GDF: Connecting People, Programs, and Policies to TB Innovations

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Chief, Global Drug Facility, Stop TB Partnership

34th Meeting of the Stop TB Partnership Coordinating Board
29 September, 2021
Geneva - remote
Session Overview

1. 2021 Key Highlights, Recent Product Launches & Introduction Update
2. New Tools on the Horizon: Opportunities & Challenges
3. Market Mapping and Partnering to Optimize Access & Incentivize Innovation
GDF 2021 Procurement Estimates: ~$260Mn to 122 Countries

Value Delivered, US$ Millions*

<table>
<thead>
<tr>
<th>Year</th>
<th>First-Line Medicines</th>
<th>Second-Line Medicines</th>
<th>Diagnostics</th>
<th>Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>10</td>
<td>20</td>
<td>5</td>
<td>30</td>
</tr>
<tr>
<td>2009</td>
<td>30</td>
<td>40</td>
<td>10</td>
<td>50</td>
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<tr>
<td>2011</td>
<td>60</td>
<td>80</td>
<td>20</td>
<td>80</td>
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<td>2013</td>
<td>100</td>
<td>120</td>
<td>30</td>
<td>130</td>
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<tr>
<td>2015</td>
<td>150</td>
<td>150</td>
<td>40</td>
<td>180</td>
</tr>
<tr>
<td>2017</td>
<td>200</td>
<td>200</td>
<td>50</td>
<td>250</td>
</tr>
<tr>
<td>2019</td>
<td>250</td>
<td>250</td>
<td>60</td>
<td>300</td>
</tr>
<tr>
<td>2021**</td>
<td>300</td>
<td>300</td>
<td>70</td>
<td>350</td>
</tr>
</tbody>
</table>

*Value includes product and shipping costs; **2021 projection as of Sep 2021

End of GF grant cycle. Alignment & push to deliver orders in time

Global Fund Funding
Other Funding
Government Funding
Total Countries

*2021 projection as of Sep 2021
GDF 2020 Savings: 30% Higher than Projected in Nov 2020

$47.2 Million 2020 Actual Savings*

$36.4 Million 2020 Projected Savings

*Equivalent to: 15% of total sales; 1.1Mn DS-TB treatments
DR-TB Regimen Price Reductions

Past WHO-Recommended Regimens

Current WHO-Recommended Regimens

• 25% decrease in BPAL regimen since end-2019 approval
• 16-24% decrease new WHO all-oral regimens since 2019
• Price decreases despite stagnant demand/volumes
TB Procurement and Market-Shaping Action Team (TPMAT)

Stakeholder Coordination & Alignment, Product Mapping & Prioritization

WHO-GDF-Global Fund TB Medicines Dashboard

Recommendations Currently Under Review:
- 20 Changes to 2021 WHO Model Essential Medicines List
- 4 Changes to GF Round 24 ERP Expression of Interest

>140 changes to 11 Guidance Docs & Lists since 2016

http://www.stoptb.org/gdf/medicinesdashboard/
http://www.stoptb.org/gdf/tpmat/
Recent Product Launches: Child-Friendly, DR-TB Formulations*

(Allocation)

Cycloserine 125mg
Ethambutol 100mg
Ethionamide 125mg
Levofloxacin 100mg
Moxifloxacin 100mg
Pyrazinamide 150mg

Clofazimine 50mg
Isoniazid 100mg

Bedaquiline 20mg

Delamanid 25mg

New: Sep-2021

In process:
Linezolid 150mg

30-80% Price Reductions

All 11 WHO-Recommended DR-TB Medicines Now Available & Accessible Despite Market Size of <1,000 Treatments/Year

*Blue indicates 2 suppliers
### Introduction of New TB Medicines & Regimens (Jun 2021)

