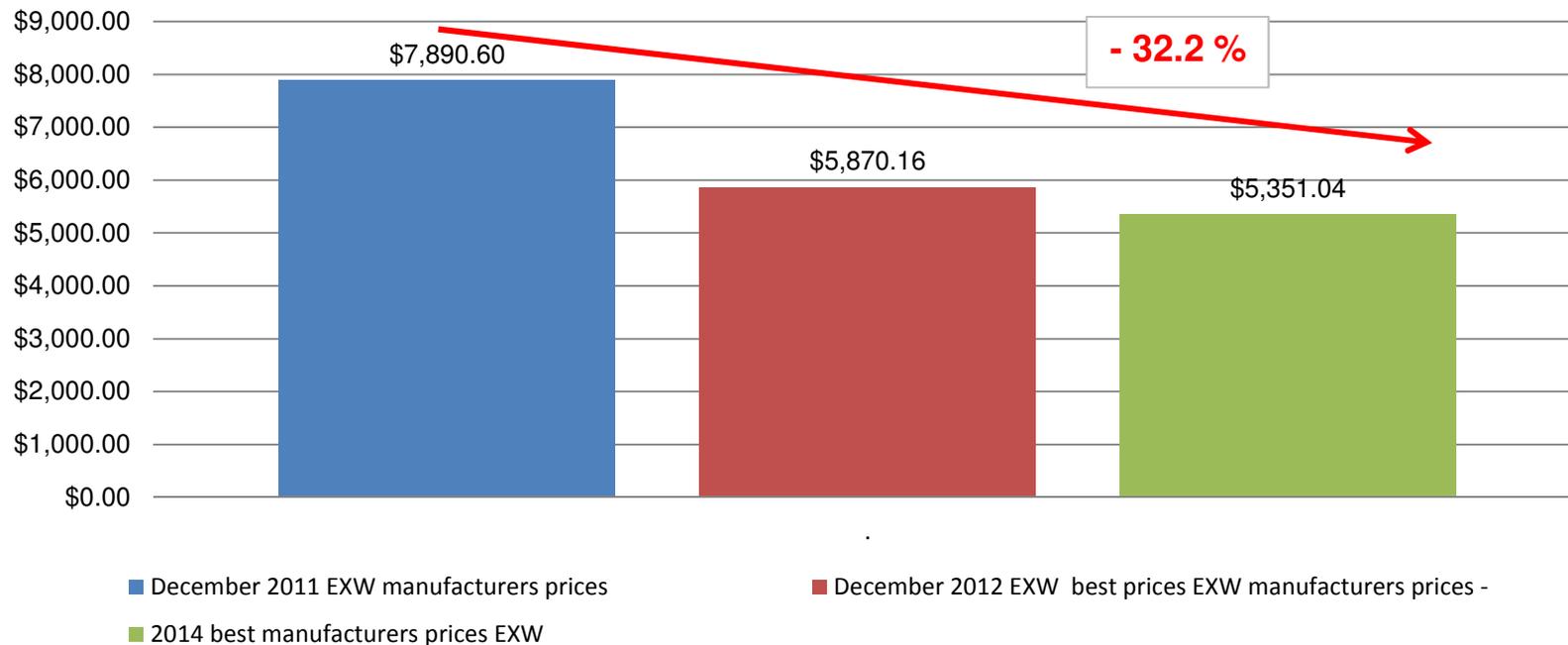
17 one-year agreements with suppliers, covering 20 product groups:

- 5 Fluoroquinolones, blister
  - 7 Bacteriostatics, blister, strips, sachet, container
  - 3 Injectables, vial, ampoule
  - 7 Third line drugs, blister and vials
- ✓ **Up to 37% price reduction** negotiated on Cycloserine for 2013, further decrease by 2% for cheapest WHO/SRA approved product
  - ✓ **Up to 32% price reduction on treatment regimens supplied (2014 vs 2012)**
  - ✓ SLD supplier base twice as big as in 2009: **10 suppliers in 2009 vs 19 in 2014**
  - ✓ Number of SLD available for supply: **12 in 2009 vs 23 in 2014**
  - ✓ 2014 news:
    - Medochemie (Levofloxacin 250mg & 500mg) – price decrease and shelf life to be / 5 years
    - Linezolid available for procurement
    - Further price reductions versus previous ITBs
      - » Cycloserine from Dong A: -24%
      - » PASER from Jacobus: -15%
      - » Capreomycin from VIANEX: -4%



