The Global Fund Sourcing Strategic Review Meeting
16-17.10.2017
Contents

▪ Welcoming and introductory remarks
  ▪ Market Shaping Strategy: Vision and Progress
  ▪ Category Highlights
  ▪ Responsible Procurement
  ▪ Provision of Market Information
  ▪ Quality Assurance
  ▪ Tuberculosis Market
  ▪ Material for breakouts
  ▪ Wrap-up
# Agenda Day 1

**Day 1 – 16th October**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.30 – 10.00</td>
<td>Welcome coffee</td>
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</tr>
<tr>
<td>10.00 – 10.20</td>
<td>Welcome remarks</td>
<td>Patrik Latin</td>
</tr>
<tr>
<td>10.20 – 11.00</td>
<td>Market Shaping Strategy: Progress &amp; Vision</td>
<td>Mariatou Tala Jallow</td>
</tr>
<tr>
<td>11.00 – 12.30</td>
<td>Category Highlights</td>
<td>Azizkhon Jafarov; Lin (Roger) Li; Martin Auton; Mathieu Courtois</td>
</tr>
<tr>
<td>12.30 – 13.30</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>13.30 – 15.15</td>
<td>Breakout 1</td>
<td>Mariatou Tala Jallow; Lin (Roger) Li; Martin Auton; Melisse Murray; Nathan Vasher</td>
</tr>
<tr>
<td>15.15 – 15.30</td>
<td>Regrouping coffee</td>
<td></td>
</tr>
<tr>
<td>15.30 – 16.00</td>
<td>Responsible procurement</td>
<td>Nick Jackson; Lin (Roger) Li</td>
</tr>
<tr>
<td>16:00 – 18.00</td>
<td>Breakout 2</td>
<td>Mariatou Tala Jallow; Lin (Roger) Li; Martin Auton; Melisse Murray; Nathan Vasher</td>
</tr>
<tr>
<td>18.30 – 20.00</td>
<td>Cocktail, incl. day one closing</td>
<td></td>
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For each of the breakout sessions, 3 simultaneous workshops will run on Leveraging Impact, Total Cost Approach and New Product Introduction.
## Agenda Day 2

### Day 2 – 17th October

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.30 – 09.00</td>
<td>Welcome coffee</td>
<td></td>
</tr>
<tr>
<td>09.00 – 10.45</td>
<td>Breakout 3</td>
<td>Mariatou Tala Jallow; Lin (Roger) Li; Martin Auton; Melisse Murray; Nathan Vasher</td>
</tr>
<tr>
<td>10.45 – 11.00</td>
<td>Regrouping coffee</td>
<td></td>
</tr>
<tr>
<td>11.00 – 12.30</td>
<td>Sharing market information</td>
<td>Nick Jackson (GF) Alexandra Hazell and Rod Carlton (Freshfields)</td>
</tr>
<tr>
<td>12.30 – 13.00</td>
<td>Quality Assurance</td>
<td>Alain Prat; Lin (Roger) Li</td>
</tr>
<tr>
<td>13.00 – 14.00</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>14.00 – 15.00</td>
<td>Tuberculosis market</td>
<td>Stop TB – <em>Presentation to be uploaded to TGF website at a later date</em></td>
</tr>
<tr>
<td>15:00 – 17.00</td>
<td>Breakout feedback and discussion</td>
<td>Patrik Latin, McKinsey &amp; Co.</td>
</tr>
<tr>
<td>17.00 – 17.30</td>
<td>Summary + Closure</td>
<td>Patrik Latin, Mariatou Tala Jallow</td>
</tr>
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</table>

For each of the breakout sessions, 3 simultaneous workshops will run on Leveraging Impact, Total Cost Approach and New Product Introduction.
Contents

- Welcoming and introductory remarks
- **Market Shaping Strategy: Vision and Progress**
  - Category Highlights
  - Responsible Procurement
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  - Tuberculosis Market
  - Material for breakouts
  - Wrap-up
Market Shaping Strategy: Progress and Vision
Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Mariatou Tala Jallow
The MSS is a key component of The Global Fund’s mission

Mission of MSS: Leverage our position to facilitate healthier global markets for health products – today and in the future
Healthy markets have 6 characteristics

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation</td>
<td>There is a <strong>robust pipeline of new products</strong>, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers.</td>
</tr>
<tr>
<td>Availability</td>
<td>New and/or superior evidence-supported, quality-assured products are <strong>rapidly introduced in the market and made available</strong> to those in low- and middle-income countries. Adequate and sustainable supply exists to meet global needs.</td>
</tr>
<tr>
<td>Demand and adoption</td>
<td>Countries, programs, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the <strong>most cost-effective products</strong> (within their local context).</td>
</tr>
<tr>
<td>Quality</td>
<td>Medicines and technologies are available at an <strong>internationally-recognized standard of quality</strong>, and there is reliable information on the quality of the product. This includes not only the quality of the final, finished product, but also the quality of starting and intermediary materials used to manufacture the final product.</td>
</tr>
<tr>
<td>Affordability</td>
<td><strong>Medicines and technologies are offered at the lowest possible price that is sustainable</strong> for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers.</td>
</tr>
<tr>
<td>Delivery</td>
<td>Supply chain systems (including quantification, procurement, storage, and distribution) <strong>function effectively to ensure that products reach end users in a reliable</strong> and timely way.</td>
</tr>
</tbody>
</table>

Source: Market Shaping Strategy, Annex 1 to GF/B4/17 - Revision 1
The market shaping strategy has come a long way

Birth of market shaping strategy

PPM is created to leverage GF volumes

Market shaping strategy 2011-2016

GF strategy 2012-2016

Call to more proactively shape markets

Vision

Adoption of objective and guiding principle of market shaping

New market shaping strategy, incl. specific instructions for ARVs

Plan for reform: value for money

PPM reaches $1bn/year

Recognition of GF’s abilities to influence market and call to extend toolkit

Reinforcement and development of market shaping objectives and toolkit

1 Market Dynamics Ad-hoc Committee
Source: Team analysis
Our efforts have borne fruit

Savings equivalent to:
>400mn courses of ACTs for under 5
>65 mn bed nets

Reduction of scale-up time

Tenders including innovation criteria

Collaboration and co-investment

85%

Terms and conditions of framework agreements extended

Large Buyer Forum in ARV market

OTIF in PPM

Introduced to prevent stockouts

Price reductions LLIN/ARV

>35% mn$ savings (2016)

Adoption of new/cost efficient products

Stimulated innovation

Contribution to GF mission

Country transition and long-term market viability

Availability and affordability Consistent quality standards

1 Since 2013 and 2014, respectively
2 In case examples
3 E.g. RSA, Kenya, PAHO
4 To other large buyers like PAHO, Kenya

Source: Team analysis
The journey to evolve sourcing needs to take place against the backdrop of existing strategies and initiatives.

