GDF Session Outline

I. 2023 Key Achievements

II. 2023 Main Challenges Encountered in Promoting Access to TB Products, and How Best to Address These Challenges

III. Discussants, Questions & Answers
I. GDF’s Key Achievements for 2023
2023 – A Record-Breaking Year for GDF Supply of TB Products

2023: GDF delivered ~1,200 orders for TB products valued at $324 million

Delivered to 134 countries, including:
- 56 with domestic funding
- 9 high-income countries
- 14 clinical research projects
2023 – A Year of Dramatic Price Reductions and Significant Savings

<table>
<thead>
<tr>
<th></th>
<th>OLD Lowest Price per Treatment Course</th>
<th>NEW Lowest Price per Treatment Course</th>
<th>Price Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bedaquiline</td>
<td>$289</td>
<td>$130</td>
<td>55%</td>
</tr>
<tr>
<td>Delamanid</td>
<td>$1,700</td>
<td>$1,190</td>
<td>30%</td>
</tr>
<tr>
<td>3HP</td>
<td>$14.25</td>
<td>$9.99</td>
<td>30%</td>
</tr>
<tr>
<td>GeneXpert MTB/RIF</td>
<td>$9.98/test</td>
<td>$7.97/test</td>
<td>20%</td>
</tr>
<tr>
<td>GeneXpert XDR</td>
<td>$19.80/test</td>
<td>$14.90/test</td>
<td>25%</td>
</tr>
</tbody>
</table>

BPaLM lowest price now $426 per treatment course

GDF Savings Over US$ 32 Million in 2023

- Flexibility to cancel/postpone orders; choose freight modes
- 3HP FDC price reduction
- GeneXpert XDR and MTB/RIF-Ultra price reductions
- DR-TB medicines price reductions
- Downward adjustment of order volumes to avoid waste

GDF Budgeting and regimen prices can be found here: [https://www.stoptb.org/buyers/plan-order](https://www.stoptb.org/buyers/plan-order)
GDF Surpassed Supply Security Targets & Maximized Stockpile Efficiency

GDF Supply Security Results, TB Medicines

<table>
<thead>
<tr>
<th>Extremely-Low Volume Medicines (e.g. pediatric DR-TB)</th>
<th>Low-Volume Medicines (e.g. adult clofazimine)</th>
<th>Medium-Volume Medicines (e.g. adult DS-TB FDCs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target: 90% of products have 2 suppliers</td>
<td>Target: 90% of products have 2–3 suppliers</td>
<td>Target: 90% of products have 4 suppliers</td>
</tr>
<tr>
<td>Actual: 94%</td>
<td>Actual: 100%</td>
<td>Actual: 100%</td>
</tr>
</tbody>
</table>

Demand of only 500-1,000 treatments per year

GDF Stockpile Eases Supply Chain Management for Suppliers

- Decrease of Purchase Orders: 1,591 to 197
- Decrease of Shipments: 1,591 to 267
- Decrease # Countries to Ship: 1,591 to 1

GDF risk-sharing decreases suppliers’ waste and transactional costs, leading to lower medicine prices
GDF Prevention of Stockouts

GDF Averted Potential Stockouts in 128 Countries By Accommodating Emergency Orders

GDF Delivered Products to 119 Countries within 2-4 Months

GDF Delivered Products to 75 Countries in Less than 2 months

...And Averted an Additional 41 Potential Stockouts in 18 GDF Priority Countries By Other Means
Pediatric DR-TB Initiative Surpassed All Milestones

Treatments Delivered

GDF delivered child-friendly formulations for DR-TB treatment to an est. 6,500 children

Including an est. 2,000 treatment courses using child-friendly bedaquiline (AVAILABLE SINCE JUNE 2020)

Including an est. 1,000 treatment courses using child-friendly delamanid (AVAILABLE SINCE NOVEMBER 2021)

Countries Procuring

Since 2018 85 countries have procured child-friendly DR-TB formulations through GDF

Including 27 WHO HIGH MDR/RR-TB BURDEN COUNTRIES

Jointly funded by:

STOP TB Partnership
GLOBAL DRUG FACILITY

UNOPS

USAID

FROM THE PEOPLE OF JAPAN

www.stoptb.org
TB Procurement and Market-Shaping Action Team (TPMAT) Remained Aligned & Coordinated with WHO, Global Fund, and other Stakeholders

