Improving Access for Quality-Assured TB Medicines + Diagnostics

Update on GDF
New Strategic Direction: Achievements and Perspectives

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Stop TB Partnerships Workshop
Union Conference- Paris - Oct 2013
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 secretariat.

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 2008 added the supply of SLDs, pediatric TB medicines and diagnostics and is a major source for GeneXpert.
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 FLDs to continue for 1 more year to allow for proper phase-out
- Grants for SLDs: under discussion with donors
- Direct procurement (DP) – TB program buys FLDs, SLDs, Diagnostics through GDF
- In-country technical assistance in procurement and supply chain management
A total of 128 different countries received the benefits from the procurement system and the multiple advantages offered by GDF across the years.

Source: GDF OMS Data / Oct 2013
First-line drugs portfolio

- 10 one-year term agreements with suppliers, covering 31 products:
  - 9 Fixed-Doses Combinations, blister & loose
  - 3 paediatric, Fixed-Doses Combinations, blister
  - 5 single dose formulations, blister
  - 2 paediatric single dose formulations, blister
  - 1 injectable, vial
  - 3 medical devices
  - 8 patient kits

- Increased number of suppliers vs 2011, with shelf-life ranging from 2 to 5 years

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<tr>
<th>Products with</th>
<th>No. of products</th>
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<tr>
<td>4 suppliers</td>
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<td>3 suppliers</td>
<td>5</td>
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<tr>
<td>2 suppliers</td>
<td>11</td>
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<td>1 supplier</td>
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Total Patient Treatments Supplied 2001-2013
First Line Drugs

Total Patient Treatments Supplied 2002 - 2013
Second Line Drugs

1. **Standard Diagnostics / Microscopy**
   - Provided to GDF clients using own funding
   - GDF Diagnostic Kits (Microscope, Equipment / Start-Up, Consumables, Sputum Containers)

2. **GeneXpert (Cepheid Inc.)**
   - TB REACH Initiative / GDF, financed by CIDA
   - Rollout to TB REACH Grantees from mid 2011
   - TBXpert Project, UNITAID financed
     Consortium among seven partners incl. GDF 2013 – 2015

   - Support to patients follow-up through conventional diagnostics (Solid and liquid cultures – FLDs-SLDs)

3. **All Diagnostics like Xpert / LPAs and standard to be supplied on a reimbursable basis to GDF clients from 2013**
Value of Orders Placed 2012 (mUSD)

- FLD
- MDR
- New Diag

74
16
58

200 M in 2013 till Oct 2013
GDF order placed value all inclusive – By Product Line
Oct 24, 2013

http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/All+inclusive+values+of+products+ordered+by+Line+and+Country&userid=GDF_ro&password=gdfread1
17 one-year term agreements with suppliers, covering 27 products:

- 5 Fluroquinolones, blister
- 8 Bacteriostatics, blister, strips, sachet, container
- 4 Injectables, vial, ampoule
- 10 Third line drugs, blister and vials.

- Up to 37% price reduction negotiated on Cycloserine
- Up to 27% price reduction on treatment regimens supplied (2013 vs 2012)
- SLD supplier base twice as big as in 2009
- Number of SLD available for supply 3 times higher vs 2009
Update on specific medicines

- Group 5 Medicines now available through:
  - Linezolid
  - Clofazimin
  - Imipinem / cilastatin

- Rifabutin currently being added to GDF catalogue
- Partial regimens now available to countries
Scale-Up of MDR-TB treatment supply with GDF medicines over the years

Report Date: Oct 24, 2013

Note: Method 6 months intensive phase injectables up to 2011, 8 months from 2012
Basic Market Facts: The market outlook has been improving from a supplier perspective

1. Market value is growing rapidly:
   - ~57 million USD in POs in 2010
   - ~76 million USD in POs thus far in 2013

2. Costs per patient course have reduced in recent years
   (sample regimens)

3. # of eligible suppliers has increased
   - From 12 in 2011 to 22 in 2013

Source: GDF & CHAI analysis of SLD market dynamics, based on GDF procurement database – Oct 2013
Key challenges are being looked at to develop a comprehensive understanding of market dynamics and build up new solutions.