- Market Shaping Strategy 2016-21
- Supply Chain Implementation Plan
- GF strategy 2017-22
- Others, incl. responsible procurement
- Implementation of wambo.org

Source: Team analysis
A range of tools support the implementation of the MSS

To deliver on the objectives of the MSS...

<table>
<thead>
<tr>
<th>Tools</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pooled procurement mechanism (PPM)</td>
<td>Consolidates recipient demand for health products, negotiates procurement, offers vehicle to deploy a variety of strategic procurement practices</td>
</tr>
<tr>
<td>The Global Fund’s Quality Assurance policies</td>
<td>Covers pharmaceutical and diagnostic products and quality requirements for other health products (incl. Expert Review Panel)</td>
</tr>
<tr>
<td>Price and quality reporting mechanism (PQR)</td>
<td>Captures transaction-level procurement data on core health products financed by GF in public database</td>
</tr>
<tr>
<td>Revolving fund (catalytic fund)</td>
<td>Supports new product introduction</td>
</tr>
<tr>
<td>The Global Fund’s guide to procurement and supply management (PSM) policies</td>
<td>Details the legal obligations that apply to GF-financed health products and other recommended best practices for PSM</td>
</tr>
<tr>
<td>Guidance provided by the grant management division’s health product management specialists</td>
<td>Interfaces with PRs on PSM topics in grant-making and implementation process and monitors grant compliance with the procurement policies described above</td>
</tr>
<tr>
<td>Cost-effectiveness analysis (HTA)</td>
<td>Informs country priority-setting and selection of health technologies commissioned by countries with GF financing or centrally via the GF’s Value for Money special initiative</td>
</tr>
<tr>
<td>wambo.org</td>
<td>Serves as “face” of PPM to increase country ownership and provides full visibility and a transparent and auditable process</td>
</tr>
</tbody>
</table>

Source: Annex 1 to GF/B34/17 – Revision 1
We identified 6 strategic priorities for which we wish to improve collaboration with partner organizations

<table>
<thead>
<tr>
<th>Strategic priority areas</th>
<th>What we have achieved</th>
<th>What we want to attain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leveraging impact</td>
<td>▪ Greatly improved affordability and availability&lt;br&gt;▪ Strong partner relationships, incl. co-investments and benefit sharing</td>
<td>▪ Define ways of SMART(^1) collaboration&lt;br&gt;▪ Sustain and extend impact achieved through, e.g., framework agreements, potential joint procurement solutions</td>
</tr>
<tr>
<td>Total cost approach</td>
<td>▪ Significant value unlocked through unit-price focused efforts</td>
<td>▪ Unlock additional benefits beyond unit price reductions through holistic cost approach</td>
</tr>
<tr>
<td>Innovation and new product introduction</td>
<td>▪ Targeted case-by-case support leveraging organically evolving collaboration</td>
<td>▪ Leverage synergetic end-to-end support based on each partner’s unique value proposition</td>
</tr>
<tr>
<td>Responsible procurement</td>
<td>▪ Societal and environmental concerns addressed through multiple ad-hoc initiatives</td>
<td>▪ Work hand in hand with partners to comprehensively ensure responsible procurement across 4 dimensions (i.e, economy, ecology, society, and business practices)</td>
</tr>
<tr>
<td>Provision of market information</td>
<td>▪ Healthier markets through generous information sharing on case-by-case basis</td>
<td>▪ Improve impact and mitigate risk through principle-based information sharing</td>
</tr>
<tr>
<td>Quality assurance</td>
<td>▪ Averting of critical quality issues/ incidences and improved patient safety</td>
<td>▪ Play more pro-active role, incl., improving of information flow and increasing ability to act upon quality relevant information</td>
</tr>
</tbody>
</table>

Source: GF; Team analysis 1 Specific Measurable Achievable Realistic Timebound
Contents

- Welcoming and introductory remarks
- Market Shaping Strategy: Vision and Progress

**Category Highlights**

- Responsible Procurement
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Highlights: Antimalarials
Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Lin (Roger) Li
Responsible procurement in Antimalarials Medicine Sourcing Strategy 2018-20

**Context**

- **Agricultural Artemisinin prices are volatile** due to, e.g.,
  - Overproduction capacity because of low technical barriers to entry
  - Lack of harmonized quality standards
  - Inconsistent in-house EHS control
  - Lack of visibility of demand and long term agreement
- **Agricultural Artemisinin price volatility causes supply interruption to ACT suppliers**

**Approach**

- **GF mitigated Artemisinin price volatility and supply interruption** by:
  - Assessing all Artemisinin manufacturers’ EHS standards through 3rd party
  - Selecting panel Artemisinin manufacturers for 2018-2020 implementation
  - Incentivizing best practices among manufacturers along upstream supply chain by offering 3 years long term agreements
- **Promoted semi-synthetic Artemisinin source** for long term sustainability

Source: GF
GF moved Antimalarials production closer to demand to decrease carbon footprint

**Description**

- **Context**
  - Most eligible suppliers have approved production sites outside of Africa where the largest ACTs demand is, translating to relatively important transportation costs
  - ACT timely demand has been a challenge
  - In-time responsiveness of manufacturers is critical

- **Approach**
  - Explicitly value “production footprint in Africa/proximity to high volume demand”
  - Encourage rapid supply mechanism through vendor-managed inventory or other innovative supply chain solutions

- **Impact**
  - **Shortened lead times** between order confirmation and arrival of goods at port of entry
  - **Lower transportation costs** to first port of entry
  - **Decreased carbon footprint**
  - **In-country economic development** towards achievement of SDGs, e.g., local employment in areas most affected by malaria

**Source:** GF

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**Map Details:**
- **Recipient countries**
- **Manufacturing countries**
- **Recipient countries and Manufacturing countries**
Highlights: LLINs

Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Aziz Jafarov
LLIN sourcing has been evolved along 2 strategic rounds

First round LLIN Sourcing Strategy
2014-2015
- Maximize investments on LLINs within a dynamic and sustainable market environment
- Address price volatility and standardization

Second round LLIN Sourcing Strategy
2016-2017
- Maintain availability and affordability
- Strive for continuous improvement
- Support investment in innovation
- Maintain flexibility and prepare for change
In order to maximize investments on LLINs within a dynamic and sustainable market environment, the first round pursued 6 targets:

- **Develop new supply chain model**, incl. direct supplier management, risk reduction, updated pooled procurement and improved delivery.
- **Create new processes**, incl. forecasting to improve net availability in line with country programs.
- **Move towards standardization of specifications** to simplify procurement and production.
- **Unlock value for GF in LLIN through improved sourcing and greater understanding** of the market.
- **Engage with other agencies and suppliers to drive innovation and collaboration**.
- **Encourage local production** to WHO standards without de-stabilizing the market (where appropriate).
The first round 2014-2015 already delivered significant impact

- Started **new way of doing business**
- Created **competitive supplier base** by selecting 9 instead of 3 suppliers to procure 167 million nets
- Enabled more **stable/predictable pricing**
- Improved demand **visibility and delivery performance**
- Initiated **support for local manufacture**
Building on the first round achievements, the 2016-2017 LLIN Sourcing Strategy set ambitious targets to shape LLIN markets

- Maintain availability and affordability
  - Ensure sufficient capacity is maintained across the 3 year replacement cycle
  - Optimize plant utilization where feasible
  - Encourage manufacture close to the customer
  - Support ROI on supplier-owned assets

- Support investment in innovation
  - Recognize the differences between origination and equivalence
  - Support ROI in new products
  - Participate in and support initiatives on durability and resistance

- Strive for continuous improvement
  - Adopt a landed cost approach
  - Improve data management

- Maintain flexibility and prepare for change
  - Prepare for product differentiation
  - Develop mechanisms to support change
  - Encourage QMS adoption prior to WHOPES PQ

These targets were reflected in the tender structure
Also the second round enabled a leap forward, but there remain challenges to be addressed

Although we achieved a lot:

**Impact**
- Procured 169 mn nets (2016-2017) with estimated value of $350 mn by mid 2017
- Quarterly allocation updates for suppliers
- Selected 10 panel Suppliers
- **Manufacture closer to customer** (lower landed cost and shorter lead time)
- Improved supplier performance management
- Increase On Time In Full deliveries to 98% in 2016
- Standardized **package of accessories** (net specifications), incl. **colour coding** the nets to support initiatives on durability monitoring
- **Stable prices** with observed decrease
- **Flexibility for new products** is built into the Framework Agreements
- **Product differentiation guidance** (e.g. PBO nets) is challenging to implement
- Limited number of **new generation nets** in the development pipeline

**Supply**
- Trade-off between evolving of **new-generation nets and availability/affordability**
- Significant **manufacturing over-capacity**
- **Align changes in the LLIN pre-qualification process and roles**
- One WHOPES-recommended new generation net, but **WHO guidance is still pending**
- Procured 169 mn nets (2016-2017) with estimated value of $350 mn by mid 2017
- **Trade-off between evolving of new-generation nets and availability/affordability**
- Significant **manufacturing over-capacity**
- **Align changes in the LLIN pre-qualification process and roles**
- One WHOPES-recommended new generation net, but **WHO guidance is still pending**

...there remain challenges to be tackled
**LLIN overcapacities**

**Problem**
- 10 out of 12 eligible LLIN manufacturers are selected as panel manufacturers in GF 2014 tender for 2015-2016 implementation
- Average deliveries to PRs are at 7.25 mn nets per month, which is just 1/4 of committed capacity
- Some of panel manufacturers offer very aggressive prices to other buyers to maintain minimum production load and skilled works

**Solution**
- GF competitive tender has adapted to the balanced supply system approach to evaluate the supply base. Both “originator” and “me-too” manufacturers are kept as panel manufacturers
- GF allocation was structured in the way to be able to respond to both low and high demand periods

**Opportunities and Challenges**
- Idle capacity can be utilized further to return value
- As LLIN are a labor intensive operation, sustainability issues become an emerging concern
- How many panel LLIN manufacturers we need to achieve our mission is at question

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1 Data source: Regular Manufacturer performance review meeting  
2 In 2017, 1 more LLIN manufacturer is pre-qualified with "me too" products
Highlights: Viral Load and Early Infant Diagnostics Testing

Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Aziz Jafarov
GF engages to provide transparency in pricing, costs, acquisition, and contracting options to tackle historical market shortcomings

Initial situation

- Historically there has been little visibility in pricing, due to country-by-country or even machine-by-machine arrangements in place
- As a result, price variability tended to be very high

Need for intervention

- Provide transparency in pricing, costs, acquisition, and contracting options
- Select a panel of manufacturers to enter into Framework Agreements to supply PRs both through PPM and through other procurement channels of GF grant recipients
- Provide inputs for defined, competitive, and transparent selection of viral load technologies by PRs
- Potentially include options for allocated or committed volumes based on aggregated forecast demand across GF PRs

1 The term and level of any commitment will follow the Global Fund evaluation of submitted proposals and subsequent second stage review
## Regulatory status of panel suppliers

<table>
<thead>
<tr>
<th>Supplier panel</th>
<th>Eligibility and Testing products</th>
<th>Technology approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO PQ</td>
<td>CE mark</td>
<td>VL, EID</td>
</tr>
<tr>
<td>WHO PQ</td>
<td>CE mark</td>
<td>EID</td>
</tr>
<tr>
<td>WHO PQ</td>
<td>CE mark</td>
<td>VL</td>
</tr>
<tr>
<td>WHO PQ</td>
<td>CE mark/WHO PQ</td>
<td>VL, EID</td>
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<tr>
<td>CE mark</td>
<td>CE mark</td>
<td>VL, EID</td>
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<tr>
<td>CE mark</td>
<td>CE mark</td>
<td>VL</td>
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<tr>
<td>WHO PQ</td>
<td>CE mark</td>
<td>VL, EID</td>
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<tr>
<td>WHO PQ</td>
<td>CE mark</td>
<td>VL</td>
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<tr>
<td>WHO PQ</td>
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<tr>
<td>WHO PQ</td>
<td>CE mark</td>
<td>VL</td>
</tr>
<tr>
<td>WHO PQ</td>
<td>CE mark</td>
<td>VL, EID</td>
</tr>
</tbody>
</table>
GF targets a range of credible, cost-effective, competitive options with more transparent pricing and contracting, which are broadly accessible to all

