Tuberculosis Market-Shaping Strategy: Overview, Updates & Priority Issues from Stop TB’s Global Drug Facility

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17 October, 2017
Montreux, Switzerland
Session Outline

1. GDF Overview
2. TB Medicines Market Evolution
3. Update on GDF 2015-2020 Strategy
4. Priority Issues & Challenges in TB Markets
5. GDF Next Steps, Conclusion
1. GDF Overview

- Established in 2001
- Initiative within the Stop TB Partnership
- Hosted by UNOPS
- Original mandate: pooled procurement mechanism to facilitate access to QA FLDs; subsequent expansion of products & services
- Clients: Governments with domestic funds, Global Fund PRs, NTPs w/other donor grants
- Web-based order system
- Funded largely by USAID
- ISO 9001 certified in 2008
GDF Procurement of TB Products: Historical Timeline

- Grants (USAID, Canada, UNITAID, etc.) were key to catalyzing TB medicines & diagnostics markets
- Global Fund funding was key to market maturation, scale-up, and expanded access
GDF Procurement Evolution: to Improve Efficiency & Shape Markets

New operating models and tools to continuously improve GDF’s performance, optimize market efficiency

✓ End 2015, switch from contracted procurement agent to **GDF in-house procurement & supply TB Diagnostics**
✓ 2017 launch of **new SRS for SLDs** to dramatically decrease delivery lead time & smoothen production cycles
✓ Establishment of **flexible procurement fund** - bridge procurement costs when funds not readily available

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<table>
<thead>
<tr>
<th>Year</th>
<th>Event 1</th>
<th>Event 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>FLDs &amp; SLDs</td>
<td>Contracted procurement agent</td>
</tr>
<tr>
<td>2010</td>
<td>SLDs</td>
<td>SRS</td>
</tr>
<tr>
<td>2015</td>
<td>Contracted procurement agent</td>
<td>New SRS</td>
</tr>
<tr>
<td>2016</td>
<td>In-house procurement &amp; supply</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>Flexible Procurement Fund (FPF)</td>
<td></td>
</tr>
</tbody>
</table>
2. Tuberculosis Medicines Markets Evolution

The power of GDF pooled procurement & market interventions (1)

SLDs: Significant increase in the number of GDF quality-assured suppliers & formulations

- 2009: start of GDF dedicated SLD sourcing
- July 2010: GDF QA policy harmonized with The Global Fund and partners

![Diagram showing increase in suppliers and formulations from 2007 to 2017](image)

- 2007: 5 suppliers
- 2009: 10 suppliers
- 2011: 18 suppliers, 24 formulations
- 2013: 20 suppliers
- 2017: 24 suppliers, 117 formulations

94.5% average supplier performance (Jan-June 2017)
The power of GDF pooled procurement & market interventions (2)

Dramatic decrease in GDF SLDs prices for MDR-TB regimens

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

$1,946.82
$1,666.53
$1,232.16
$1,099.26

- 43.5 %

2012 EXW manufacturers prices  2014 weighted average prices
2015 weighted average prices  2016 average prices
The power of GDF pooled procurement & market interventions (3)

Lower prices means more SLDs purchased with less money

Value*/volume of SLDs orders (as 30 Sept 2017)

*All costs included

26.2 M savings
GDF Facts and figures (2001 through 30 Sep, 2017):

2001 through 30 Sep, 2017:

- Supplied medicines to 138 countries
  - 28 Mn adult FLD treatments
  - 277,100 adult SLD treatments
  - 1.9Mn pedi FLD treatments
- Supplied diagnostics to 86 countries
  - $183Mn worth of diagnostics

Jan – Sep 2017:

- $270Mn TB products ordered
- $195 Mn TB products delivered
  - 1.5Mn adult FLD treatments; 92% OTIF
  - 37,800 adult SLD treatments; 83% OTIF
  - SRS lead time* 57 days

*from order placed date to actual arrival date
3. GDF Strategy 2015-2020

**Strategic Objective 1 – Apply Market Intelligence**
- Improved market coordination, global policy
- Improved supply security
- Lowest possible sustainable prices
- Facilitated production planning