# GDF Impact on SLD Dynamics: 2011 vs. 2014 treatment cost comparison / High end regimen

**2011/2014 Change in Regimen costs: High end regimen  
with cheapest suppliers  
12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS**



# GDF/UNITAID MDR-TB Scale-Up Project

- ❑ UNITAID support ended 2013
- ❑ Supported countries and patient treatments delivered, from the inception of Scale-Up initiative:
- ❑ 4 countries received additional support in 2013

Azerbaijan	1170
Burkina Faso	60
Cambodia	200
Dominican Republic	323
DR Congo	550
Guinea	74
Haiti	211
India	9850
Kenya	475
Kyrgyzstan	818
Lesotho	550
Malawi	100
Moldova	150
Mozambique	100
Myanmar	784
Nepal	600
Senegal	30
Timor-Leste	20
Uzbekistan	614
<b>TOTAL:</b>	<b>16,679</b>

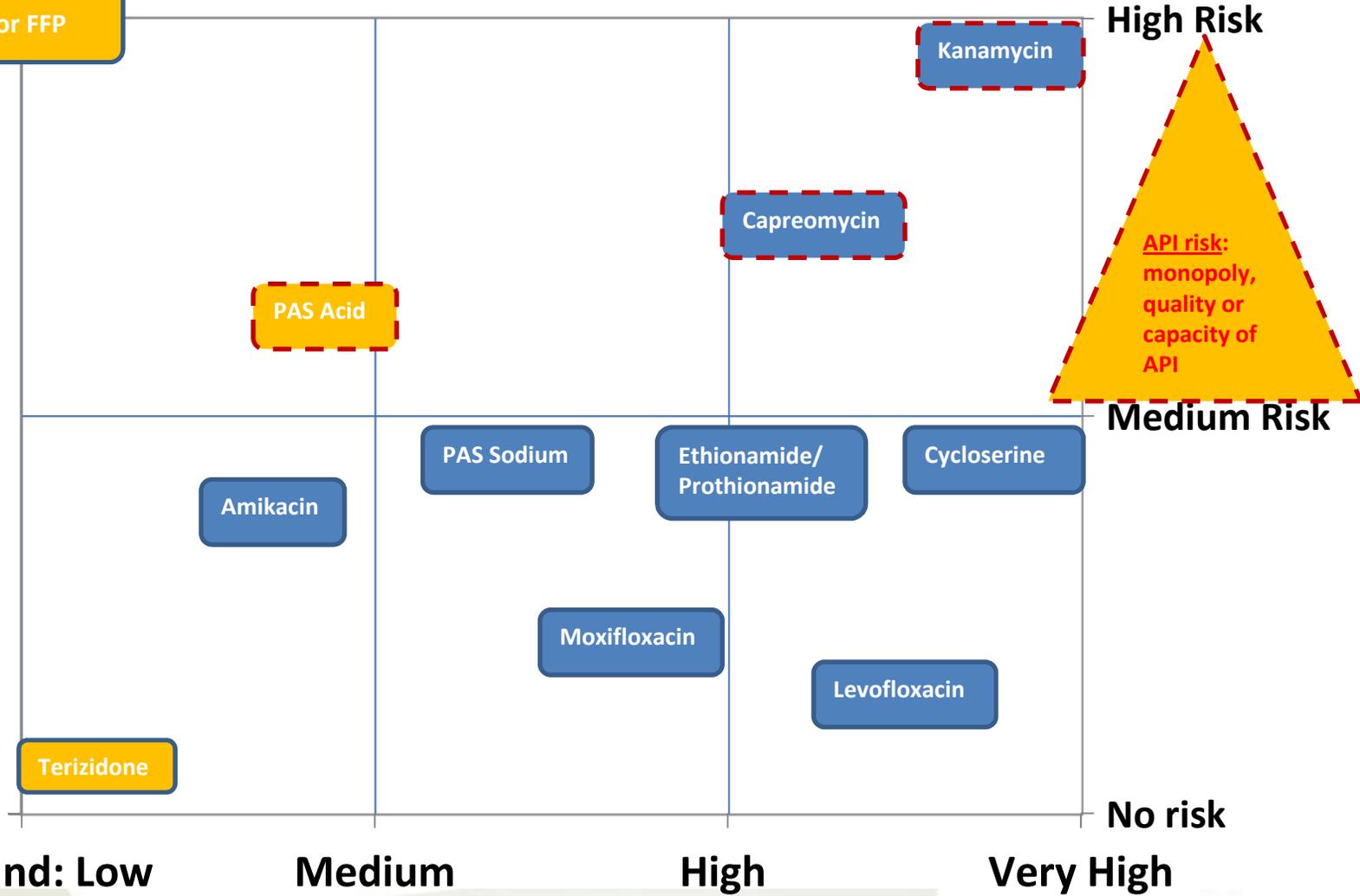
Country for support in 2013	Number of patient treatments ordered in 2013
Guinea	24
Kenya	166
Kyrgyzstan	218
Myanmar	584
<b>Total new patient treatments:</b>	<b>992</b>