>20 Recommendations Accepted by WHO and Global Fund

5 New TB Medicine Formulations Launched & Added to GDF Catalog

<table>
<thead>
<tr>
<th>2023 TPMAT Recommendations Accepted</th>
<th>2023 TPMAT Product Achievements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO Essential Medicines List</strong></td>
<td>3 Medicines WHO-Prequalified:</td>
</tr>
<tr>
<td>Add pretomanid 200mg for use in BPaL(M) for DR-TB</td>
<td>• Linezolid 150mg dispersible tablet</td>
</tr>
<tr>
<td><strong>WHO Essential Medicines List for Children</strong></td>
<td>• Bedaquiline 100mg tablet</td>
</tr>
<tr>
<td>Remove age restrictions on bedaquiline and delamanid in children for DR-TB</td>
<td>• Rifapentine 300mg tablet</td>
</tr>
<tr>
<td>Remove non-optimized paediatric formulations (e.g. non-dispersible, liquids)</td>
<td></td>
</tr>
<tr>
<td><strong>Expert Review Panel Expressions of Interest</strong></td>
<td>2 Medicines Approved by Global Fund Expert Review Panel:</td>
</tr>
<tr>
<td>15 Medicines for standard list</td>
<td>• 2nd Paediatric 3-FDC (rifampicin/isoniazid/pyrazinamide)</td>
</tr>
<tr>
<td>2 Medicines for Priority List:</td>
<td>• Rifapentine 150mg dispersible tablet</td>
</tr>
<tr>
<td>• Clofazimine 50mg dispersible tablet</td>
<td></td>
</tr>
<tr>
<td>• Rifapentine 150mg dispersible tablet</td>
<td>All above medicines added to the GDF Medicines Catalog</td>
</tr>
</tbody>
</table>

GDF Passed Another ISO Audit with Zero Non-Conformities

---

**CERTIFICATE**

ISO 9001:2015

The management system includes The provision of quality-assured, tuberculosis medicines, diagnostics, medical devices, and other health products and related services

End certification date: 04/3/2015
Date of issue: 29/12/2020
Expiry date: 04/3/2025

www.stoptb.org
Scale-Up of New, Short Regimens for DR-TB and TB Prevention

BPaLM*

BPaLM Scale-Up Status in 53 Priority Countries:
- 21/53 countries have started
- 32/53 countries have plans to start

And, 61 countries ordered 60,000 Pretomanid treatments via GDF for use in BPaLM regimens**

3HP (3 months of rifapentine/isoniazid)*

3HP Scale-Up in 53 GDF priority countries
- 31/53 countries have started
- 13/53 countries have plans to start
- 9/53 countries considering options

And, 40 countries ordered 780,000 3HP treatment regimens for TB Preventive Treatment***

* Data as of 10 January 2024;  ** Final Confirmed Orders from 1 October 2022 to 31 December 2023  *** Final Confirmed Orders in 2023

USAID supporting 11 high-burden countries with procurement of 1.7 million 3HP treatments in 2024
II. 2023 Main Challenges Encountered in Promoting Access to TB Products, and How Best to Address These Challenges

• Transition of old Procurement Agent to New Procurement Agent
• Global supply constraints, domestic procurement
• Optimizing Use of Savings from Price Reductions
Medicines Procurement Agent (PA) Transition

Goal: Seamless transition to ensure business continuity, maintain client confidence, uphold mission to promote access

Challenges:
• Simultaneous mgt of 2 PAs
  o Phase-Out Old PA
  o Phase-In New PA

Risks:
• Stockouts & treatment interruptions
• Delay in new product introduction & scale-up
• Failure to meet GF grant, USAID project deadlines
• Wasted medicines in stockpile
• Negative impact on client satisfaction
• Failure to pass Dec ISO audit

Management:
• Established Hypercare: systematic, ultra-scrutiny and monitoring of all 1,200 orders across both PAs to detect and resolve issues that could lead to delays.
Global Supply Constraints

Medicines

- Pretomanid
- Fixed-Dose Combination (FDC) Medicines for Drug-Sensitive TB

GDF Response

- Data sent by countries is analyzed to prioritize & ration medicines to meet scale-up plans & avoid stockouts
- Send multiple small shipments instead of 1 large shipment
- Monthly production planning with suppliers
- Addition of medicines to GDF Strategic Rotating Stockpile
- Interventions to address API shortage

Challenges

- When there are global supply constraints, NTPs procuring domestically also have difficulty securing medicines in a timely manner
  - GDF can serve as a safety net for these countries by way of emergency procurement. The more notice and the more data shared, the better GDF can support
  - Some NTPs not eager to share data for products procured outside GDF

Global shortage of active pharmaceutical ingredients needed to produce medicines
2023 Overview of Domestic Financing & Procurement of TB Medicines in 53 GDF Priority Countries*

Numbers being validated.
Reallocation of Savings From Price Reductions in Global Fund Grants: Bedaquiline, Delamanid, 3HP, GeneXpert

40 Countries

Estimated $43.5 Million Savings

GDF Approached 38 NTPs to Offer Support in Reallocating $39.3 Mn Savings in Global Fund Grants

31 Countries Accepted Support to Reallocate $28.6 Mn

30 Countries Reallocated All (26) or Some (4) Savings to TB Product Procurement

1 Country Reallocated Savings to Other Programmatic Activities*

7 Countries Declined Support to Reallocate $10.7 Mn

Action Needed to Finalize/Implement

*Country is funding > 90% TB procurement with domestic funds

$39.3 Mn Global Fund Savings in 38 Countries:
- $0.6 Mn Grant Cycle 6
- $38.7 Mn Grant Cycle 7 (2023-2025)

$4.2 Mn Other Savings in 8 countries:
- $2.8 Mn Domestic
- $1.4 Mn Miscellaneous

Assessment & Reallocation Still Needed
Thank you

Brenda Waning, Chief, Global Drug Facility
brendaw@stoptb.org

Acknowledgements

With thanks to the:
• Entire GDF staff
• National TB Programmes, suppliers, and partners who contributed to 2023 results
• Donors who funded and supported this work