**Strategic Objective 2 - Strengthen Procurement & Global Supply Systems**
- Quality-assured products
- Shorter lead times
- Improved On Time In Full (OTIF)
- Improved forecasts

**Strategic Objective 3 - Facilitate Uptake of New TB Tools**
- Expedited uptake of new TB regimens, medicines, formulations and diagnostics
SO1: Apply Market Intelligence: GDF Role in Market Coordination (1)

Creation of the **TB Procurement & Market-Shaping Action Team (TPMAT)**

- Composed of procurers, donors, implementers, international organizations & civil society
- Aim to address existing challenges of TB medicines and diagnostics markets in a coordinated manner
- Focus areas: diagnostics, new medicines, harmonization & prioritization

**Interventions to Date**

- WHO PQ Annual Fee Waivers for At-Risk TB Medicines – Done
- Policy Guidance to Accelerate Uptake of New Medicines/Regimens Introduction
  - GF Guidance on Medicines Policy Wastage (pedi FDCs, STRs) - done
  - WHO Guidance on Importance of Pedi FDCs – done
  - Global Fund ERP EOI Prioritization – Awaiting approval & implementation

**Future areas of work**

- WHO Guidelines, PQ EOI, EML, GF ERP EOI, GDF Catalog harmonization
- TB Medicines Formulary to consolidate market around fewest # formulations
- Revision to WHO 75% Remaining Shelf Life Guidance
- Global Fund Sustainability, Co-Financing, and Transition m&e, policy development
SO1: Apply Market Intelligence: GDF Role in Market Coordination (2)

- Active participation in DR-TB STAT
  - Monthly procurement updates; link to programmatic challenges w/ introduction
- **GDF – Global Fund MoU** for procurement & market shaping
- **GDF–UNDP MoU** for SLD procurement
- **GDF–MSF MoU** for delamanid procurement
- **GDF–FIND–MSF–UNDP negotiations** w/BD (expand access pricing for MGIT diagnostic)
- GDF participation in HIV POC Working Group
- Ongoing coordination around missions and TA
- GDF Support to new UNITAID TB projects
  - EGPAF pedi TB
  - Aurum latent TB
### Accelerated uptake of STR with GDF (and other partner) assistance in priority countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Original Transition Date</th>
<th>Accelerated Transition Date</th>
<th>Value of Old stock to be removed (USD)</th>
<th>Value of New Drugs ordered 2017/2018 (USD)</th>
<th>Operational cost saving</th>
<th>GF status</th>
<th>Number of patients benefited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>Dec 2017 (all at once)</td>
<td>All eligibles in Oct/Nov 2017</td>
<td>143,000</td>
<td>68,000</td>
<td>500,000</td>
<td>GF approved NTP to implement</td>
<td>200</td>
</tr>
<tr>
<td>Indonesia</td>
<td>July 2017 to Dec 2018 (phased approach)</td>
<td>All eligibles in July 2017</td>
<td>2,610,052</td>
<td>NTP has enough stock</td>
<td>Not calculated</td>
<td>GF approved NTP to implement</td>
<td>7,888</td>
</tr>
<tr>
<td>Malawi</td>
<td>June 2018</td>
<td>Q1 2018</td>
<td>0</td>
<td>31,312</td>
<td>Not calculated</td>
<td>GF approved NTP to implement</td>
<td>42</td>
</tr>
</tbody>
</table>
## GDF 2016 Sales of PQ products Compared to Annual PQ Fees

