Market shaping to improve equitable access to drug-resistant TB treatment

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What is market shaping?

ChatGPT:

Market shaping is the process of actively influencing and changing the conditions of a market to create new opportunities, drive innovation, and generate greater value for consumers and businesses. It involves leveraging a variety of strategies and tactics to reshape the competitive landscape and establish new market dynamics that benefit all participants.

USAID:

A well-functioning healthcare market...requires manufacturers to produce high-quality products, distributors to deliver the necessary quantities, providers to administer them correctly, and patients to be educated and active participants in their own health.

Market shaping can disrupt current practices or transform existing market structures, creating efficiencies that lead to better health outcomes.

MedAccess:
Website accessed 3 Apr 2023.

Market shaping is the act of influencing and constructing markets to improve their ability to make products widely accessible to patients who could benefit from them.
The global health community has created a variety of market shaping and innovative finance tools...

<table>
<thead>
<tr>
<th>RESEARCH &amp; DEVELOPMENT</th>
<th>NORMATIVE &amp; REGULATORY</th>
<th>MANUFACTURE &amp; COMMERCIALIZATION</th>
<th>PROCUREMENT &amp; SUPPLY MANAGEMENT</th>
<th>INTRODUCTION &amp; SCALE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prize</strong></td>
<td><strong>Development Incentive Grant</strong></td>
<td><strong>Advance Market Commitment</strong></td>
<td><strong>Product Subsidy</strong></td>
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<tr>
<td><strong>Volume Guarantee</strong></td>
<td><strong>Procurement Guarantee</strong></td>
<td><strong>Payment Guarantee</strong></td>
<td><strong>Working Capital Facility</strong></td>
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<td><strong>Impact Investment</strong></td>
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<td><strong>Regulatory Incentive</strong></td>
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Image Source: Clinton Health Access Initiative, 2021.
...which must be tailored to address specific access barriers and to complement existing health programs/initiatives

<table>
<thead>
<tr>
<th>Step 0</th>
<th>DEFINE THE PUBLIC HEALTH PROBLEM THAT NEEDS TO BE SOLVED</th>
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<tbody>
<tr>
<td></td>
<td>Develop a clear understanding of the public health problem you are trying to solve, whether it aligns with government priorities, and the extent to which the product or service can address the problem.</td>
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<table>
<thead>
<tr>
<th>Step 1</th>
<th>MAP OUT ALL EXISTING AND/OR ANTICIPATED BARRIERS TO ACCESS FOR THE PRODUCT OR SERVICE</th>
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<tbody>
<tr>
<td></td>
<td>Review the barriers listed in Part A and identify all which are applicable to the product or service in question.</td>
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<thead>
<tr>
<th>Step 2</th>
<th>IDENTIFY THE INTERVENTION(S) THAT CAN HELP ADDRESS THE BARRIERS FOR THE PRODUCT OR SERVICE</th>
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<tr>
<td></td>
<td>Based on the results from Step 2, review the interventions listed in the corresponding slide(s) in Part B to determine which intervention(s) can address the identified barriers. Ensure that all critical barriers are being addressed by the selected intervention(s).</td>
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<table>
<thead>
<tr>
<th>Step 3</th>
<th>DETERMINE WHETHER A FINANCIAL TOOL IS CRITICAL TO SUCCESSFULLY IMPLEMENT THE INTERVENTION(S)</th>
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<tbody>
<tr>
<td></td>
<td>In some cases, financial tools may be needed to augment the selected intervention(s). Review the financial tools in Part C and develop a short list of options based on when each financial tool should be used and the type/magnitude of financing required.</td>
</tr>
</tbody>
</table>

*Image Source: Clinton Health Access Initiative, 2021.*
Market shaping partnerships have been successful in increasing equitable access to health products

### Public health challenge
Routine HIV viral load testing is a vital part of HIV care, as it can detect when treatment is failing.

### Market situation
In 2018, VL products and services were procured in a fragmented manner, which resulted in low price transparency, increased cost per result, and high instrument downtime.

### Market shaping intervention
MedAccess and partners provided a volume guarantee to Hologic in exchange for an all-inclusive ceiling price of $12 per patient result and a commitment to register its viral load testing platform in Africa & Asia.

### Impact (as of 2021)
- Supported product introduction in 13 countries
- 554K PLHIV who are not virally suppressed identified
- $27M in direct procurement savings for governments and donors
- 101K people living with HIV will complete LTBI treatment and 25K fewer people will be hospitalised due to adverse effects from the medication
- $12M in projected direct procurement savings

### 3HP TB Preventive Therapy
Addressing latent TB is essential to reducing incidence and mortality of TB in high-risk populations. 3HP is a fixed-dose, short course regimen effective at treating and curing latent TB.

### Market situation
In 2019, 3HP access was limited. A single manufacturer produced 3HP singles under significant supply constraints and at a price that exceeded the cost-effectiveness threshold.