Achievements

<table>
<thead>
<tr>
<th>Leveraged volumes</th>
<th>▪ Enabled volumes to be leveraged and promoted maximum up-time and throughput</th>
</tr>
</thead>
</table>
| Transparent contracting | ▪ Guided new selection and establish contracting modalities and templates  
  ▪ Benchmarked existing arrangements with forward-applicability in many cases  
  ▪ Delivered framework contracts and transaction agreements |
| Transparent costing | ▪ Provided standardized costing enabling easier and more transparent decision-making  
  ▪ Provided clear cost build-up to Total Cost of Ownership for a more meaningful and fair comparison |
| Additional acquisition models | ▪ Provided options of different acquisition models (i.e., purchase and reagent rental)  
  ▪ Made available “reagent rental” from majority of suppliers that is comparable with the equivalent “all in” bottom up price – no/small “premium”  
  ▪ Identified various value-added solutions available  
  ▪ Introduced bundling approach |
| Broader supplier base | ▪ Included 2 new offerings for lab-based systems  
  ▪ Included 3 new entrants for lower throughput/near-Point-of-Care offerings  
  ▪ Established process for new entrants with a clear target for pricing and contracting |
| Global visibility | ▪ Enabled better global visibility and framework for performance management (rather than fragmented country-level) and sustained delivery  
  ▪ Included agreement to make key elements of this RFP “available” in the public domain including TCO calculations |
We introduced a HIV Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool

<table>
<thead>
<tr>
<th>Country scenario</th>
<th>Programming &amp; funding</th>
<th>RFP process/outcomes</th>
<th>Platform/technology selection</th>
<th>Pricing options</th>
<th>Contracting option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan to scale-up</td>
<td>Implementation plans</td>
<td>RFP objectives and process</td>
<td>Supplier panel</td>
<td>Total Cost of Ownership explanation</td>
<td>Comparison between options</td>
</tr>
<tr>
<td>Exploit new arrangements</td>
<td>Funding requests</td>
<td>RFP outcomes</td>
<td>Supplier information</td>
<td>VL – comparison</td>
<td>Supplier options</td>
</tr>
<tr>
<td>Procure and implement</td>
<td>Other guidance</td>
<td>Commercial results</td>
<td>Technical summary</td>
<td>EID – comparison</td>
<td>Key principles</td>
</tr>
</tbody>
</table>

NOTE: This tool is being continually updated and the latest version of this tool can be downloaded from https://www.theglobalfund.org/en/sourcing-management/health-products/viral-load-early-infant-diagnosis/. We welcome receiving any comments or suggestions - contact details are provided on the webpage link above.
wambo.org update

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Mathieu Courtois
The wambo.org vision

Wambo.org is built upon the vision of an online procurement platform which can tackle several challenges faced by PRs

An innovative online procurement platform with several important benefits

- **Search and compare** price and lead time across suppliers
- **Select** desired specifications, order terms and place order
- **Track and trace** requisition, direct payment
- **Easy reporting**, allowing for better, more specific forecasting

- **Reduces market complexity and need for intermediaries**
- **Decreases administrative burden**: for PPM PRs, automates PPM ordering
- **Acceleration of the procurement process**
- **PRs able to procure more efficiently**
wambo.org connects PRs to the best available sourcing options

**Products from multiple sources**

wambo.org ambitions to promote **best in class** LTAs and sourcing options, **internally** through the Global Fund or **through partners**, and make them available to its users.

- **Global Fund LTAs**
  - LLINs
  - ACTs and other anti-malarials
  - ARVs
  - Viral Load / EID

- **Outsourced LTAs**
  - Condoms & Lubricants (UNFPA)
  - Vehicles & Generators (UNOPS) *soon!*

- **Outsourced catalogues**
  - RDTs
  - Other diagnostics
  - Non-core pharmaceuticals
  - Laboratory supplies
  - Medical equipment

**POs transit through PSAs* (and equivalent)**

wambo.org issues Purchase Orders (POs) on behalf of its users to **PSAs** (and equivalent) who **cascade** them to the relevant manufacturers and logistics providers.

*PSA: Procurement Services Agent
All PPM transactions are now flowing through wambo.org

Launch of product categories

wambo.org has launched all of the product categories available to PRs through PPM at a careful pace and is now looking to expand to non-health through the UNOPS MoU and TB through the GDF MoU.

On-boarding of Global Fund PRs

wambo.org is available to nearly 700 users from 90 PR organisations in 56 countries. The Global Fund ran 8 regional workshops in 2016 to train and on-board these users: wambo.org is configured to the needs of each individual PR’s approval governance.

By the end of June 2017, all PRs historically ordering through the manual process had been on-boarded to wambo.org: all transactions are now electronic.

Spend on wambo.org by Category*

Since its launch in January 2016, over 300 POs have been processed through wambo.org for a total value of over $715 million.

*excludes impact of logistics costs, data January 2016 – September 2017
The Global Fund is taking wambo.org to the next stage and piloting the use of domestic funds

**Background**

In May 2017, the Board approved a **pilot** for the procurement through wambo.org of **10 purchase transactions using domestic funds**. Findings will inform the extension of wambo.org into Phase 2 beyond the Global Fund.

**Pilot scope**

- Only **government** PRs that are **currently PRs** (no NGO, only countries w/ active grants)
- Can purchase **any product available** on wambo.org
- **Upfront payment**
- Limit of 10 transactions
- Key caveats
  - Subject to manufacturers agreeing to extend price
  - May or may not go beyond pilot phase
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Responsible procurement
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Nick Jackson, Lin (Roger) Li
Partners, donors and other stakeholders expect GF to deliver a responsible procurement approach that supports the Sustainable Development Goals.

In 2015, countries gathered and committed to end poverty, protect the planet and ensure prosperity for all.

Increasingly, partners and donors are requesting guarantees for social and environmental responsibility in procurement.