# SLD supply vulnerabilities: Risk management approach in a dynamic environment

More than 2 suppliers for each FFP

1 supplier for FFP



**High Risk**

**Medium Risk**

**No risk**

**API risk: monopoly, quality or capacity of API**

Demand: Low

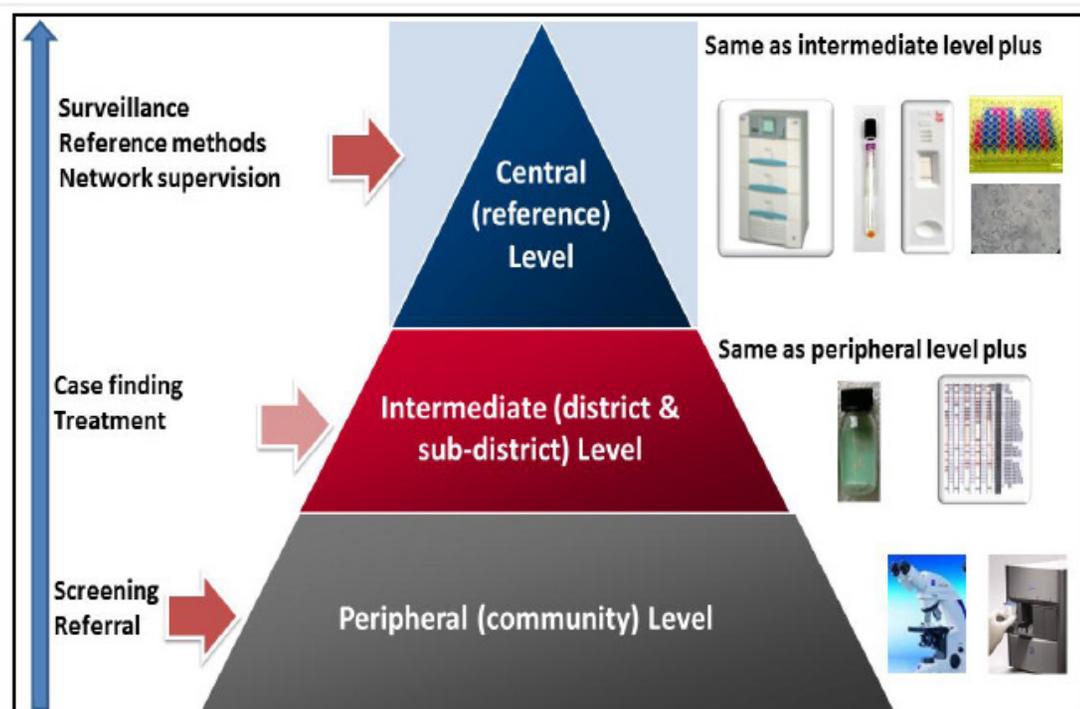
Medium

High

Very High



# Diagnosics Methods available via GDF



## Number of diagnostics delivered 2007 - 2013

← TB on Liquid culture : 696,300 tests  
DST on Liquid Culture : 118,160 tests

← Line Probe Assay: 621,888 tests

← Xpert MTB/RIF: 1,084,360 tests

← Sputum container: 16,105,000 units

Source : [http://www.who.int/tb/publications/tbDiagnostics\\_factsheet.pdf](http://www.who.int/tb/publications/tbDiagnostics_factsheet.pdf)

GDF platform supports key global initiatives like TB REACH / Expand TB / TB Expert in partnerships with GLI , FIND and WHO Global TB Programme

# What is GDF Mandate today?

GDF is more than a traditional procurement mechanism – it is a **one-stop access for provision of medicines and diagnostics** through:

- **Emergency one year grants** - bridge TB program gaps for FLDs
- **Grants for SLDs: under discussion with donors**
- **Direct procurement (DP)** – Any country, TB program, NGO can buy FLDs, SLDs, Diagnostics through GDF
- **Regional support** in procurement and supply chain management