<table>
<thead>
<tr>
<th>Annual GDF Sales</th>
<th>Number of Products</th>
<th>% of GDF Portfolio</th>
<th>WHO PQ Annual Fee</th>
<th>Estimated 2016 Profit (Assuming 10% Profit x 2016 Sales)</th>
<th>Annual WHO PQ Fee as % of 2016 Estimated Annual Profit</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$20,000</td>
<td>6</td>
<td>11%</td>
<td>$20,000</td>
<td>$2,000</td>
<td>Fee exceeds profit</td>
</tr>
<tr>
<td>$20,000-$100,000</td>
<td>6</td>
<td>11%</td>
<td>$20,000</td>
<td>$2,000-$10,000</td>
<td>Fee exceeds profit</td>
</tr>
<tr>
<td>$100,001-$200,000</td>
<td>9</td>
<td>17%</td>
<td>$20,000</td>
<td>$10,000-$20,000</td>
<td>Fee exceeds or = profit</td>
</tr>
<tr>
<td>$200,001-$500,000</td>
<td>7</td>
<td>13%</td>
<td>$20,000</td>
<td>$20,000-$50,000</td>
<td>41-99%</td>
</tr>
<tr>
<td>$500,001-$1 Mn</td>
<td>5</td>
<td>9%</td>
<td>$20,000</td>
<td>$50,000-$100,000</td>
<td>21-40%</td>
</tr>
<tr>
<td>$1,000,001 - $3 Mn</td>
<td>11</td>
<td>20%</td>
<td>$20,000</td>
<td>$100,000-$300,000</td>
<td>8-20%</td>
</tr>
<tr>
<td>$3,000,001 - $5 Mn</td>
<td>1</td>
<td>2%</td>
<td>$20,000</td>
<td>$300,000-$500,000</td>
<td>5-7%</td>
</tr>
<tr>
<td>$5,000,001- $10 Mn</td>
<td>7</td>
<td>13%</td>
<td>$20,000</td>
<td>$500,000-$1Mn</td>
<td>2-4%</td>
</tr>
<tr>
<td>&gt;$10 Mn</td>
<td>1</td>
<td>2%</td>
<td>$20,000</td>
<td>&gt;$1Mn</td>
<td>&lt;2%</td>
</tr>
</tbody>
</table>

For **21 (39%)** of products, fee = or exceeds profit

For **23 (42%)** of products, fee accts large % of profit

46 (81%) products at risk
## SO2: Strengthen Procurement & Global Supply Systems

Cost-savings of GDF Interventions with country orders (q1-q3 2017)

<table>
<thead>
<tr>
<th>Type of Intervention</th>
<th>Action</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order cancellation (waste averted)</td>
<td>Proactive analysis of country data and order adjustment</td>
<td>Saved US$ 3,232,648</td>
</tr>
<tr>
<td>Order reallocation (waste averted)</td>
<td>Orders that cannot be cancelled were relocated to other clients</td>
<td>Saved US$ 1,264,548</td>
</tr>
<tr>
<td>Order postponement (waste averted)</td>
<td>Proactive analysis of country data and order rescheduling</td>
<td>Saved US$ 2,572,868</td>
</tr>
<tr>
<td>Pre-order modification of quantity</td>
<td>Proactive analysis of quantification data and quantity adjustments to</td>
<td>Avoided treatment</td>
</tr>
<tr>
<td>(stock-outs averted)</td>
<td>prevent potential stock outs</td>
<td>interruption of 1607 DR-TB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cases</td>
</tr>
</tbody>
</table>

>$7 Million in Savings from Jan to Sep 2017
The Case for a Strategic Rotating Stockpile for SLDs

Value of SLDs delivered from 2013 to 2016 (Except India)

Unpredictable purchase Patterns;

High peaks and severe lows complicate production & supply planning

Results in order-specific Production & long lead times
The **new SRS**: an innovative logistic solution

GDF has created a **new Strategic Rotating Stockpile (SRS)** to supply SLDs to countries with the aim to dramatically decrease delivery lead time and smooth supplier’s production cycles.

