Challenges in the TB medicines market and sustainable pricing: getting the balance right

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Presentation Outline

1. What is GDF?
2. GDF collaborative approaches/solutions with suppliers and partners to improve supply security and ensure sustainable affordable prices of quality-assured medicines
3. GDF key achievements
4. GDF key challenges
1. What is GDF?
Stop TB Partnership and its Global Drug Facility (GDF)

- GDF was established in 2001
- Part of the United Nations
- Within the Stop TB Partnership which is hosted by United Nations Office for Project Services (UNOPS)
- Largely funded by USAID

Original mandate:
Pooled procurement mechanism, to facilitate access to quality-assured first-line drugs. Then, subsequent expansion of products & services.

Today:
One-stop shop for TB products
GDF Catalogs

GDF Diagnostics Catalog

GDF Medicines Catalog

- Medicines categorized by:
  - Adult and pediatric formulations
  - Single and fixed-dose combination formulations
  - WHO indication for each product

Catalogs designed to promote rational use

http://stoptb.org/gdf/drugsupply/product_catalog.asp
Technical information notes / order tool

Diagnostic Order Tool

Technical Information Notes:
- LAM test
- LAMP test
- Microscopy kits
- Xpert Ultra test
designed to promote rational use of diagnostics

Facilitates order planning by providing product specifications and shipment logistics information, and automating costing

http://stoptb.org/gdf/drugsupply/product_catalog.asp
GDF’s Geographic Coverage

- There are no “GDF Countries”: **ALL Countries** are **eligible** to procure from GDF, in line with national regulations, including private sector.
- GDF now providing TB medicines to high-income countries.
- GDF service to all countries consistent with its commitment to equitable access and with the 2018 UN Political Declaration on TB:

  “We, Heads of State and Government and representatives of States and Governments […] (15) **encourage all nations** to use the Stop TB Partnership/Global Drug Facility.”

- **GDF Clients**: Governments (National TB Programs, Central medical stores...), Global Fund principal recipients, UN agencies (UNDP, WHO, UNICEF, PAHO...), bilateral agencies (USAID, Canada, Japan...), NGOs (MSF, PIH...), UNITAID projects, Research centers for clinical trials...

$US 236 million*

of TB products delivered in 2018 to

118 countries

GDF client base in

143 countries

* $US 179 million for medicines, $US 57 million for diagnostics
GDF strategic objectives 2015-2020

- Apply Market Intelligence and Coordinate Partners
- Strengthen Country Procurement & Global Supply Systems
- Facilitate Uptake of New TB Tools

GDF is much more than a procurement mechanism
GDF Organization

- Headquarters in Geneva at Global Health Campus
- 38 staff plus consultants
  - 28 staff in Geneva
  - 10 regional staff across the world
  - Consultant roster(s)
- Organized into 3 teams
  - Strategy/Policy
  - Demand
  - Supply

Manager - Demand

Country Supply
Country Supply Officers (CSOs)

Demand and Technical Assistance
Regional Technical Advisors (RTAs)
Consultant Roster

Manager - Supply

Procurement
- Sourcing
- Quality assurance
- Diagnostics
- SRS
- ISO 9001

Business Intel.
- IT & Business intelligence
- Data Management

Chief

Strategy/Policy
- Medicines
- Diagnostics
- Knowledge Mgt
2. GDF collaborative approaches/solutions with suppliers and partners to improve supply security and ensure sustainable affordable prices of quality-assured medicines
GDF procurement strategy

• GDF only procures TB medicines that are WHO prequalified, SRA approved or ERP approved and recommended by WHO Global TB program.
• The objectives of the GDF procurement strategy are:
  ➢ To maintain enough suppliers in the market by understanding and supporting suppliers’ interests and by encouraging new suppliers to enter the market;
  ➢ To ensure affordable and competitive pricing through competitive, fair and transparent tenders, and by minimizing supplier production costs through improved GDF procurement planning;
  ➢ To encourage supplier to increase production capacity by improving demand visibility through improved GDF forecasts;
  ➢ To limit the risk of expirations and write-offs by encouraging suppliers to extend product shelf life (to 60 months where possible);
  ➢ To reduce supply chain risks by encouraging suppliers to register their products in countries.