# GDF Strategic Direction and Framework (2013-2016)

**Universal access for quality assured TB medicines and diagnostics for GDF clients**

**Partner Linking**

**Market Shaping**

**Services and Products**

**New TB Tools**

**Product Quality Assurance**

**Capacity Building**

**Evidence from Countries**

**Market Research & Forecasting**



# Rationale for GDF New Strategic Future Direction

- Aim at zero tolerance for stock-outs in countries to re-shape operations
- Continue to further shape the market for more affordable prices with no compromise on the international quality standards for TB drugs
- Incorporate new TB drugs and diagnostics within GDF platform
- Promote innovative tools for forecasting, M&E to countries and leverage communication/collaborative actions with partners for improved planning
- Mobilize and catalyze partners expertise, including in-country technical assistance programs to improve service delivery and data management
- Foster countries shared responsibility, accountability and sustainability for supply chain systems strengthening, regulatory aspects and rational use
- Work closer and focus on country needs and feedback to improve operations



# Key GDF achievements – Operational Strategy & Framework

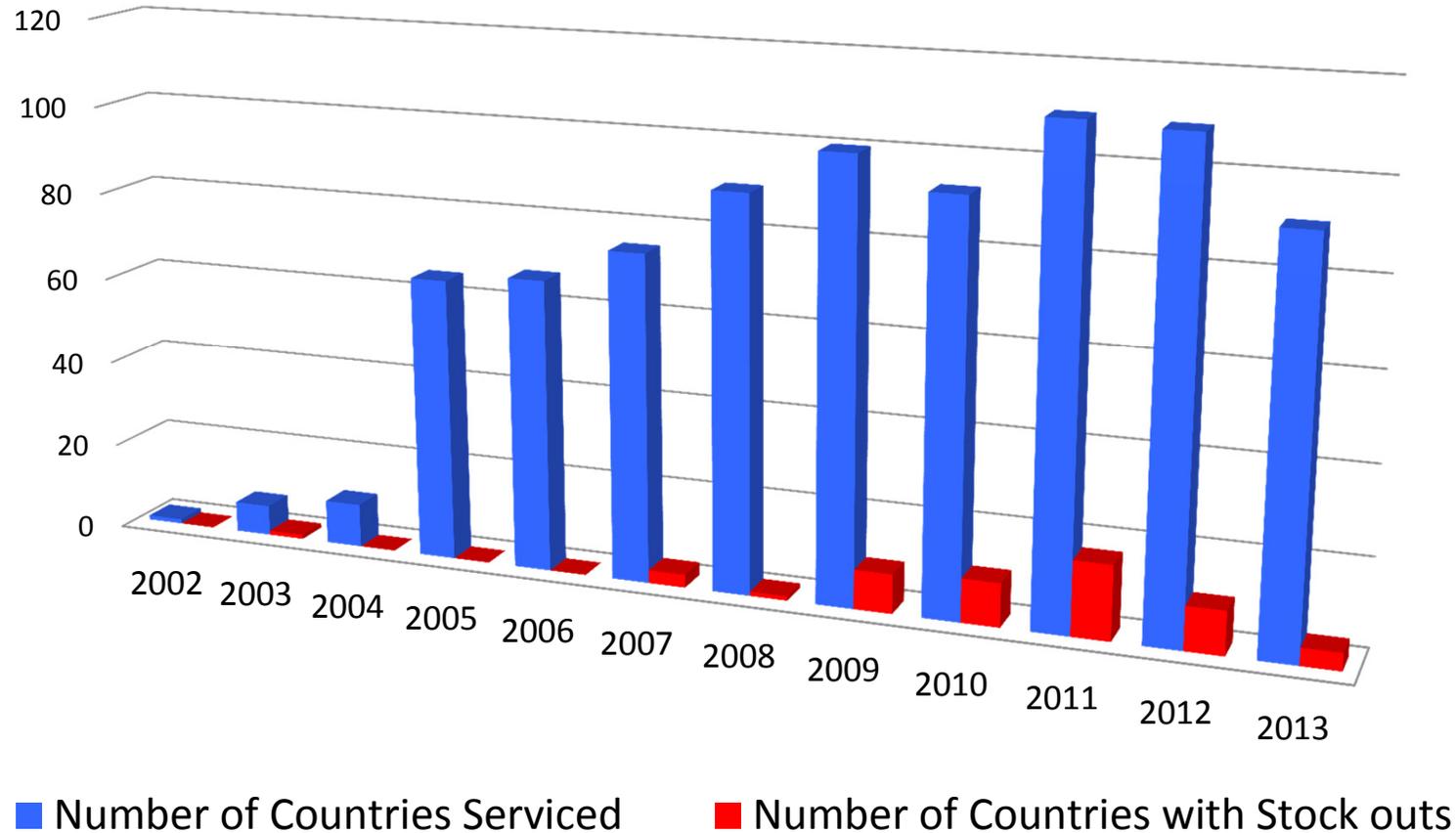
- ❖ Merging of FLDs + SLDs + Diagnostics procurement lines / country
- ❖ UNITAID Board approved GDF cost extension proposal to double the value of current Strategic Rotating Stockpile (+14,5 M USD) => SLDs (including new TB Drugs) + FLDs
- ❖ GFATM Strategic collaboration on Rapid Supply Mechanism + closer working relationships with PSM Teams
- ❖ New Guarantee Fund with USAID implemented to avoid upfront payments
- ❖ Roll-out of new strategic tools like QuanTB + Early Warning Stock Out with partners for improved global forecasting
- ❖ On-going SLDs market review analysis with CHAI => basis for operations re-modelling + Strategic discussions on innovative financing with Gates Foundation



