GDF Approach to Access & Recent TB Medicine Price Reductions

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TB Situation Room Webinar
GDF Works End-to-End Approach across Entire Product Lifecycle to Promote **Equitable Access to TB Products**

**Partnership Approach**

Goal is to have quality, optimized, affordable products developed and accessible to those who need them as quickly as possible.
Adult Rifapentine/Isoniazid 300/300 (3HP) for TB Prevention

- **Lupin and Macleods:**
  - **Price:** New price is $9.99 - $10.96 per treatment course (EXW)
    - 23-30% decrease from previous price of $14.25
  - **Validity:** Sep 2023 through end 2024
  - **Eligibility:** All countries
  - **Estimated Savings:** $16.5 million over the 16-month contract period, an amount sufficient to procure an additional 1.7 million 3HP treatment courses
  - **Note:** Collaboration with USG who committed to $25 million in funding for 3HP procurement

- **GDF Next steps:**
  - Explore market for additional suppliers
  - Prepare for potential demand increase pending ongoing rifapentine research & WHO Guidelines
  - Launch a competitive tender mid-2024 with new contract start date of 1 Jan, 2025
Delamanid 50mg for DR-TB Treatment in Adults

- **Otsuka:**
  - **Price:** New price is $1,190 per treatment course (EXW)
    * 30% decrease from previous price of $1,700 per treatment course
  - **Validity:** Aug 2023 onward (sole supplier)
  - **Eligibility:** 89 low- and middle-income countries
  - **Estimated Annual Savings:** $3 million

- **Viatris:**
  - Delamanid in final stages of WHO PQ evaluation for active pharmaceutical ingredient

- **GDF Next steps:**
  - Launch a competitive tender if/when Viatris receives WHO prequalification approval
  - Prepare for potential demand increase pending ongoing delamanid research & WHO guidelines
  - Monitor progress on additional suppliers entering market
Bedaquiline 100mg for DR-TB Treatment in Adults

- J&J and Lupin, plus Macleods as auxiliary supplier:
  - **Price**: New price is $130-$194 per treatment course (EXW)
    - 33-55% decrease from previous price of $289 per treatment course
  - **Price Validity**: Sep 2023 through end 2024
  - **Eligibility**: 134 low- and middle-income countries
  - **Estimated Savings to GDF Clients**: $8 million in savings over the 16-month contract period, an amount sufficient to procure more than 51,000 additional bedaquiline treatments

- Other potential generic suppliers:
  - 2 other suppliers have submitted applications to WHO Prequalification

- GDF Next steps:
  - Prepare for entry of additional suppliers; Develop strategy for supplier management in a low-volume market
  - Launch a competitive tender mid-2024 with new contract start date of 1 Jan, 2025
## New GDF Regimen Prices by Medicine*: BPaLM and BPaL

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Old Lowest Price</th>
<th>New Lowest Price</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BPaLM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bedaquiline 100mg**</td>
<td>$289</td>
<td>$130</td>
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<tr>
<td>Pretomanid 200mg</td>
<td>$238</td>
<td>$238</td>
</tr>
<tr>
<td>Linezolid 600mg</td>
<td>$31</td>
<td>$31</td>
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<tr>
<td>Moxifloxacin 400mg</td>
<td>$27</td>
<td>$27</td>
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<tr>
<td><strong>BPaL</strong></td>
<td>$558</td>
<td>$399</td>
</tr>
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*GDF prices as of 30-Aug-2023

**BDQ used for 26 weeks (rather than 24 weeks)
GDF Services & Resources

• These 3 medicine price reductions alone are expected to save GDF clients at least $27 million over the next 15 months
  o Considerable savings considering GDF delivered ~$71 million worth of DR-TB medicines in 2022
  o Timely development given TB funding constraints

• GDF Technical Assistance
  o Support with procurement and supply planning to phase-in new products/regimens and phase out old products/regimens
  o Quantification and early warning systems to prevent stockouts
  o Budget revisions to optimize use of savings

• GDF prices can be found in the GDF Catalog and in GDFs on-line order system

• To order via GDF, visit the STBP website

Proactive, Multi-Stakeholder Interventions via TPMAT to Expedite Access

Bedaquiline 100mg: Process begins with WHO Guidelines

- **2015**
  - Signal to Generic Suppliers to Develop Product

- **2018**
  - WHO Prequal EOI
  - Global Fund ERP EOI

- **2019**
  - Global Fund ERP Approval

- **2022**
  - Jul 2023: Primary Patent Expiry

- **2023**
  - Jul: Advance planning to tender immediately after patent expiry
  - Aug 2023: Addition to GDF Catalog

Work to develop generic bedaquiline began 5 years before primary patents due to expire

Thank you

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