The new SRS is an innovative logistic solution that aims to:

- **Improve GDF service to clients:**
  - Decrease lead time by serving country orders from SRS (target <3 months); 57 days in 2017
  - Flexibility of supply in case of overstocking or stock-out situations (postponement/cancellation of orders or emergency orders)

- **Improve GDF forecasts/order planning to be a client of choice for suppliers:**
  - Provide more reliable forecasts
  - Improve the GDF order cycle by a better scheduling of orders to suppliers
  - Adapt replenishment orders & supplier’s production capacity to smooth peaks in the GDF ordering

New IT systems/tools developed to operationalize new SRS: replenishment tool & dynamic batch allocation tool
SO3: Facilitate Uptake of New Tools

Bedaquiline: Procurement Status (donations & purchases)

Bedaquiline delivered to 55 countries; 10 addtl countries with orders in process;
GDF support aDSM, adherence WHO Guidelines; GDF overs transport costs of BDQ donation when ordered separately

<table>
<thead>
<tr>
<th></th>
<th>2015</th>
<th>2016</th>
<th>Jan-Sep 2017</th>
<th>Total 2015-Sep 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatments* in early stage of order process</td>
<td></td>
<td></td>
<td>3,098</td>
<td>3,098</td>
</tr>
<tr>
<td>Treatments* in late stage of order process</td>
<td></td>
<td></td>
<td>6,139</td>
<td>6,139</td>
</tr>
<tr>
<td>Treatments* Delivered</td>
<td>1,001</td>
<td>1,474</td>
<td>4,303</td>
<td>6,778</td>
</tr>
<tr>
<td>Total</td>
<td>1,001</td>
<td>1,474</td>
<td>13,540</td>
<td>16,015</td>
</tr>
</tbody>
</table>

In-process:
- China
- Ecuador
- Iraq
- Kosovo
- Malawi
- Nepal
- Rwanda
- Sierra Leone
- Somalia
- Zambia

Delivered:
- Afghanistan
- Armenia
- Azerbaijan
- Bangladesh
- Belarus
- Benin
- Bolivia
- Burkina Faso
- Cambodia
- Cameroon
- Chile
- Cote d’Ivoire
- DPRK
- DRC
- Djibouti
- Dom Republic
- Eq. Guinea
- Ethiopia
- Georgia
- Guinea
- Haiti
- India
- Indonesia
- Jordan
- Kazakhstan
- Kenya
- Kyrgyzstan
- Lebanon
- Lesotho
- Liberia
- Mali
- Mongolia
- Mozambique
- Myanmar
- Namibia
- Niger
- Nigeria
- Pakistan
- Papua New Guinea
- Peru
- Philippines
- Rep. Moldova
- Senegal
- Sri Lanka
- Sudan
- Swaziland
- Tajikistan
- Thailand
- Turkmenistan
- Uganda
- Ukraine
- Un. Rep Tanzania
- Uzbekistan
- Viet Nam
- Zimbabwe

In 2017, India accounts for 3,500 treatments (660 delivered & 2,840 in process)
Delamanid Procurement Status

Delamanid delivered to 26 countries; 14 addtl countries w/ orders in process; Support aDSM, adherence WHO Guidelines

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>Jan-Sep 2017</th>
<th>Total 2016 – Sep 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatments* in early stage of order process</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatments* in late stage of order process</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatments* Delivered</td>
<td>620</td>
<td>970</td>
<td>1,590</td>
</tr>
<tr>
<td>Total</td>
<td>620</td>
<td>3,250</td>
<td>3,870</td>
</tr>
</tbody>
</table>

Would not have been possible w/o SRS (many orders <5 tx)

MSF EndTB accounts for ~50% orders in 2016, ~30% in 2017

Delivered:
- Afghanistan
- Armenia
- Bangladesh
- Belarus
- Cameroon
- Cote d'Ivoire
- DPRK
- Dom Republic
- Ethiopia
- Georgia
- India
- Jordan
- Kazakhstan
- Kenya
- Kyrgyzstan
- Mali
- Morocco
- Mozambique
- Myanmar
- Nigeria
- Papua New Guinea
- Peru
- Russia
- South Africa
- Sri Lanka
- Swaziland