# Strengthening Regional Support

- *Regional Support Officers based in WHO Regional Offices:*
  - *Francophone Africa (Libreville, Gabon) Mr Julien Deschamps*
  - *Eastern Mediterranean Regional Office (Cairo, Egypt) Mr Khaled Khalil*
  - *South East Asia Regional Office (Delhi, India) Ms Caroline Bogren*
  - *European Regional Office: under recruitment*
- *Terms of Reference:*
  - *Direct country support to all GDF clients (1<sup>st</sup> stop)*
  - *Assist in the application for 1<sup>st</sup> line adult and paediatric grants*
  - *Assist in the quantification of 1<sup>st</sup> and 2<sup>nd</sup> line anti-TB drugs for budgeting and ordering*
  - *Facilitate order execution and delivery*
  - *Assist in relieving financial bottlenecks (ie. Fund disbursement)*
  - *Planning and conducting monitoring visits (where possible)*
  - *Data collection for EWS*
  - *Partner coordination in-country*

# Number of Countries Receiving Services from GDF and Number of Stock-outs per Year

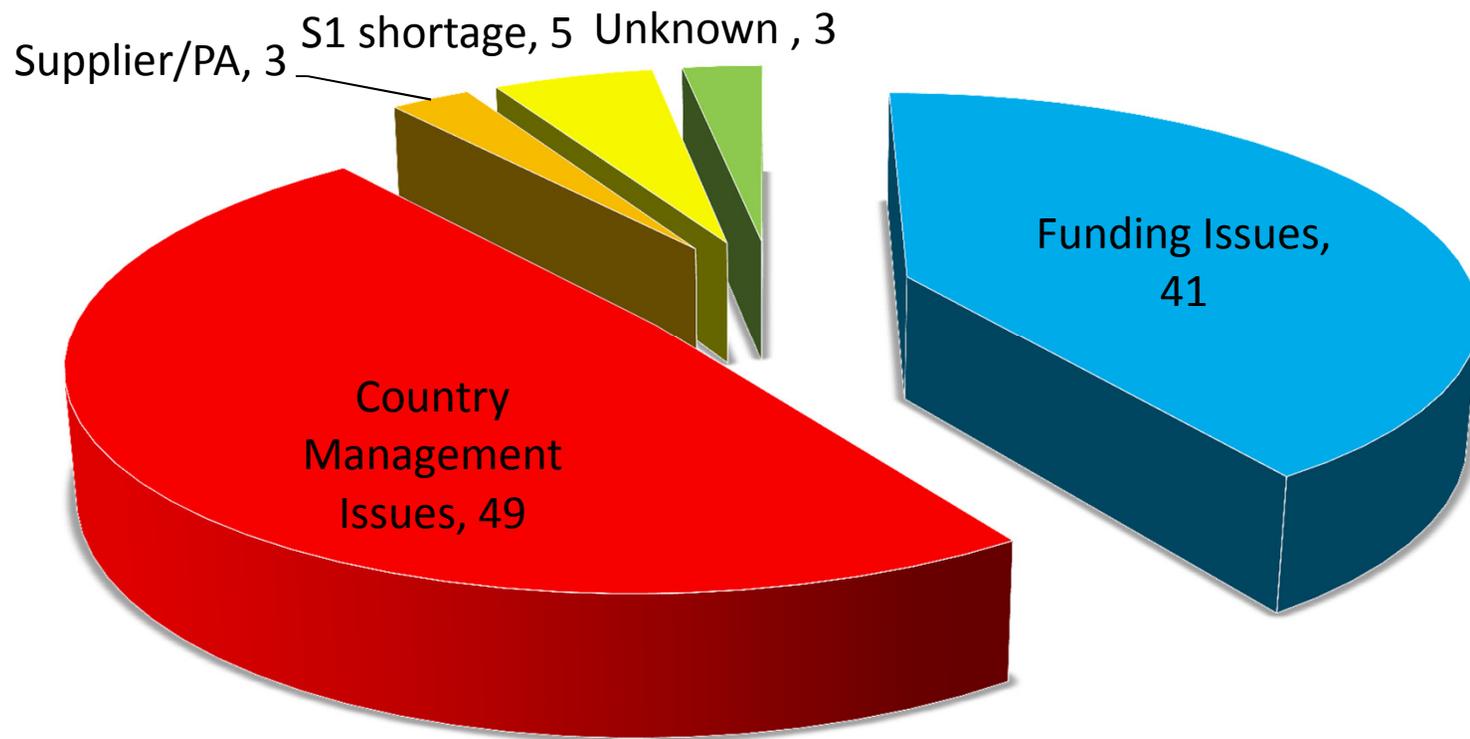


## Stock-outs root causes : Main findings

- From a total of 65 reported stock outs from 2007-2013:
  - 54 were confirmed by different documents
  - 10 were confirmed as Non-stock-outs
  - 1 report was related with laboratory material - no to medicines procurement.