Collaborative and coordinated efforts between GDF, suppliers and partners
GDF Operational Model

- **End-to-End oversight by GDF** of the supply chain of TB products

- **Bundled services**: procurement and supply of TB products along with the provision of technical assistance to countries on forecasting and order planning, reducing the risks of stock-outs and expiries, introducing the new medicines, regimens and diagnostics

- **Strategic procurement and innovative logistics solutions for TB products performed**
  - With its contracted procurement agent (IDA Foundation) for medicines
  - In-house for diagnostics

- **Global, regional, national engagement on policy, advocacy** to identify & address barriers that slow down access to TB products
Market Stewardship: TB Medicines Dashboard (1)

- Identify areas of divergence across contributing institutions (WHO Global TB program, WHO PQP, GF ERP and GDF)

- Develop a roadmap of actions needed to improve alignment and efficiency

http://stoptb.org/gdf/medicinesdashboard/
GDF Launchpad: GDF Pediatric DR-TB Initiative

GDF launched in 2018 an initiative to expedite introduction of new formulations in collaboration with key partners

The initiative has taken a three-pronged approach to facilitate introduction:

• **at country level**, support programmes to ensure alignment with current international normative guidance, including the use of new medicines and provide financial support for initial procurement (Grants);

• **at global level**, coordinate procurement to align demand with supply

• **develop approaches to raise awareness** of these new formulations among caregivers, clinicians and programmes

The Pediatric DR-TB Initiative is only possible thanks to the support provided by USAID and the Government of Japan

In less than 15 months, 56 countries had access to new pediatric DR-TB formulations
In 2019, 77% of SLDs order lines have been supplied by GDF to countries via its SRS.

What is the added value of GDF SRS for suppliers?

- GDF has reduced the total number of Purchase Orders (PO) placed with suppliers by 55% with the use of the SRS*
- One PO to replenish the SRS serves multiple country orders (1 SRS PO is replacing an average of 6.4 B2B** POs)

- Decreased number of administrative documents (POs, Invoices, ...)
- Saving time and reducing administrative costs for suppliers

* Q1 2017 to Q3 2019
** B2B PO means a PO placed with one supplier to serve a specific country order
What is the added value of GDF SRS for suppliers?

- POs are placed with suppliers in line with product batch size/production schedule
- SRS allows to serve small country orders timely
- SRS facilitates the launch of new products/regimens
- Less variation in quantities purchased from suppliers
- SRS can “absorb” country requests for postponement/cancellation of orders, instead of suppliers

**Example of SRS added value for products with MOQ or long delivery lead time***

If product has an MOQ too high to serve small and middle size country orders
If product delivery lead time is not in line with GDF standard delivery lead time to countries (max 6 months)

The SRS allows GDF to serve a country order even for 1 pack of product. Median SRS lead time is 3.5 months

*only accepted for products with production constraints
GDF support for registration of TB medicines in countries

GDF is supporting the registration of medicines by:
• facilitating the communication/process between suppliers and relevant organizations/authorities in countries
• identifying registration fee support when needed

GDF is currently supporting registration in additional countries: Philippines, Madagascar, Laos, Vietnam
3. GDF key achievements
Historical timeline for TB products introduction in GDF catalogs

- Grants from USAID, Canada, UNITAID and Japan via GDF are key to catalyzing TB medicines markets
- Global Fund funding is key to market maturation, scale-up, and expanded access
GDF TB Products availability (2)

Pipeline of products to be added to GDF catalog

- **Oxford Immunotec T-SPOT.TB IGRA**
  - Q1 2020
  - Nipro LPA for detection of INH, RIF resistance, NTMs

