Current challenges in DM

Dr Kaspars Lunte,
Team Leader MDR-TB supply, GDF

December 2012
2nd Africa Regional Conference on management of TB medicines
What is the Global Drug Facility?
An initiative of the Stop TB Partnership (2001), hosted in WHO and managed by the Stop TB Partnership secretariat

The mandate of the Global Drug Facility (GDF) includes
• Expanding access to quality-assured first-line drugs (FLDs) and diagnostics’ and second-line drugs (SLDs) for GLC approved projects
• Contributing to the development of sustainable procurement and supply management for countries in need

GDF began supplying first-line drugs in 2001, and in 2008 added regular supply of second-line drugs, pediatric TB medicines and diagnostics, and is major source for GeneXpert today.
GDF Facts

- GDF operates without a fee, therefore it is primarily a donor-supported organization
- GDF is an agency for placing planned orders
- Has successfully catalyzed rapid DOTS expansion
- Has developed the market for fixed-dose combinations and patient kits
- Substantially increased the number of quality-assured multi-drug resistant (MDR)-TB second-line drugs (SLDs) available for procurement through GDF from 11 in 2008, to 32 in end 2011
- Conducts international bidding regularly to achieve competitive, transparent, sustainable for SLDs, pricing
- Has aligned quality assurance policy with the Global Fund
- Provides technical assistance in drug management during periodic in-country monitoring visits
GDF is the Largest Supplier of Anti-TB Products on the Public Market

In just over 10 years GDF procured
• 22 million FLD patient treatments
• 92,398 SLD patient treatments (x 4 in 4 years)
• Orders with a total value of 685 million US dollars (USD)
GDF Expansion Since 2001

- FLD grants: 2001
- FDL DP: 2004
- 2nd line DP: 2005
- Diagnostic kits: 2006
- Pediatric grants: 2007
- SLDs: 2008
- TB Reach Expand TB: 2010
- GeneXpert: 2011
- Strategic Rotating Stockpile
Business Volume 2011 (USD, ex works)

New Diagnostics
6,405,667 USD

GeneXpert
6,489,297 USD

SLD
85,291,452 USD

FLD
56,511,227 USD
TB Drug Supply Chain Management Cycle

- **Annual**
- **Identify problems**
- **Under/overstocking**
- **Recommendations**
- **MSH review**
  - 4–6 weeks
- **Procurement Cycle**
  - **Initiation Stage** (NTP)
    - **Quantification**
    - **Procurement plan**
    - **Funding**
    - 1–2 years
  - **Procurement** (GDF)
    - **Retrospective analysis**
    - **Annual bidding for long-term agreements**
    - 2–3 months
  - **Production** (GDF/Suppliers)
    - **Place purchase order on receipt of funded requisition**
    - **Manufacturing period, including ordering of APIs**
    - 10–12 weeks
- **Monitoring Missions** (GDF/NTP)
  - **Logistics** (GDF/NTP)
    - **Pre-shipment inspection**
    - **Batch testing**
    - **Freight forwarding**
    - **Clearance**
    - **Medical storage depot**
    - 6–10 weeks
- **Review**
Technical Assistance in Drug Management

- In-country technical assistance missions conducted annually for all grants and some direct procurements. Currently this is free of charge to direct procurement clients; reports shared with the GF FPMs where applicable.
- TA team consists of two experts: TB program and procurement and supply management (PSM).
- Regional support officers being recruited for AFRO and EMRO (Q4 2012).
- Regional support officers to provide individualized assistance to countries for order calculation, placement, and in-country drug management training.

### Number of country missions

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>52</td>
</tr>
<tr>
<td>2011</td>
<td>44</td>
</tr>
<tr>
<td>2012 (estimated)</td>
<td>~65</td>
</tr>
<tr>
<td>Longer TA provided ad hoc</td>
<td></td>
</tr>
</tbody>
</table>
GDF Added Value

• Pooled procurement for GDF customers: GDF is able to aggregate demand for anti-TB products for more timely and simplified procurement.

• Pricing: GDF conducts international bidding for Procurement Agent (PA) services and for medicines (via PA) regularly to achieve competitive, transparent pricing. New SLD bidding due November 19, 2012.