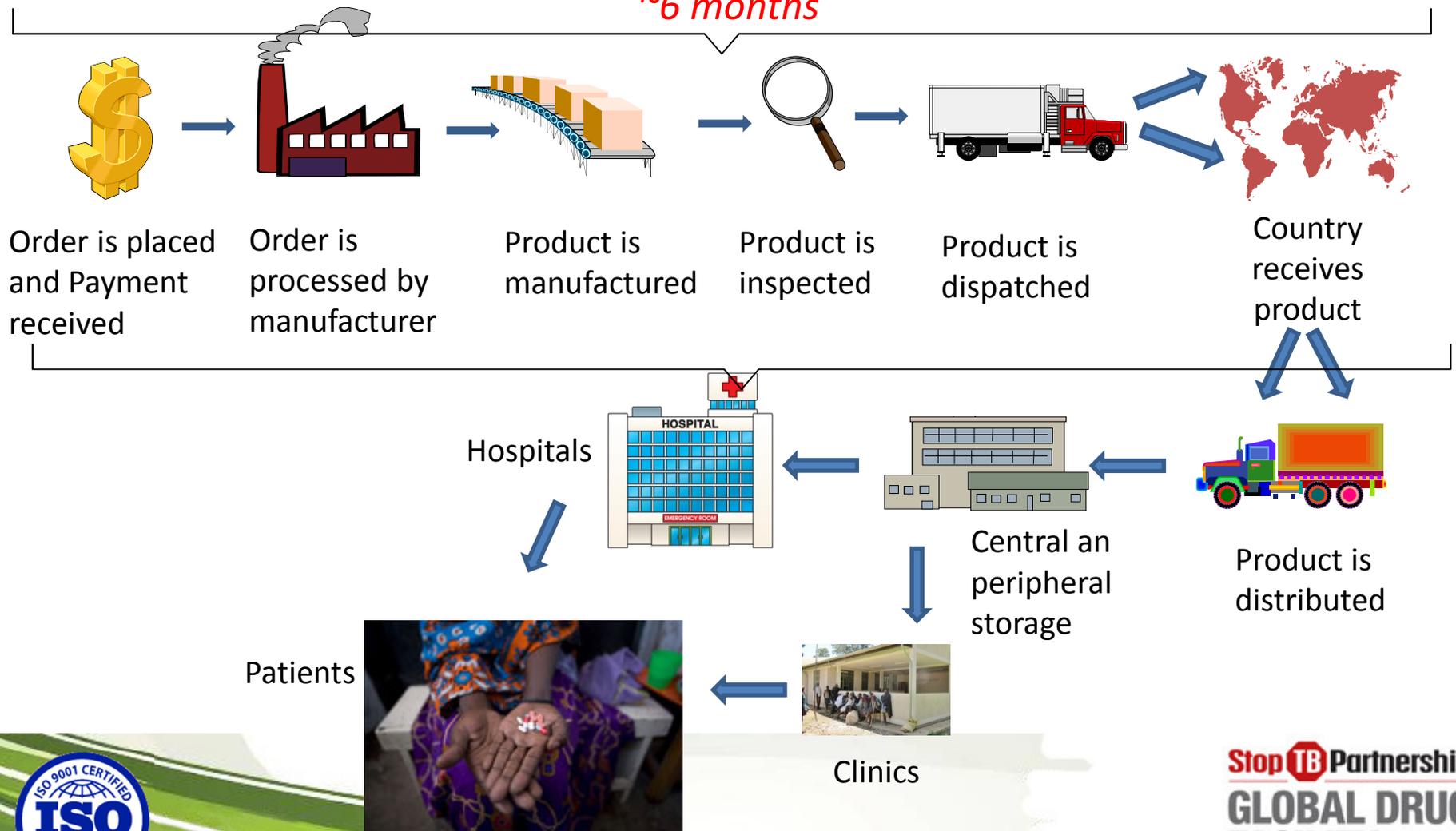


# Countries with Stock-outs per Primary Cause (%)

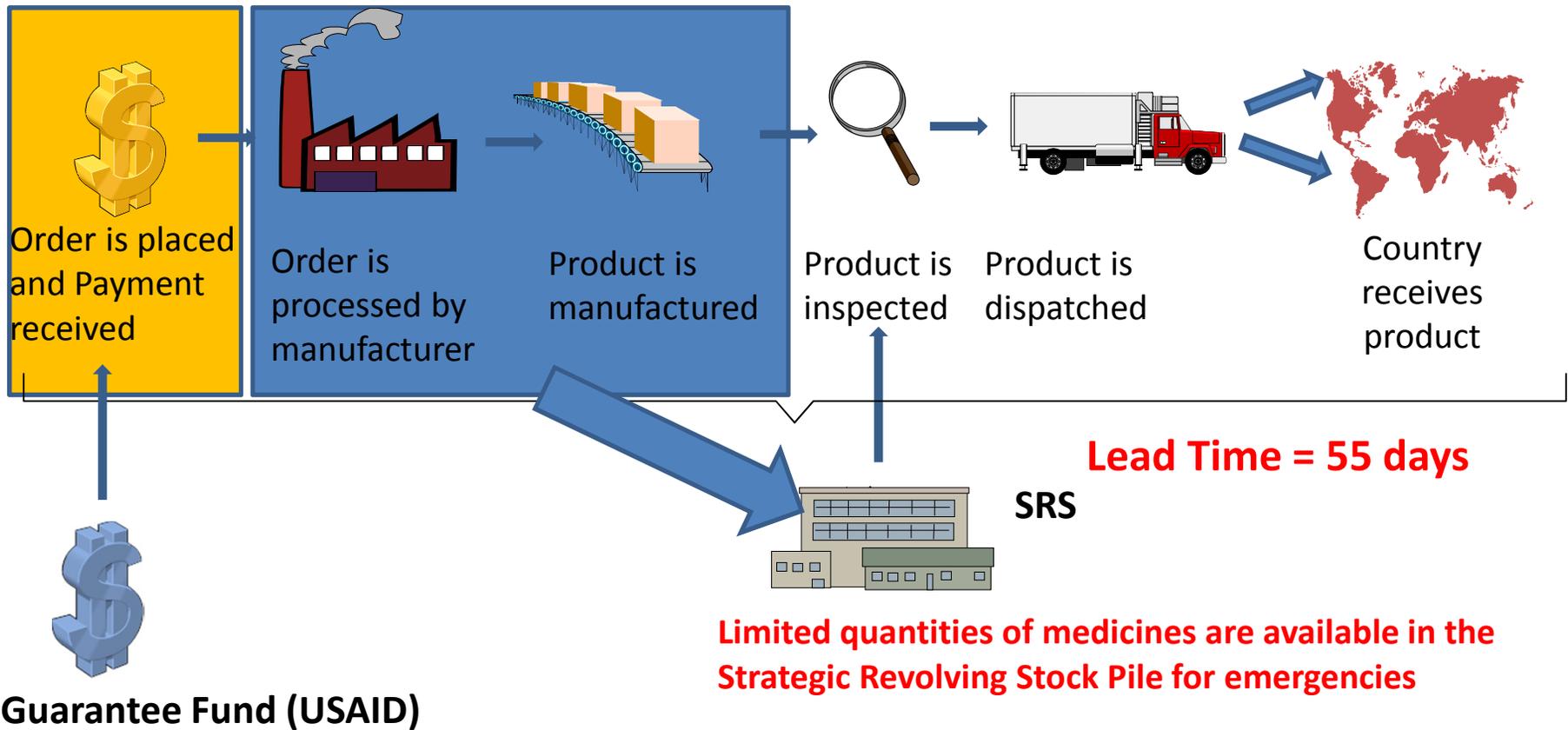


# Current GDF Supply Chain Process

~6 months



# Supply Chain Process with Guarantee Fund and SRS



# Strategic Rotating Stockpile: 2014 update

- New expanded SRS (12 500 patient treatments serves as a baseline), 21.87 million USD worth of products
- Increased amount of injectables
- New: limited quantities of Third Line Drugs and commodities are included in the stockpile
- New: limited quantities of bedaquiline is proposed to be included
- Support to clinical trials / studies with partners (Union...)
- Final Project plan currently undergoing UNITAID clearance / link with the GF Rapid Supply Mechanism