In-process:
- Azerbaijan
- DRC
- Indoneisa
- Malawi
- Nigeria
- Pakistan
- Philippines
- Rep. Moldova
- Rwanda
- Sierra Leone
- Turkmenistan
- Un. Rep Tanzania
- Uzbekistan
- Zimbabwe
# Uptake of STRs with GDF (and other partner) assistance in priority countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
<th>Timeline/Plan</th>
<th>Country</th>
<th>Status</th>
<th>Timeline/Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>Plan</td>
<td>Q1 2018</td>
<td>Nigeria</td>
<td>Started</td>
<td>Q2 2017</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>Started</td>
<td>April 2017</td>
<td>Pakistan</td>
<td>Plan</td>
<td>Q1 2018</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Plan</td>
<td>Nov 2017</td>
<td>Philippines</td>
<td>Started</td>
<td>July 2015 (trial) /Q1 2017 (scale-up)</td>
</tr>
<tr>
<td>DR Congo</td>
<td>Started</td>
<td>2013-2015, 2016 (scale-up)</td>
<td>South Sudan</td>
<td>Started</td>
<td>Q2 2017</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Plan</td>
<td>Q1 2018</td>
<td>Tajikistan</td>
<td>Started</td>
<td>Q2 2017</td>
</tr>
<tr>
<td>India</td>
<td>Plan</td>
<td>Jan 2018</td>
<td>Tanzania</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Started</td>
<td>Sept 2017</td>
<td>Uganda</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Kazakhstan</td>
<td>Plan</td>
<td>Q4 2017</td>
<td>Ukraine</td>
<td>Plan</td>
<td>Q3 2018</td>
</tr>
<tr>
<td>Kenya</td>
<td>Started</td>
<td>Q3 2017</td>
<td>Uzbekistan</td>
<td>Plan</td>
<td>Q1 2018</td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>Started</td>
<td>Q1 2017</td>
<td>Vietnam</td>
<td>Started</td>
<td>April 2016</td>
</tr>
<tr>
<td>Malawi</td>
<td>Plan</td>
<td>Q1-2 2018</td>
<td>Zambia</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Plan</td>
<td>2016 (trial)/Q4 2017 (scale up)</td>
<td>Zimbabwe</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Plan</td>
<td>Oct 2017</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Out of the Tier 1 countries (n=25):
- 10 countries have implemented as of 30-Sept-2017
- 8 countries will be implementing by the end of 2017
- 7 countries will be implementing by June 2018
### Countries that have Ordered New Paediatric FDCs from GDF

|-------------|------|-------|-------------|---------|-----------|----------|-------------------------|------|------|-------|--------------|------|-----|--------------|----------|---------|-------|----------|---------|-------|----------------|---------|----------|-------------|----------|----------|--------|---------|----------|--------|--------|----------------|---------|----------|----------|------|-------|---------|

**68 Countries have ordered ~500,000 treatment courses* of new paediatric FDCs as of end Aug 2017**

- 59 countries have had FDCs delivered (~410,000 treatments); 9 countries in ordering process

**Practically no pedi FDC procurement outside of GDF**

*Treatment course estimated for children in the third weight band [3 tablets daily] with 2 months of intensive phase and 4 months continuation phase*
GDF outcomes on diagnostic orders over the years (2):

Significant increase of Xpert MTB/RIF Cartridges ordered by GDF

- 2015 and 2016 actual procurement: 6.2 million
- 2017 forecasted procurement: 6.9 million
- Rest of world: +27 to 53%
- GDF-supplied NTPs: +53%
- India (via GDF): +190%
- South Africa: 0%

GDF now largest single purchaser of Xpert

2017 data: South Africa NHLS, GDF data (India, 42 other countries), NTPs from Kenya, Philippines; estimated 27-53% growth for remaining 77 countries

Inadequate forecasting, quantification, order management

• **Aspirational forecasts**
  • Forecasts in concept notes sometimes aspirational; set to meet unrealistic treatment targets
  • If orders placed against over-ambitious targets, result is over-ordering
  • End-year, end-grant disbursement pressure can also lead to over-ordering
  • Over-ordering often leads to requests for postponements & cancellations