1. Country concentration and risk of exit
2. Fragmentation
3. Order predictability
4. Product specific case studies

Source: GDF & CHAI analysis of SLD market dynamics, based on GDF procurement database – Oct 2013
GDF Impact on SLD Dynamics: 2011 vs. 2013 treatment cost comparison / High end regimen

2011/2013 Cost of treatment
12 Cm Pto Cs Mxf PAS / 12 Pto Cs Mfx PAS

TOTAL COST PER PATIENT FOR 24 months:

- 14.5% decrease 2011 USD
- 26.2% decrease 2013 USD

2011 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS / 12 Pto Cs Mfx PAS
2013 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS / 12 Pto Cs Mfx PAS same suppliers than 2011
2013 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS / 12 Pto Cs Mfx PAS best prices
GDF Impact on SLD Dynamics: 2011 vs. 2013 treatment cost comparison / Low end regimen

2011/2013 Cost of treatment
8 Am Eto Cs Lfx/ 16 Eto Cs Lfx

TOTAL COST PER PATIENT FOR 24 months:

- 12.3 %
- 26.7 %

- 2011 USD Drug Breakout for 8 Am Eto Cs Lfx/ 16 Eto Cs Lfx
- 2013 USD Drug Breakout for 8 Am Eto Cs Lfx/ 16 Eto Cs Lfx same suppliers than 2011
- 2013 USD Drug Breakout for 8 Am Eto Cs Lfx/ 16 Eto Cs Lfx best prices
10 key evidence-based messages about GDF during the last decade

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<tr>
<td>1</td>
<td>GDF is the largest supplier of quality assured TB products by value</td>
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<td>2</td>
<td>GDF’s pooling of TB medicines has contributed to reducing treatment costs by 30%</td>
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<td>3</td>
<td>GDF’s strategy to attract multiple suppliers increases production capacity and access</td>
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<td>4</td>
<td>GDF supplies medicines at the lowest fee among peers supporting strategy to charge a fee for DP services</td>
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<td>5</td>
<td>GDF reduced lead-time by 22% for &quot;order placement-to-delivery in country&quot; since 2007</td>
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<tr>
<td>6</td>
<td>GDF produces Key Performance Indicators (KPIs) from real transaction data collected by the order management system</td>
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<td>7</td>
<td>GDF clients and donors are safe with proven quality assured TB medicines (QA policies harmonized with GF &amp; WHO -2010)</td>
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<tr>
<td>8</td>
<td>GDF is also about providing in country Technical Assistance</td>
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<tr>
<td>9</td>
<td>Today market research data show that GDF suppliers can double production on short notice for SLDs</td>
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<tr>
<td>10</td>
<td>As a ISO 9001 certified organization, GDF offers a platform for providing feedback on its services</td>
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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
• Build on lessons learnt from the past and regular market dynamics research
• 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
GDF Strategic Direction and Framework (2013-2016)

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

- Partner Linking
- Services and Products
- Product Quality Assurance
- Evidence from Countries
- Market Shaping
- New TB Tools
- Capacity Building
- Market Research & Forecasting
Current TB Supply Chain Process

GDF procurement process is only a small share of the overall procurement system.

NTP Procurement & Funding planning
12 to 24 months
75%

NTP Procurement planning

NTP Funding plan & request

NTP calculates theoretical drugs requirements

NTP assess stocks & shelf life

NTP surveillance data collection: enrollment rates, etc

If Drugs in stock + immediate payment

GDF supply chain = 1/4
From 1 to 12 months
25%

If late payment, delayed PO => production
MDR-TB Current TB Supply Chain Process

1. Cost Extension submitted to Unitaid Oct 2013 to double the SRS in anticipation of growing demand
2. SRS Operating model under changes
3. Bedaquiline to be included in SRS

Limited quantities of medicines are available in the Strategic Revolving Stock Pile for emergencies

Lead Time = 55 days
New Tools and Monitoring Model for Countries

Translate the key data of # of months of stock on hand into the country classification:

