Improving Access for Quality-Assured TB Medicines + Diagnostics

Update on GDF Model & Activities

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GDF Manager
Stop TB Partnership Forum—Union Congress
October 27th, 2014 - Barcelona
1. What is the Global Drug Facility?

2. Key achievements to date & how is GDF model evolving?

3. What are the current TB supply chain vulnerabilities & challenges?

4. Discussion / Q&A
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 Mission and Evolving Mandate

Mission
Ensure timely access to quality assured, affordable TB drugs and diagnostics and contribute to the development of sustainable TB drug management capacity for countries in need.

GDF Mandate
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 - bridging TB program gaps for FLDs or
• 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) – Any country, TB program, NGO can buy FLDs, SLDs, Diagnostics through GDF
• In-country technical assistance in procurement and supply chain management

⇒ Pooled procurement platform with market shaping impact
⇒ Alignment with GFATM New Funding Model > ensuring drugs needs are in concept notes with accurate quantification
⇒ Increased focus on data collection / management for strengthening overall supply chain
GDF Strategic Objectives

1. **Save lives** by ensuring an uninterrupted supply of quality-assured, affordable anti-TB drugs and diagnostics to population in need.

2. **Strengthen national drug supply management systems** and sustainable procurement capacity by providing tailored technical assistance, innovative tools to countries/organizations in need and enhance partners’ engagement for technical and financial support.

3. **Contribute to TB commodities market shaping** by linking strategic interventions on the demand and supply sides with stakeholders/partners, focusing on market analysis, supply security, suppliers engagement, affordable and sustainable prices, innovation and new products introduction/uptake by countries.

4. **Maximize impact and value for money** by enhancing efficiency/effectiveness of operations focusing on quality of services and clients/partners feedback.
133 countries benefited from GDF procurement / bundled mechanism

- > 23,7 M Adult FLDs & 1,3 M pediatric treatments & 131,559 SLDs patient treatments delivered since inception (overarching goal of 25 M patient treatments reached in 2014)

- > 1 billion USD of TB commodities procured since 2002
- Market shares in 2013 (public sector) around:
  - 25% for FLDs (all notified cases)
  - 34% for SLDs (reported on treatment)
  - 59% for paediatrics (all notified cases)

- GDF model & processes restructured
  - FLDs / SLDs / Diagnostics procurement lines merged
  - + friendly Direct Procurement platform (88% activity)
  - greater SLDs supply security (26 products – 12 suppliers => more than x 2 since 2011)
  - new financial flexibilities
  - new tools and TA model for improved forecast
  - on-going new stockpile policies
**Country Support**
- One-stop mechanism
- Improved quantification at country & regional level
- Capacity building to strengthen in-country supply chain system
- TA coordination with partners and countries
- Prevent stock out

**Market Shaping**
- Visibility of Demand
- Global Forecasting
- Market landscape analysis
- Diversifying Suppliers and product portfolio
- Price reduction
- Supporting new drugs and diagnostics introduction

**Changes in GDF operations to maximize impact**
- Evolve from Grant model toward Direct Procurement model
- Foster closer/earlier interaction for GF NFM Order placement optimization by using advance ordering
- GDF strategic stockpile to contemplate FLDs + SLDs
- Financial flexibility
- Quality Management

**Donors, partners & NGOs in countries**
- Order
- Treatment regimen
- Stock level
- Quantification data
- Budget

**Value for Money**
- Uninterrupted supply of quality-assured TB commodities at affordable price to clients
- First-line drugs
- Second-line drugs
- Diagnostics

**Suppliers**
- Manufacturers
  - (for active pharmaceutical ingredients/finished pharmaceutical products/diagnostics)
- Consolidated order
- Stock-based production
- Information flow
  - Fund
  - Medicaes and diagnostics
  - GDF tools
  - Partners’ tools

**Striving suppliers engagement**
- Monitor key supply chain vulnerabilities with stakeholders
- Change from production to order to production to stock
- Increasing stockpile capacity to meet production challenges
- Products: Unified multilingual packaging/ longer shelf life
SLD treatments supplied as of October 23, 2014

Source: GDF OMS Consulted 24 Sept 2014
2011/2014 Change in Regiment costs: High end regimen cheapest suppliers
12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS

December 2011 EXW manufacturers prices

December 2012 EXW best prices EXW manufacturers prices - 32.2%

2014 best manufacturers prices EXW
<table>
<thead>
<tr>
<th>Country</th>
<th>Main regimen</th>
<th>Costs 2012</th>
<th>Costs 2013</th>
<th>Costs 2014</th>
<th>Trend</th>
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<tbody>
<tr>
<td>Azerbaijan</td>
<td>12 Z-Ami-Lfx-Eto-Cs-PAS / 12 Z-Lfx-Eto-Cs-PAS</td>
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<td>Bangladesh</td>
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<td>Georgia</td>
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<td>12 Z-Cm-Lfx-Pto-Cs-PAS / 12 Z-Lfx-Pto-Cs-PAS</td>
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<td>India</td>
<td>6 Km-Lfx-Eto-Cs-Z/E / 18 Lfx-Eto-Cs-E</td>
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<td>12 Z-Am-Pto-Cs-PAS-LFx / 12 Z-Pto-Cs-PAS-LFx</td>
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<td>2,181</td>
<td>1,972</td>
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</tbody>
</table>

**H/M/L regimen costs definition:**

- **USD**
  - **High costs**: 3501-6000
  - **Medium costs**: 2001-3500
  - **Low costs**: 1400-2000
GDF is adjusting its operating model to address key supply chain challenges & new drugs introduction

Shift from one-shot technical assistance
- to support countries with SCM needs:
  - new Tools adapted for drugs supply monitoring & for new drugs / regimens introduction
  - Systems Interfaces for better demand consolidation and easier data management (accuracy / validation / online submission)

Strategies focused on GDF clients
- GF + other donors supported countries (ie. USAID bilat. agreements)
- DP from countries transitioning from donors support to domestic funding
- More flexible financial platform

Focus on key demand and supply challenges
- Market Research & Monitoring
- Country & Global forecast strategies
- Strive Suppliers engagement
- Production to stock model / SRS
- Supporting Regional Registration Mechanisms
DATA COLLECTION
- QuanTB
- Country Monitoring Mission
- GeneXpert/TB Reach/ TB Xpert
- OMS
- Information from partners and donors

DATA ACCURACY VERIFICATION
- Data screening for typo mistakes

FINAL FORECAST VALIDATION
- Vs Orders in pipeline
- Vs GF Enrollment data
- Vs Historical data and trends
- Vs other GDF available data

PRIMARY FORECAST VALIDATION
- Country CSOs makes data qualitative validations
- Contact country in case of additional questions

FORECAST UPDATE IN STOCKPILE TOOL
- Country parameter and forecast input
- Output of future supply plan
- Arbitration and outlook sharing internal and external stakeholders

Demand Forecasting Process Cycle

Country Master File and Country Profile Update

ISO 9001 CERTIFIED
Progress on Forecast: 
Towards an holistic approach

Based on GDF order management system & data on quantities / products supplied:
⇒ New forecasting tool developed to support GDF operations & strategies
⇒ Impact on NTP planning, management of orders, suppliers’ relations and market shaping

⇒ Additional data sources required to be fed into the forecasting tool regularly
⇒ Data Validation Processes
Forecast Visualization 1
Country Level and Global View
Forecast Visualization 2
Country Level and Global View
Discussion

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