• **Inaccurate forecasts**
  • Result in under- over-ordering
  • Methods/Numbers don’t match across CN, PSM, GDF mission quantification, Orders
  • New DR-TB drugs, shorter regimens complicating quantification
    • Need eligibility estimates
    • Need access to enrollment plans & actual enrollment (e.g., BDQ experience)
Global Fund Sustainability, Transition, and Co-Financing Policy

What the 2016 Policy includes:
• Requires all countries progressively absorb the costs of key program components, including procurement of essential drugs and commodities

What the 2016 Policy doesn’t include:
• Explicit goal to ensure markets created by Global Fund are sustained
• Risk management plan to protect markets and access
• Clear m&e of procurement practices & outcomes

• Implementation observations to date:
• Guidance differs country to country
• “Bottom-up” approach not connected to a “top-down” market strategy
• Many countries advised to first absorb smaller cost products- such as pediatric TB medicines
  • Approach runs counter to a market-shaping approach which would aim to keep procurement of low-volume medicines centralized
GDF Observations of National Tenders w/ Co-financing, Transition

As countries co-finance or transition, national laws, rules & regulations dictate procurement practices

Observed outcomes on national procurement:

- **Protracted tendering and contracting** processes
- **Failed tenders**: no bids submitted, bid prices too high, service terms unacceptable
- **Delays** in allocation of government funds to pay which delays ordering & deliveries
- **Poor service**: distributors, agents, suppliers fail to meet delivery times & volumes
- **Lack of clarity on roles & payor**: customs clearance, import duties, in-country transport
- **Inability to access concessional pricing** for certain products (Xpert MTB/RIF Cartridges)
- **Increased prices** charged by global & local suppliers/distributors

- Countries pop in and out of the GDF/International QA market over time
  - Analyses to date show no clear trends
  - Order a product from GDF once or twice, go away, then order again years later
  - Unknown why - perhaps addressing some of the problems above? Others?

Result in shortages, stockouts
## Observations on WHAT countries buy: Will NTPs Revert to Pre-GF Practices? (Meds)

<table>
<thead>
<tr>
<th>Pre-Global Fund</th>
<th>Global Fund</th>
<th>Co-Financing/Transition</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td>Continue using FDCs</td>
</tr>
<tr>
<td>Multiple, single tablets and injections</td>
<td>Fixed-dose combinations</td>
<td>Or, Go back to multiple tablets, irrational regimens</td>
</tr>
<tr>
<td>Not optimized, not user-friendly</td>
<td>Optimized, user-friendly</td>
<td></td>
</tr>
<tr>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
<td>Continue to use Quality-Assured Products</td>
</tr>
<tr>
<td>Unknown quality status</td>
<td>Quality-assured products</td>
<td>Or, Revert to products of unknown quality</td>
</tr>
<tr>
<td><img src="image5.png" alt="Image" /></td>
<td><img src="image6.png" alt="Image" /></td>
<td>Continue to use optimized regimens at low prices via some type of pooled procurement</td>
</tr>
<tr>
<td>Expensive second line treatment (&gt;$5000 per treatment course)</td>
<td>Large Price decreases ($800 for shorter MDR regimens)</td>
<td>Or, Pay higher prices as a single buyer</td>
</tr>
</tbody>
</table>
## Observations on WHAT countries buy: Will NTPs Revert to Pre-GF Practices? (Dx)

<table>
<thead>
<tr>
<th>Pre-GLOBAL FUND</th>
<th>DURING GLOBAL FUND</th>
<th>CO-FINANCING/TRANSITION</th>
</tr>
</thead>
</table>
| **Solid culture TB diagnosis & DST** | **Automated liquid culture TB diagnosis & DST (MGIT)** | • Countries may reduce amount of liquid culture performed, reverting to solid culture for testing of patient groups of lesser priority  
• National/regional distributors of Becton Dickinson sometimes significantly mark-up prices |
| • Slower, less sensitive  
• Inexpensive, materials sourced locally | • Faster, more sensitive  
• Expensive, sole source, reliable provider  
• (Becton Dickinson) | |
| **Microscopy** | **Xpert MTB/RIF** | • Countries may revert to microscopy, or reduce amount Xpert performed  
• Countries may not be able to access concessional prices when national regulations require payment in local currency upon delivery; national distributors known to mark-up 50%-800% |
| • Low sensitivity  
• Does not provide information on drug resistance  
• US$ 1-2 / test, sourced locally | • High sensitivity  
• Provides information on drug (rifampicin) resistance  
• US$ 9.98/test, sole source provider (Danaher/Cepheid), USA offering concessional prices when paid in US$ upfront | |
GeneXpert service and maintenance: background