SOURCE: WHO; Team analysis
GF is on a journey to build a holistic responsible procurement approach

### Dimensions

<table>
<thead>
<tr>
<th>Approach</th>
<th>What we have achieved</th>
<th>What we want to attain</th>
</tr>
</thead>
<tbody>
<tr>
<td>GF addressed responsible procurement reactively through specific ad hoc cases</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Guidelines

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>What we have achieved</th>
<th>What we want to attain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidelines created by initiative in specific cases (e.g., Artemisinin; Supplier Code of Conduct) but not holistic codification</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GF proactively employs a responsible procurement approach tailored to its end-to-end value chain with 4 dimensions: economy, ecology, society and business practices.

GF intends to build responsible procurement guidelines by leveraging existing ones.

SOURCE: Team analysis
GF plans to define a tailored, holistic responsible procurement approach across 4 elements

**Dimensions**

- **Economy**
  - Provide additional economic benefits to in-country community
  - Empower community by sharing knowledge

- **Ecology**
  - Mitigate effect on environment along the end-to-end supply chain
  - Use knowledge and skills to contribute to a constant rise in eco-efficiency

- **Society**
  - Promote fundamental human rights, e.g.,
    - Advocate for decent labor conditions
    - Promote children rights
  - Promote workers’ health and safety

- **Business practices**
  - Promote best business practices among suppliers and other buyers

**Principles to build holistic standards**

- Build on existing guidelines
- Provide practical guidance
- Include phased approach
- Focus on procurement
- Align with GF objectives

SOURCE: Adapted from corporate responsibility’s framework by Crane et al, 2014
GF has addressed each dimension of responsible procurement’s framework through a case-by-case approach

<table>
<thead>
<tr>
<th>Dimension addressed</th>
<th>Case examples</th>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
</table>
| LLINs               |               | ▪ LLINs manufacturing countries have weak regulators’ focus on textile  
▪ Plastics and insecticides used for LLINs present high chemical risks for environment  
▪ Historical reputational issues related to corruption, environment and disposal | ▪ GF mandated social and environmental assessment by a 3rd party in 2015 for 7 LLIN production sites in 3 countries  
▪ GF provided action plans for each site assessed to implement environmental and labor regulations |
| Artemisinin         |               | ▪ Agricultural artemisinin prices are volatile due to:  
  – Overproduction capacity because of low technical barrier to entry  
  – Lack of harmonized quality standards  
▪ Agricultural artemisinin price volatility causes supply interruptions to ACT suppliers | ▪ GF mitigated artemisinin price volatility by visiting upstream agricultural artemisinin producers:  
  – GF conducted agricultural artemisinin manufacturer qualification through 3rd party  
  – GF incentivized best practices among manufacturers by offering 3 years allocation |
| ARV                 |               | ▪ 40% GF procured ARV products were shipped by air in 2014 during spot tenders  
▪ Poor performing suppliers lobby when loosing volumes | ▪ GF included in suppliers’ tenders quarterly ARV allocation. As a result, 85% of ARV volume is shipped by ocean in 2016 |

SOURCE: Team analysis
Partner and donor organizations have raised concerns about responsible procurement which GF has addressed through several initiatives.

- GF introduces the supplier code of conduct
- GF addresses LLIN ecological concerns through its anti-malaria strategy
- GF starts risk assessment per product category
- GF appoints its first ethics officer
- GF signed the Joint Intergency Statement for sustainable procurement
- GF joined the SPHS\(^1\) task team on sustainable procurement
- DFID raised concerns about LLINs misuse
- GF sign contribution agreement with Norway on eco-footprint

\(^1\) SPHS: Sustainable Procurement in the Health Sector

SOURCE: WHO
GF will continue to work hand in hand with partner organizations towards delivery of sustainable procurement

**Stepping stones going forward**

- Gather and address inputs from partner organizations
- Refine holistic responsible framework based on best practices
- Build resilience to lobbying and promote best business practices
Contents

- Welcoming and introductory remarks
- Market Shaping Strategy: Vision and Progress
- Category Highlights
- Responsible Procurement
- **Provision of Market Information**
  - Quality Assurance
  - Tuberculosis Market
  - Material for breakouts
  - Wrap-up
Provision of Market Information

Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Nick Jackson, Rod Carlton (Freshfields)
**WHY:** Sharing information is critical to building healthy markets

**Market shaping process**
- Understand
- Shape
- Monitor

**Importance of mutual information sharing**
- Use data for operational and strategic decision-making
- Enable diagnosing market dynamics challenges and identifying opportunities for improvement
- Increase visibility on market to strengthen competition, and reduce prices/price volatility
- Enable partners and recipients
- Monitor and control utilization of GF funds with respect to price, product and service quality
- Establish impact and “value for money”

---

*Data is the “essential foundation of sound market dynamics and procurement practices”*

*“Disclosure of information (...) is a matter of principle and will facilitate a process leading to lower prices”*
**WHAT:** GF aims to share with each recipient data that is crucial to them

### Recipients of market information

<table>
<thead>
<tr>
<th>Key dimensions</th>
<th>Manufacturer</th>
<th>Partner organisation and other buyers</th>
<th>PRs / countries</th>
</tr>
</thead>
</table>
| **Objective**  | ▪ Healthy supply structures  
▪ Innovation and uptake of new products  
▪ Demand data and prediction  
▪ Procurement pathways  
▪ Eligibility  
▪ Benchmark pricing | ▪ Standardized and aligned market practices/strategies  
▪ Healthy markets  
▪ Market intelligence  
▪ Risk identification  
▪ Supply chain logistics best practices  
▪ Supplier assessment | ▪ Availability and affordability of products  
▪ Capability and capacity building  
▪ Pre-negotiated price lists for budgeting/benchmarking  
▪ Selected and quality assured product selection  
▪ Best practice supplier interaction/assessment  
▪ Specifications/alternative products, incl. view on total cost |
| **Types of information to share** | | | |
| **Modes of information sharing** | | | |

*Tailored channel mix, incl. PQR, standard market intelligence and on-demand information*