• Reaching 8 months or Less than 8 months : Red alert (urgent imminent risk of shortage: immediate action taking for new drugs supply)

• Between 8 and 12 months: orange alert (action taking is required to ensure next supply will meet current needs, and revising stock levels is urgently needed)

• 12 months or more supply : green light situation - smooth supply guaranteed for more than 1 year
Strategic interventions & new tools to avoid stockouts

• On-going discussion for a flexible Procurement Fund and Strategic Stockpile for FLDs + SLDs + Diagnostics with TGF and donors

• New Forecasting Tools + Early Warning Stockout System: GDF and its partners are developing new forecasting systems to quantify needs for the coming years and these systems are continuously being improved upon, esp. for SLDs

• Promoting M&E systems inter-operability for better data exchange and SLDs consumption at country and global level

• Information sharing and in country partners leveraging: closer monitoring model of in country supply chains information being implementing with RSOs, and partners collaboration (WHO, rGLCs, Donors funded programs like TB CARE, Technical Agencies, NGOs, Regional Association, Private sector...
Expected outcomes of GDF’s future strategy direction if supported by donors and partners

GDF will...

- Offer **quicker response time** for medicines/diagnostics
- Reshape operations, work on new financial strategies (service fee)
- Be able to place orders in **advance of payment** by NTPs
  - Stockpile and flexible fund will jointly promote the quick and reliable handling of offers
- Have direct access to a **sufficient number of QA suppliers** for all GDF products and will pro-actively perform shared forecasting based on reliable information from GDF clients
- Offer even **better prices for SLDs** and will better impact the market by procuring and delivering low-cost high quality products
- Contribute to **better availability of APIs + longer shelf life for FPP + climatic zone 4 compliance (FLDs)**
- Collect and connect **critical data** to disseminate to stakeholders on pending stock-out situations
- Catalyze more **synergetic interventions with partners** to unblock supply barriers and avoid in country stock-outs
Discussion

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jkeravec@msh.org
Main GDF Achievements since 2012

1. Focus on services delivery & Operations => Results

- >M US$ 200 since 2013 (vs M US$ 151 in 2012)
- New ITBs for SLD
- TRC 28 finalized / TRC 29 planned
- X 2,4 # suppliers / 2009
- X 3,2 # products / 2009
- SLD treatment price reduced up to 27% (2012 vs 2013)
- Lead times decreasing
- Support to TBREACH, TBEXPERT and EXPANDTB

2. Moving ahead with the new strategic framework implementation

- Closer country monitoring & support (New RSOs + New quantification tools)
- Merging FLDs/SLDs/Diag.
- Concept note on the global strategic stockpile + flexible procurement fund + discussions engaged with donors
- New organogram /TORs for new staff
- ISO 9001 status maintained
- New ordering system being developed

3. Focus on data analysis / evidences from countries to better adapt GDF model

- Consultancy on stock-outs root causes – on-going
- Consultancy on SSP+FPF (final stage of selection)
- TA activities back on board
- Stock-outs Early-warning System + e&M Health Project
- New Communication Strategy with partners and civil society

4. Aligning forces & partners for anticipating future demand / supply landscape

- Discussion for rational introduction models for new TB drugs (bedaquiline / Delamanid)
- Stakeholders Meeting suppliers & donors& partners
- Strategic meetings with WB – PAHO on harmonization and capacity building / landscape
- Linking GF portfolios
- Managers/grant Mngt
- Cooperation’ s agreements being concluded: with CHAI (SLDs), TB Alliance and STPHI (paediatrics )

Remaining Challenges

- Paediatric Grants at risk (Unitaid $ ending 2013)
- FLDs Grants / Emergency Gaps at risk
- SLDs grants ending (Unitaid $ ending 2013)
- GDF staffing to support new framework
- Roll-out of new tools in countries
- In country supply chain issues still a barrier
- Current GF procurement reform
- Strategic Stockpile and Flexible procurement fund urgently needed
- SLDs still fragmented and fragile market
- Innovative actions required on demand + supply side
- GeneXpert /Diagnostic monitoring is key for accurate forecast