### Market shaping intervention
- Unitaid and CHAI provided commercialisation support to 3HP fixed-dose combination manufacturers
- MedAccess provided a volume guarantee to Macleods to secure a reduced price and expanded production capacity
- Aurum supported 3HP introduction & initial procurement

### Impact (as of 2021)
- 101K people living with HIV will complete LTBI treatment and 25K fewer people will be hospitalised due to adverse effects from the medication
- $12M in projected direct procurement savings

### Partners
- HOLOGIC
- PEPFAR
- THE GLOBAL FUND
- Unitaid
- UNITAID
- 3HP TB Preventive Therapy
TB is a priority for market shaping, given the potential for innovations to improve health outcomes and equitable access to care.

In 2021, WHO estimates that 1.6 million people died from TB – an increase from 1.4m in 2019. In 2021, 187,000 people living with HIV died from TB.

WHO has called for increased investment in new TB diagnostics, drugs, & vaccines to support programs to meet TB elimination goals.

More effective, shorter course TB treatment and preventive regimens are now available. Currently, 77% of PLHIV co-infected with TB are treated successfully.

Following WHO’s 2022 communication, BPaL/M need grew significantly, but the market faced a potential high price-low volume trap

**Limited BPaL/M use from June 2020-May 2022**

- WHO recommends BPaL only for pre-XDR patients, under operational research conditions
- Addressable market is small (~4,000 pre-XDR patients)
- High prices/limited supply for pretomanid & bedaquiline

**Step change in potential impact 2022-on**

- 89% of patients successfully treated with BPaL/M vs. 52% who received standard-of-care in recent RCT\(^1\)
- WHO recommends BPaL/M for MDR/RR-TB patients under programmatic conditions, including PLHIV
- Potential market grows to 170,000+ patients per year
- Order volumes still uncertain; pricing remains high

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**DR-TB Patients Identified & Treatment Eligibility**

(Globally at year end – WHO data and MedAccess projections)

<table>
<thead>
<tr>
<th>Year</th>
<th>Estimated Eligible for BPaL/M</th>
<th>Estimated Not Eligible for BPaL/M</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>187K</td>
<td>202K</td>
</tr>
<tr>
<td>2019</td>
<td>153K</td>
<td>4K</td>
</tr>
<tr>
<td>2020</td>
<td>163K</td>
<td>4K</td>
</tr>
<tr>
<td>2021</td>
<td>170K</td>
<td>16K</td>
</tr>
<tr>
<td>2022*</td>
<td>194K</td>
<td>18K</td>
</tr>
</tbody>
</table>

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MedAccess and partners initially focused on pretomanid, the newest and most expensive product in the BPaL/M regimen.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Market health</th>
<th>Market context</th>
<th>Access barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication</strong></td>
<td><strong>Good</strong></td>
<td><strong>Moderate</strong></td>
<td><strong>Low</strong></td>
</tr>
<tr>
<td><strong>Linezolid &amp; Moxifloxacin</strong></td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Bedaquiline</strong></td>
<td><strong>Moderate</strong></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Pretomanid</strong></td>
<td><strong>Poor</strong></td>
<td></td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Market health**
- Good:
  - Multiple suppliers
  - Commonly used and procured antibiotics
  - Prices between $27-$31 per patient course (per GDF catalogue)

**Market context**
- Moderate:
  - Single supplier
  - Widely available
  - Currently used for treat DR-TB
  - Price has come down, but still remains high
  - Patent blocks generics in many countries

- Poor:
  - Single supplier
  - Most expensive product in regimen
  - New product – requires support
  - Small market – only used to-date in ops research

**Access barriers**
- Low
  - Limited, as patent landscape presents biggest challenge

**Opportunity to address access barriers**
- N/A
- Limited, as patent landscape presents biggest challenge
- Adoption could by facilitated by a price reduction
The agreement announced in December 2022 secured a 34% price reduction to support BPaL/M scale-up

A price reduction for pretomanid, brings BPaL/M closer to the price of the lowest cost previous standard of care

A coordinated effort from multiple global stakeholders will facilitate access & scale up

- **MedAccess** proposes to guarantee minimum pretomanid order volumes to Viatris, a supplier of pretomanid.
- **Viatris** reduces its pretomanid price by 34% to $240 per patient course and registers the product in key markets within 3 – 9 months.
- **Civil society** advocates for rapid introduction of pretomanid and uptake of the BPaL/M regimen, and supports patient/provider education.
- **Governments and procurers** adopt guidelines, develop introduction plans, and initiate procurement to ensure treatment is available.

*Partner and exact scope of work to be identified.

(1) Gupta et al. 2022 (https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0001287); (2) Stop TB Partnership Global Drug Facility, November 2022 Medicines Catalog (https://www.stoptb.org/file/9891/download);

(3) Assumes 20% discount is realised for orders in multiples of 10 packs