**SOURCE:** Team analysis
**HOW: GF employs 3 key channels for information sharing**

<table>
<thead>
<tr>
<th>Key channels</th>
<th>Status quo</th>
<th>Benefits</th>
<th>Mid-term opportunities</th>
<th>Long-term vision</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selected</strong></td>
<td><strong>Description</strong></td>
<td><strong>Benefits</strong></td>
<td><strong>Refine value proposition for the needs of 2017</strong></td>
<td><strong>Create fully transparent markets to generate healthy structures and fierce competition</strong></td>
</tr>
<tr>
<td>PQR</td>
<td>Public database</td>
<td>Sharing of price data, benchmarks, and forecasting</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Transaction-level procurement data</td>
<td>Potential identification of “value for money” opportunities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard market intelligence</td>
<td>Set of regularly updated, standardized reports, e.g., tender outcomes, strategy documents, and reference prices</td>
<td>Broad spectrum of high-level market intelligence</td>
<td>Collaborate with partners to provide broader perspective</td>
<td>Provide pre-processed market intelligence to cater for a variety of needs and increase visibility and awareness for the broader public</td>
</tr>
<tr>
<td><strong>On demand</strong></td>
<td>Solicited information sharing</td>
<td>Needs-based in-depth provision of information</td>
<td>Define clear principles for evaluating requests</td>
<td>Enable partners by ensuring that market shaping never fails due to the inaccessibility of available information</td>
</tr>
<tr>
<td></td>
<td>Provision based on legitimate needs</td>
<td>High relevance due to tailoring to specific context/circumstances</td>
<td>Develop joint platform/mechanism to institutionalize sharing</td>
<td></td>
</tr>
</tbody>
</table>

**SOURCE:** Team analysis
Information sharing is constrained from 3 angles:

- Information that could distort markets might violate antitrust law
- IP law or contractual obligations set further constraints
- GF will always “better be safe than sorry” and prudent in information sharing

Safeguard GF’s reputation

- A trusted source of reliable information
- Both market and stakeholders place high expectations in the quality and relevance of intelligence provided by GF
- Credibility is crucial for GF to be taken seriously in the market and remain a trusted partner

Uphold high ethical standards

- Stakeholders place high trust in GF
- Trust- and loyalty-based relationships are the foundation of GF’s ability to shape markets in the long-term
- GF will protect confidences and share information only to the extent that does not infringe upon legitimate stakeholder interests

Ensure rigorous compliance with applicable regulations and obligations

- Information that could distort markets might violate antitrust law
- IP law or contractual obligations set further constraints
- GF will always “better be safe than sorry” and prudent in information sharing

Credibility

- Stakeholders place high trust in GF
- Trust- and loyalty-based relationships are the foundation of GF’s ability to shape markets in the long-term
- GF will protect confidences and share information only to the extent that does not infringe upon legitimate stakeholder interests

Regulation

- Information that could distort markets might violate antitrust law
- IP law or contractual obligations set further constraints
- GF will always “better be safe than sorry” and prudent in information sharing

Ethics

- Stakeholders place high trust in GF
- Trust- and loyalty-based relationships are the foundation of GF’s ability to shape markets in the long-term
- GF will protect confidences and share information only to the extent that does not infringe upon legitimate stakeholder interests

SOURCE: Team analysis
A set of key principles aims to maintain GF’s integrity and credibility

<table>
<thead>
<tr>
<th>Principles</th>
<th>Examples of “don’ts”</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uphold highest data quality</td>
<td>▪ Share un-validated raw data</td>
<td>▪ Increase level of confidence by sharing only validated, cross-checked and consolidated data</td>
</tr>
<tr>
<td>Stay within GF’s mandate</td>
<td>▪ Make commitments on behalf of others</td>
<td>▪ Set clear boundaries to ensure conformity with relevant guidelines and policies</td>
</tr>
<tr>
<td>Maintain credibility</td>
<td>▪ Give ad-hoc commentary on market dynamics</td>
<td>▪ Do not share premature insights</td>
</tr>
<tr>
<td>Safeguard legitimate stakeholder interest</td>
<td>▪ Provide manufacturer technical and commercial information</td>
<td>▪ Protect confidences and trust-based relationships with all stakeholders</td>
</tr>
<tr>
<td>Ensure compliance</td>
<td>▪ Share data protected by NDAs or law (e.g., IP, antitrust sensitive data)</td>
<td>▪ Uphold zero-tolerance policy towards breaches of law or contractual obligations</td>
</tr>
</tbody>
</table>

SOURCE: Team analysis
Key principles that GF will need to bear in mind

<table>
<thead>
<tr>
<th>Key principles</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whether exchanging information is permissible will depend upon the type of</td>
<td>▪ Public/confidential?</td>
</tr>
<tr>
<td>information requested</td>
<td>▪ Historic/forward-looking?</td>
</tr>
<tr>
<td></td>
<td>▪ Aggregated/anonymised?</td>
</tr>
<tr>
<td></td>
<td>▪ Relating to prices/volumes?</td>
</tr>
<tr>
<td></td>
<td>▪ What was the purpose of the information disclosure?</td>
</tr>
<tr>
<td></td>
<td>▪ Was the information solicited? (NOTE: There is a presumption of usage)</td>
</tr>
<tr>
<td></td>
<td>▪ Is the information confidential? Is there an NDA?</td>
</tr>
<tr>
<td></td>
<td>▪ What is the purpose of the request?</td>
</tr>
<tr>
<td></td>
<td>▪ Are safeguards necessary to protect the data?</td>
</tr>
<tr>
<td></td>
<td>▪ Was the information requested during a tender process?</td>
</tr>
<tr>
<td></td>
<td>▪ Could a hub-and-spoke arrangement be in operation?</td>
</tr>
</tbody>
</table>
It is crucial to understand the potential impact of the information on the market.

Could the information exchange impact on key parameters of competition?

- Price
- Product quality
- Product variety
- Innovation
- Quantity

Source: Team analysis
Contents

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**Quality Assurance**
- Tuberculosis Market
- Material for breakouts
- Wrap-up
Quality Assurance

Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Alain Prat; Lin (Roger) Li
GF strives to evolve to further promote consistent quality standards

### Strategic priorities
- Break-down information barriers to increase patient safety
- Improve setup and enlarge leeway to effectively act-upon quality-relevant information

### Mission
- **Uphold consistent quality standards** for health products
- **Leverage position** as a large financing institution to promote international collaboration

### Vision
- **Medicines/technologies are available at an internationally-recognized standard** of quality
- There is **reliable and timely information** on the quality of the product

Source: GF
GF has already attained significant achievements in Quality Assurance

**What we have done**
- Evolved QA policies to shape market
- Managed ERP\(^2\) process with partners
- Refined understanding of marketed products
- Improved visibility on patients’ safety (incl. better and more timely information)
- Mitigated risk of quality issues

**What we have achieved**
- Increased and refined toolkit\(^1\)
- Accelerate access to >40 innovative products
- Improved ability to identify and act upon signals from the market
- Actively managed quality risks

**What opportunities remain**
- Play more (pro-)active role in Quality Assurance
- Facilitate sharing of information
- Integrate multiple stakeholder approaches
- Refine and act upon own QA risk appetite

---

\(^1\) E.g., PSM guide
\(^2\) Expert Review Panels

Source: GF
Further reducing patient risk is impeded by different challenges observed in the Quality Assurance ecosystem.