- Cepheid’s standard warranty is widely considered by TB stakeholders to be inadequate & overpriced
  - Does not cover in-country travel for module swapping, repairs
  - Refurbished modules do not arrive in country in a timely manner
  - Warranty cost of US$ 2,898 / year
  - Many countries are not buying the warranty, resulting in even more machine downtime

- In selected countries (including South Africa, Pakistan, Uganda, Kenya), Cepheid or their distributor has proposed cartridge surcharges for “enhanced” or “comprehensive” maintenance, as a replacement for warranties
  - Services offered vary but generally include in-country travel for swapping, repairs, maintenance
  - Terms and conditions of proposed contracts are vague
  - No reporting that would allow for monitoring of performance of service provider
  - Surcharge prices are not clearly based on cartridge volumes or subject to annual revision
  - Included in Concept Notes under a separate funding line from machine & cartridge procurement
GeneXpert service and maintenance: proposed path forward

- GDF and MSF developed model Service Level Agreement (SLA)
  - Shared with and supported by TB and HIV stakeholders (POC Consortium)
  - Model SLA includes a comprehensive list of clearly described minimum services, terms and conditions (countries may add additional activities as desired)
  - Model SLA includes standard reporting requirements that would allow for monitoring of performance of service providers by country, procurement agent and GF
- Targets have been proposed that can be used to refine payments or introduce penalties
5. GDF Next Steps

• **SO1: Apply Market Intelligence (via TPMAT)**
  - Harmonization: WHO Guidelines, WHO EML, WHO PQ EOI, GF ERP EOI, GDF Catalog harmonization
  - Consolidation: TB Formulary
  - Revision of WHO Guidance on 75% Remaining Shelf Life
  - Systematic analyses, modeling procurement with co-financing, transition; policy guidance, as needed

• **SO2: Strengthen Procurement & Global Supply Systems**
  - Increase procurement frequency of NTPs to 2x/year; increase # orders through SRS
  - Implement new data warehouse & ERP system – on-line dashboard; link to Wambo
  - Explore new SCM activities, roles; explore track & trace package options
  - Improve Cepheid terms on service & maintenance
  - Work with GF on improved quantification, order planning; potential joint negotiations

• **SO3: Facilitate the Uptake of New TB Tools**
  - **Ongoing:** pedi FDCs, BDQ, DLM – implications of new VLs, STRs, Xpert
  - **New:** LAM diagnostic; portable X-ray; rifapentine; new pedi MDR-TB formulations
Conclusions

• The Global Fund & other donors have together made incredible progress to build TB medicines markets that have undoubtedly contributed to increased access to quality TB care

• GDF’s pooled procurement, Strategic Rotating Stockpile (SRS) for SLDs, and other org’s interventions have facilitated price reduction, dramatically lower lead times, development of optimized formulations, emergency response, and new product introduction

• Despite this progress, most TB markets are fragile at best. Many are failed markets
  • For many TB medicines, there is actually an absence of market – remove supports propping the “market” & the products will likely disappear

• Dynamic global policy envt. Many threats to TB markets that will decrease volumes, increase costs, decrease availability
  • Changes in financing & procurement, new WHO guidances, PQ fees, natl registration fees and other policies
  • Proactive stakeholder engagement & risk management must be done before new policies are implemented
  • If TB medicines volumes decrease, unclear how long the QA market can be held together

• Global community – including donors need to decide if sustaining QA markets created by GF (and others) is a priority
  • If yes, market sustainability must be an explicit goal of all policies & practices to ensure long-term access to quality-assured, optimized, affordable products
Thank you

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