• Quantification and forecasting: GDF assists client countries in identifying their drug needs

• Quality assurance policy aligned with the Global Fund

• Technical assistance and monitoring: Periodic monitoring of GDF clients and identification of their PSM challenges
### Where GDF works

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Number of Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFRO</td>
<td>39</td>
</tr>
<tr>
<td>EMRO</td>
<td>17</td>
</tr>
<tr>
<td>AMRO</td>
<td>5</td>
</tr>
<tr>
<td>SEARO</td>
<td>10</td>
</tr>
<tr>
<td>WPRO</td>
<td>13</td>
</tr>
<tr>
<td>EURO</td>
<td>17</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>101</strong></td>
</tr>
</tbody>
</table>

All are low income countries if receiving grants (GDF criteria) and low to low-middle income countries if NTP orders by DP.
How NTPs Improve Through GDF TA

A total of 1047 recommendations were made to NTPs during monitoring missions in 24 countries analyzed (2001-2010)

Source: MSH/SPS/GDF Report
Financing the Order

Financing delays undermine effective aggregation of demand because manufacturers cannot plan their production and the delays reduce response time to emergencies and disrupt procurement planning cycle.

**DELAYS IN DISBURSEMENTS OF FUNDS COULD BE DUE TO:**

- Agreements with the donors have not yet been finalized and signed
- Documentation required by the authority releasing the funds is not completed
- Funds were not secured and they are not available at the time of the price quote confirmation
- Budget available not sufficient to cover the costs of the order
GDF: Future Directions

• Early warning system for stock-outs headed by SIAPS in pilot phase in several African countries. The system will capture key data and information which define stock data, treatment plans, and medicines used.

• GDF uses forecasting systems to quantify needs for the coming years and these systems are continuously being improved. The information is provided to manufacturers to help them plan in terms of production capacity.

• Smaller HQ staff, regional support officers in the regions
Request for Quotation Challenges

• Prices: 2011 new price bid resulted in seeing some FLDs prices increase, SLDs prices remained constant. New bidding in November 2012.
• Buffer stock and shelf life: GDF recommends calculating a buffer stock but to consider shelf life of the products (most products are 24 months); either order 50% buffer stock or if 100% buffer, client should request staggered delivery of drugs to maximize shelf life.
• Cost efficiency: limit air freight to save costs
• Quotations for first-line drugs are only valid for 90 days and for SLDs, 60 days. Client should clear any deviations in their PSM plan with the GF FPM prior to a request for quotation. This will save weeks in quotation revisions (i.e., freight estimates take longest to calculate)
Manufacturing Challenges

- No stockpile available for first-line drugs (production takes 8-12 weeks); strategic rotating stockpile available for certain second-line drugs for emergencies
- Active pharmaceutical ingredient not always available, especially for rifampicin
- Batch requirements for pediatric and some FLDs and third-line drugs for MDR-TB (manufacturers will wait until they receive enough orders for minimum batch quantities before production in started)
- Manufacturers will not always communicate production delays to GDF to allow for planning and arranging alternative options
Technical Assistance: Monitoring Missions

• Objective
  – Validate stock levels
  – Monitor GDF terms and conditions (grants and direct procurement)
  – Assess overstocking and stock-outs
  – Assist with quantification of medicine needs
  – Highlight problems in medicine management

• Key Observations
  – Gaps in PSM staff capacity/training
  – Lack of standard operating procedures
  – Poor information management (manual versus computerized)
  – Inadequate planning for medicine needs/funding
  – Reliance on donor funding and associated volatility
  – Political commitment to change is not always evident
Technical Assistance: Quantification Tool

Developed in partnership with MSH for FLDs and with GLC for SLDs

• Objective
  – Quantify countries’ annual needs for procurement planning and budgeting purposes
  – Determine quantities of stock on hand
  – Determine trigger dates for reordering
  – Adjust buffer stock percentage based on projected demand and available budget

• Observations
  – The tool has been in use for few years and is helpful for both national tuberculosis programs and GDF.
  – NTP responsible staff members need to be trained on the tool to make best use of it at the country level.
  – To use the tool, the program needs to have a clear picture on the treatment plans (enrollment data), treatment regimens, and available stock in-country.
Technical assistance: Drug Management Workshops

With our partners, GDF organizes drug management workshops focused on helping countries identify their PSM bottlenecks and develop an improvement plan.

Curriculum includes—

- Selection
- Rational medicine use
- Quantification
- Quality assurance
- Procurement
- Inventory control
- Hosting country site visit to relevant sites (Central National Tuberculosis Program, central warehouse, national regulatory authority, health centers)