- **Patient adherence technologies**
  - Q2-3 2020
  - Pending WHO recommendations:
    - Molbio TrueNat*
    - Nipro PZA LPA

- **Additional 106 generic lab supplies, including expanded infection control**
  - Q3-4 2020
  - Digital X-ray equipment

- **Pending WHO recommendations**
  - Q3-4 2020
  - Fujifilm LAM test*
  - GeneXpert Omni
  - QFT-Access (IGRA)
  - Hain Fluorotype*
  - BD BDMax*
  - Xpert XDR cartridge

- **Pending WHO recommendations**
  - 2021 and onwards
  - CAD X-ray software
  - Gene sequencing instruments

*May be earlier, pending outcome of GF Expert Review Panel
GDF TB Products availability (1)

Dramatic increase in number of GDF eligible suppliers and products for **Second-Line Drugs**

From 2007 to 2019:
- >6-fold Increase # Suppliers
- >11-fold Increase # Products

Dramatic increase in number of eligible pediatric products the last 5 years

From 2015 to 2019:
- >4-fold Increase # Products
GDF supply security for TB medicines (1)

% of products with more than 3 suppliers (for high volume products)
and with more than 2 suppliers (for medium volume products)

**TB medicines with high volume**
Target: 3 suppliers/product

- 80% of products with less than 3 eligible suppliers
- 20% of products with 3 or more eligible suppliers

n=20 products

**TB medicines with medium volume**
Target: 2 suppliers/product

- 88% of products with less than 2 eligible suppliers
- 12% of products with 2 or more eligible suppliers

n=8 products

* 10,000,001 units (tablets, vials,...) or higher, annually

** 500,001-10,000,000 units (tablets, vials,...), annually
GDF supply security for TB medicines (2)

Very few GDF products with only one eligible supplier in 2019.
GDF is looking for additional suppliers and new formulations for the products below.

### Additional suppliers needed for:

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult SLDs</td>
<td>Bedaquiline* 100mg</td>
</tr>
<tr>
<td></td>
<td>Delamanid* 50mg</td>
</tr>
<tr>
<td></td>
<td>Pretomanid 200mg</td>
</tr>
<tr>
<td>Pediatric FLDs</td>
<td>3FDC RHZ 75/50/150 dispersible</td>
</tr>
<tr>
<td></td>
<td>Ethambutol 100mg dispersible</td>
</tr>
<tr>
<td>Others</td>
<td>Pyridoxine 50mg</td>
</tr>
<tr>
<td></td>
<td>Pyridoxine 100mg</td>
</tr>
</tbody>
</table>

### New formulation needed for:

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult LTBI</td>
<td>Rifapentine 300mg scored</td>
</tr>
<tr>
<td></td>
<td>Rifapentine/Isoniazid 300/300mg FDC</td>
</tr>
<tr>
<td>Pediatric FLDs</td>
<td>Rifapentine 150mg Dispersible</td>
</tr>
<tr>
<td>Pediatric SLDs</td>
<td>Bedaquiline* Dispersible</td>
</tr>
<tr>
<td></td>
<td>Delamanid* Dispersible</td>
</tr>
<tr>
<td></td>
<td>Linezolid 150mg Dispersible</td>
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</tbody>
</table>

* IP = Intellectual property constraints
Affordability of GDF TB products (1)

➢ For the April 2018 – March 2019 period, GDF allowed countries to save $US 36 million for the procurement of TB medicines thanks to significant price reduction.

Savings were equal to 960,000 DS-TB treatments or 53,000 shorter MDR-TB* treatments, or 37,000 MDR-TB conventional treatments*

➢ For the April 2019 – March 2020 period, savings are estimated to be $US 16 millions for Second Line Drugs (SLDs).