### Quality assurance ecosystem

- **Robust regulatory authorities**
- **Pre-qualification, Market Authorizations, variations**
- **Manufacturers**
- **International financing channels**
- **Post-market assurance**
- **Sharing of information**
- **National authorities**

### Challenges observed, selected

1. **Limited capacities of countries** to generate adequate information in a timely manner.
2. **Insufficient information quantity and quality from the field** for RRA authorities to effectively act upon.
3. **Current setup constraining ability to fully act upon quality issues observed**.
4. **Manufacturers informing predominantly RRA authorities** and only partially countries on quality-relevant issues.
5. **Limited sharing of information between countries and stakeholders**.

---

Source: GF
There are multiple levers for GF to tackle challenges and further improve safety of patients

**Nature of GFs involvement**

**Play catalytic role**

1. **Foster in-country capacity** to ensure generation of quality-relevant data/information
   a) Leverage external resource partners
   b) Structure GF financing for increased coherence

2. **Systemize and structure information sharing mechanisms** to accelerate and increase actionability

3. **Refine policies to enable application of own risk assessments**
   a) Clarify GF’s position to employ own risk appetite
   b) Formalize process for decision making

4. **Extend rigorous information loop** to all national authorities, facilitate information flow

5. **Pool and leverage resources, knowledge, and data** of GF and other organizations by sharing of regulatory data with key stakeholders (e.g., PRs)

**Engage (pro-) actively**

Source: GF
Key takeaways

**Situation**
- GF has **contributed to the reduction of patient risk** through its continuous efforts in Quality Assurance
- There **remain opportunities to further mitigate risk** and play a more proactive role in the quality ecosystem

**Challenges**
- Effective Quality Assurance relies on an **ecosystem of multiple stakeholders**
- **Key challenges observed** relate to the **flow of information/data** within the ecosystem as well as the comprehensive integration and **leveraging of stakeholder** aspirations to the benefit of Quality Assurance

**Opportunities**
- GF continues to play a **catalytic role and instigates measures to facilitate and improve information flow** within the Quality Assurance ecosystem
- Further, GF envisions to **actively be part of the solution**, e.g., by **partaking in pooling and sharing** of resources and information

Source: GF
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Playback of breakout-sessions

1. Leveraging Impact
2. New Product Introduction
3. Total Cost Approach
Breakout: Leveraging impact

Sourcing Strategic Review Meeting, Montreux, 16/17 October 2017

Mariatou Tala Jallow; Melisse Murray
Leveraging impact at a glance

<table>
<thead>
<tr>
<th>What is this?</th>
<th>SMART(^1) and effective collaboration, including leveraging volumes between TGF, international financing partners and public health bodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why this is relevant?</td>
<td>Collaboration can enable significant additional impact on the journey to create healthy markets</td>
</tr>
<tr>
<td>Where the challenge is?</td>
<td>Identify, prioritize and seize opportunities for collaboration while maintaining focus and respecting resource constraints</td>
</tr>
<tr>
<td>How it matters to partners?</td>
<td>SMART coordination offers the opportunity to get the most of existing resources, incl. leveraging TGF’s benefits</td>
</tr>
</tbody>
</table>

Source: Team analysis  1 Specific Measurable Achievable Realistic Timebound
Our journey

<table>
<thead>
<tr>
<th>What we have achieved</th>
<th>Where we want to get</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Greatly improved <strong>affordability and availability</strong> through leveraging of pooled volumes, e.g., 38% reduction in LLIN prices since 2014</td>
<td>- Sustaining of impact achieved while <strong>extending framework agreements</strong>, <strong>direct engagement</strong> and information sharing to/with further suppliers</td>
</tr>
<tr>
<td>- <strong>Healthier markets</strong> through collaboration and benefit sharing, e.g., extension of framework agreements to additional geographies, incl. Georgia</td>
<td>- Strengthened impact leveraging of non PPM ecosystems, e.g., through <strong>information sharing, coordination and collaboration</strong>, joint procurement solutions</td>
</tr>
<tr>
<td>- <strong>Strong partner relationships</strong>, incl. collaboration, co-investments and benefit sharing leading to tangible impact, e.g., collaboration with PAHO, PEPFAR, South African government</td>
<td>- Strengthened impact leveraging within international ecosystems, e.g., through <strong>improving coordination, increasing visibility</strong>, developing strategic sourcing</td>
</tr>
</tbody>
</table>

Source: Team analysis
Through collaboration we can unlock significant benefits and deliver on the Market Shaping Strategy.

**Sources:** Estimates based on Institute of Health Metrics and Evaluation; UNAIDS report on global AIDS epidemic 2013; Global Tuberculosis Report 2013; World Malaria Report 2013; TGF; extreme scenarios excluded.
Collaboration across all of these areas delivers benefits for markets and beneficiaries

**TGF**
- Extend benefits through synergies and economies of scale in order to increase impact through collaborative initiatives
- Leverage larger data volumes and information pools to capture network and learning effects by sharing information with partners
- Better root/embed impact in countries

**International financing**
- Collaborate and use TGF’s momentum to extend benefits to larger volume
- Capture network and learning effects

**Total public health spend**
- Receive broader scope of support and synergies between different kinds of support, e.g., tap into health worker training and networks
- Share experiences, best practices, information and tools with other public health systems

**Health markets**
- Sustain and develop healthier markets, e.g., stable supply structures and predictable demand
- Improve market shaping interventions through synergies, e.g., end-to-end support through partners with different lifecycle focus

**Beneficiaries**
- Benefit from increased availability and affordability of existing and new products, i.e., better coverage, higher OTIF, and more innovation
- Benefit from better access to more products on key diseases

Source: Team analysis
The nature and focus of partnerships will vary by category depending on the existing level of collaboration.