<table>
<thead>
<tr>
<th>Phase</th>
<th>New TB Medicines and Regimens</th>
<th>GDF Board KPI Progress (# Countries Introduced/ # Priority Countries)</th>
<th># Countries Procuring from GDF</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Paediatric FDCs (DS-TB)</td>
<td>25/25</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>Bedaquiline 100mg</td>
<td>25/25</td>
<td>112</td>
</tr>
<tr>
<td></td>
<td>Delamanid 50mg</td>
<td>26/26</td>
<td>88</td>
</tr>
<tr>
<td>2-3</td>
<td>Paediatric DR-TB formulations</td>
<td>51/53</td>
<td>75</td>
</tr>
<tr>
<td>3</td>
<td>All-oral, longer regimens for DR-TB</td>
<td>51/53</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>All-oral, BDQ-based shorter regimens for DR-TB, inc. Modified</td>
<td>44/53</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Uptake Among GDF 53 Priority Countries**

- **All-Oral Longer Regimen**: Target: GDF 53 Priority Countries
- **All-Oral Shorter Regimen, inc. Modified**
- **Injectable-based Shorter Regimen**
- **All-Oral BPaL**
Approach to Life-Cycle Management is end-to-end:

- Historically, product-specific approach used
- Even new regimen introduction involved substituting one medicine with another
- But new research is generating many new drugs and treatment options, leading to frequent changes in WHO guidelines
  - Drugs no longer used for DS-TB or DR-TB; now see overlap in use of drugs for both types of TB
  - Multiple regimens, each have different impact on demand for a particular drug
  - Shorter regimens ultimately result in even smaller global market
- Innovation is most welcome! But, increasingly challenging to manage market to optimize access
### TB Regimen Evolution - New Tool Horizon Scanning

<table>
<thead>
<tr>
<th>Drug-Sensitive TB</th>
<th>2017</th>
<th>2021</th>
<th>&gt;2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regimens</td>
<td>1 Rifampicin-based regimen</td>
<td>New Rifapentine-Based Regimen</td>
<td>New drugs &amp; many new regimens</td>
</tr>
<tr>
<td>Duration</td>
<td>6 months</td>
<td>4 months</td>
<td>&lt; 4 months</td>
</tr>
<tr>
<td>Overlap w/DR-TB</td>
<td>None</td>
<td>Starting to overlap</td>
<td>Increased overlap</td>
</tr>
<tr>
<td>FDC Available</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Market</td>
<td>Consolidated</td>
<td>Potential to Fragment</td>
<td>Increased Fragmentation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Regimens</td>
<td>Many injectable-based regimens</td>
<td>Move towards all-oral regimens</td>
<td>New drugs &amp; many new regimens</td>
</tr>
<tr>
<td>Duration</td>
<td>18-24 months</td>
<td>9-20 months</td>
<td>&lt; 6 months</td>
</tr>
<tr>
<td>FDC Available</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Market</td>
<td>Fragmented</td>
<td>Fragmented</td>
<td>Increased Fragmentation</td>
</tr>
</tbody>
</table>

### Goal: Pan-TB Regimen(s)
- ✓ Same treatment for DS-TB & DR-TB
- ✓ Likely to include new & newer drugs
- ✓ Market consolidation
- ✓ Safer
- ✓ Shorter
- ✓ FDC
- ✓ Pediatric formulation available early
- ✓ Quality Assured
- ✓ Multiple Suppliers
- ✓ Affordable
Treatment Evolution & Market Complexity Require Shift in Approach

Regimen Road Maps
- Multiple medicines
- Multiple regimens
- One indication

Product-Specific Road Maps
- One medicine at a time
- One regimen
- One indication

Market Access Maps
- Multiple medicines, many new
- Multiple new regimens
- Multiple indications

+ Domestic financing
+ Decentralized procurement
+ Local supplier preference
+ New Suppliers
+ Products of unknown quality
+ Logistic challenges
+ Licensing Restrictions
+ More Players
Summary

• Lots of progress in 2021, despite COVID impacts. Big push to support GF PRs with end-of-grant spending, new concept notes

• Dramatic surge in TB treatment research resulting in frequent WHO guideline changes

• Results are encouraging and welcomed as treatment becomes safer, shorter, easier to tolerate

• But numerous, competing regimens and other factors make it more challenging to manage/consolidate market to achieve access goals

• GDF and TPMAT will need to expand/alter approach to mapping and managing markets to keep suppliers engaged, minimize losses, and promote access to optimal, affordable, quality-assured treatments
Thank You
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