Clofazimine 100mg B/100:  from 98 to 50$US** (50%)
Linezolid 600mg B/100:  from 140 to 75 $US** (46%)

* 2016 WHO guidelines, ** GDF reference price
Affordability of GDF TB products (2)

GDF price reductions for MDR-TB regimens from 2012 to 2019

<table>
<thead>
<tr>
<th>2016 WHO guideline Update</th>
<th>2019 WHO guideline Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Longer MDR-TB Regimen (20 months)*</td>
<td></td>
</tr>
<tr>
<td>$1,947</td>
<td>$1,667</td>
</tr>
<tr>
<td>Shorter MDR-TB Regimen (9 months)**</td>
<td></td>
</tr>
<tr>
<td>$787</td>
<td>$562</td>
</tr>
<tr>
<td>2017</td>
<td>2018</td>
</tr>
</tbody>
</table>

62% Price Reduction 2012 to 2019

48% Price Reduction 2017 to 2019

Price reductions achieved in 2019 are no longer relevant due to the change of treatment regimens as per the 2019 WHO DR-TB Guideline update

*8 Km Lfx Eto Cs Z / 12 Lfx Eto Cs Z, weighted average prices, 46-55kg weight band, **4 Km Mfx Ctz Pto E H Z / S Mfx Ctz E Z, weighted average prices, 30-50kg weight band
Affordability of GDF TB products (3)

GDF price reductions for 2019 WHO DR-TB Regimens

- **2019 WHO guideline Update**
  - **2019 WHO all oral Regimen w Mfx (20 months)**
    - 2018: $1,861
    - 2019: $1,434
    - **23% Price reduction**
  - **2019 WHO Shorter Regimen w Amikacin (9 months)**
    - 2018: $621
    - 2019: $484
    - **22% Price reduction**

* 6 Mfx Bdq Lnz Cs Czf / 14 Mfx Cs Czf, weighted average price, 46-55kg weight band
** 4 Am Czf E H Mfx Pto Z / 5 Czf E Mfx Z, weighted average price, 30-50kg weight band
3. GDF key challenges
GDF key challenges (1)

• **Domestic Procurement Issues**
  - Countries are facing challenges to procure quality-assured and affordable products with domestic funds (failed tenders, products offered with unknown quality, high price paid, inability to mobilize domestic financing in an efficient manner, late deliveries .... ) leading to medicine stock-outs and shortages.
  
  GDF is working with countries on solutions to overcome barriers* for procurement through GDF with domestic funds.

• **Supply Constraints**
  - Risk of disruptions in production for few TB medicines, due to **limited number** of suppliers of API, starting materials and/or intermediate and consolidated in only a few countries.
  - Risk of disruptions of production of API / FPP due to implementation of **new environment requirements**

*Mainly national procurement legislation and restricting prepayment.
GDF key challenges (2)

- **Country demand forecasting**
  - Complex because individualized TB treatments based on drug-susceptibility testing (DST)
  - GDF is developing the process/methodology and the IT tools to automatically generate country demand forecasting and forecasts to suppliers
  - According to UNHLM targets, the global demand for MDR-TB diagnosis and treatment targets will increase from 144’843 in 2019 to 461’418 in 2022

Key takeaways

• GDF is the world’s largest mechanism for pooled procurement of quality-assured TB medicines and diagnostics (One-stop shop for TB products)
• GDF can provide products to all countries using any funding source at the most competitive prices from a secure base of suppliers
• GDF is playing a leading role in partner coordination and market stewardship
• GDF is a launchpad platform for expediting introduction of new medicines and diagnostics in countries
• GDF, with its SRS, allows for predictable manufacturer production schedules and shorter lead-times for delivery of TB medicines to countries
• Success is only possible with close collaboration and coordination across GDF, suppliers, TB programs, partners, and stakeholders.
If you want to become a GDF suppliers to participate to global access to TB products, please visit our GDF website at:

http://stoptb.org/gdf/becomeSupplier.asp
Thank you
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