# Discussion



medicines • ij • marcia zoei



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# LIST OF ELIGIBLE SUPPLIERS, SLDs (1)

#	SLDs	# Eligible suppliers, 2011	# Eligible suppliers, 2012	# Eligible suppliers, 2013	# Eligible suppliers, 2014	Manufacturer & QA status
1	Amikacin 500mg/2ml vial	2	2	4	4	Medochemie (SRA) Mylan (SRA) Cipla (WHO PQP) Pharmatex (SRA)
2	Capreomycin 1 g vial	1	1	3	2	Eli Lilly (FDA USA) until 2011 Akorn (FDA, USA) Vianex (SRA)
3	Cycloserine 250mg tablet	3	3	6	7	Aspen (WHO PQP, backup) Chao Centre (FDA USA, backup) Macleods (WHO PQP) Lupin (ERP) Dong-A (WHO PQP) Cipla (ERP) Biocom (WHO PQP, backup)
4	Ethionamide 250mg tablet	1	1	4	4	Macleods (WHO PQP) Cipla (WHO PQP) Lupin (WHO PQP) Microlabs (WHO PQP)
5	Kanamycin 1gr vial	1	2	2	2	Meiji (SRA) Panpharma (SRA)
6	Levofloxacin 250mg tablet	3	3	4	4	Cipla (WHO PQP) Hetero (ERP) Microlabs (WHO PQP) Macleods (ERP*)
7	Levofloxacin 500mg tablet	3	3	4	4	Cipla (WHO PQP) Hetero (WHO PQP) Microlabs (WHO PQP) Macleods (ERP)
8	Moxifloxacin 400mg tablet	2	2	4	5	Bayer (SRA) Cipla (WHO PQP) Hetero (WHO PQP) Macleods (ERP) Sandoz (ERP)
9	Ofloxacin 200mg tablet	1	1	3	4	Cipla (WHO PQP) Microlabs (WHO PQP) Macleods (WHO PQP) Remedica (SRA)

# LIST OF ELIGIBLE SUPPLIERS, SLDs (2)

10	Ofloxacin 400mg tablet	2	2	2	3	Cipla (WHO PQP), Microlabs (WHO PQP) Remedica (SRA)
11	PAS acid granules	3	3	3	3	Jacobus (SRA)
	PAS sodium granules					Macleods (WHO PQP)
	PAS sodium powder					Olainfarm (WHO PQP/SRA)
12	Prothionamide 250mg tablet	1	2	2	3	Fatol (SRA) Microlabs (WHO PQP) Cadila (ERP)
13	Terizidone 250 mg capsule	1	1	1	1	Fatol (SRA)
14	Amoxi/Clavunate 875+125mg tablet	0	0	2	3	Medochemie (SRA) Reig Jofre (SRA) Microlabs (WHO PQP)
15	Amoxi/Clavunate 500+125 mg tablet	0	0	3	4	Remedica (SRA) Medochemie (SRA) Reig Jofre (SRA) Microlabs (WHO PQP)
16	Amoxi/Clavunate 250+125 mg tablet (+2 suppliers for suspension)				3	Remedica (SRA) Medochemie (SRA) Microlabs (WHO PQP)
17	Clarithromycin 500 mg tablet	0	0	2	2	Remedica (SRA) Medochemie (SRA)
18	Clarithromycin 250 mg tablet	0	0	2	2	Remedica (SRA) Medochemie (SRA)
19	Clofazimine 100 mg capsule	0	0	1	1	Novartis through Victoria Pharmacy (SRA)
20	Linezolid 600 mg tablet	0	0	2	2	Pfizer (SRA) Hetero (ERP)
21	Imipenem/Cilastatin 500mg + 500mg injectable, IV (vial/ampoule)	0	0	2	3	Panpharma (SRA) Labatec (SRA) Demo (SRA)

**NOTE: backup supplier - approved, but either cannot produce large volumes and/or does not provide appropriate packaging (i.e. loose product only)**