<table>
<thead>
<tr>
<th>Level of collaboration</th>
<th>Strategic priorities</th>
<th>Examples</th>
<th>Insights</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Gain visibility</td>
<td></td>
<td>• Depending on the stage of the market in terms of level of collaboration, different levers have the potential to increase impact</td>
</tr>
<tr>
<td></td>
<td>on procurement practice and planning</td>
<td></td>
<td>• Both degree and focus of collaboration/mutual impact leveraging should be tailored to specific level of collaboration</td>
</tr>
<tr>
<td>2</td>
<td>Coordinate</td>
<td></td>
<td>• TGF seeks to collaborate with the right partners at the right point in time to achieve optimal results</td>
</tr>
<tr>
<td></td>
<td>tender cycle and timeline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Align principles</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>of performance-based procurement approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Join/pool</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>procurement practice</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Examples:
- **Gain visibility**: UNICEF, PMI
- **Coordinate**: PEPFAR, South Africa
- **Align principles**: E.g., Kenya/Ethiopia/UNDP and other non-PPM country procurement
- **Join/pool**: PAHO

Source: Team analysis
### Strategic initiatives and activities

<table>
<thead>
<tr>
<th>Partners</th>
<th>Examples of initiatives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TGF</strong></td>
<td>▪ Continue to drive the <strong>extension of framework agreements</strong> to further categories&lt;br&gt;▪ Advance <strong>direct engagement and sharing of information uniformly with suppliers</strong></td>
</tr>
<tr>
<td><strong>PPM</strong></td>
<td>▪ Drive <strong>visibility into current demand and procurement practices</strong>&lt;br&gt;▪ <strong>Coordinate approach</strong>, e.g., when to tender, go-to-market timings&lt;br&gt;▪ Encourage and facilitate <strong>sharing of best practices</strong>&lt;br&gt;▪ Enter into <strong>joint procurement</strong>&lt;br&gt;▪ Improve <strong>access to innovative products through procurement solutions</strong>, i.e., generate visibility on demand, identify demand levers, explore procurement solutions (e.g., bundling, catalytic funding, leveraging existing supplier relationships)</td>
</tr>
<tr>
<td><strong>Non-PPM</strong></td>
<td>▪ Improve <strong>visibility into current demand and procurement practices</strong>&lt;br&gt;▪ <strong>Coordinate approach</strong>, e.g., when to tender, go-to-market timings&lt;br&gt;▪ Facilitate <strong>development of strategic sourcing</strong>, e.g., further drive initiatives to improve OTIF and quality metrics&lt;br&gt;▪ <strong>Secure supply and mitigate price volatility</strong> on emerging, declining and low volume/fragmented products&lt;br&gt;▪ <strong>Coordinate with other major buyers</strong> on provision of upstream demand forecasts in order to generate secure supply and minimize price volatility&lt;br&gt;▪ Continue to <strong>promote product standardization and quality</strong> as part of Innovation to Impact, e.g., establish clear normative guidelines on policy, co-ordinate buyers to streamline inputs to suppliers</td>
</tr>
<tr>
<td><strong>International financing</strong></td>
<td><strong>Initiatives broken down to:</strong>&lt;br&gt;▪ Disease areas (Malaria, HIV, TB)&lt;br&gt;▪ Stakeholders (e.g., PRs, partners)</td>
</tr>
</tbody>
</table>
Instructions for exercise: opportunities for collaboration

**Objective:** Identify additional preliminary opportunities to mutually leverage impact with TGF

**Instructions:**

1. There are post-its at your disposal. Each post-it signifies 1 opportunity you see to collaborate with TGF

2. Write each of the opportunities you see as well as your organization on a post-it and stick it onto the poster

3. The color stands for the impact potential you expect the opportunity to have:
   - High impact
   - Medium impact
   - Low impact

Source: Team analysis
Exercise: Opportunities for collaboration

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Information sharing             | ▪ Pool resources and information  
                                 |   ▪ …                                                                      |
| Capability/capacity building    | ▪ Integrate activities to use synergies  
                                 |   ▪ Utilize economy of scale  
                                 |   ▪ …                                                                      |
| Supplier management approach    | ▪ Align supplier management approach and metrics  
                                 |   ▪ Share best practices across volumes  
                                 |   ▪ …                                                                      |
| Mechanisms and contracts        | ▪ Build and strengthen automatisms to extend beneficiary conditions  
                                 |   ▪ …                                                                      |
| Other ideas                     | ▪ …                                                                      |

Source: Team analysis
Breakout: Total Cost approach

Sourcing Strategic Review Meeting, Montreux, 16/17 October 2017

Lin Roger Li; Nathan Vasher
# Total Cost approach at a glance

<table>
<thead>
<tr>
<th>What is this?</th>
<th>An estimate of <strong>the direct and indirect costs involved in acquiring, shipping, operating and disposing of a product from the moment the demand is logged until the product has been delivered to the point of care</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Why this is relevant?</td>
<td>Looking systematically at all cost buckets at each stage of the end-to-end value chain will <strong>generate significant benefits</strong> (incl. savings, supply chain, social, environmental benefits) that will empower country capability and enable achievement of SDGs</td>
</tr>
<tr>
<td>Where the challenge is?</td>
<td>Allocation and optimization of each cost bucket for each product and stage of the value chain requires <strong>SMART coordination with partner organizations</strong> to generate highest benefits while maintaining highest product quality</td>
</tr>
<tr>
<td>How it matters to partners?</td>
<td><strong>SMART coordination</strong> and sharing of information among partners is needed to <strong>maximize savings/supply chain/environmental/social benefits for all partners</strong></td>
</tr>
</tbody>
</table>

Source: Team analysis

1 Specific Measurable Achievable Realistic Timebound
TGF’s approach to analyzing cost has progressed through 3 horizons, towards a Total Cost approach tailored to the TGF value-chain.

**Phase 1 – Unit cost plus initial total cost considerations**
- Product unit cost negotiation with potential suppliers
- Broader mindset adopted in selected instances
- Transport/logistics costs and shelf lives factored-in in some procurement decisions (e.g., pharmaceuticals)

**Phase 2 – Holistic TC¹ approach tailored to GF value-chain**
- Tailored Total Cost approach to TGF value chain
- End-to-end mapping of the value chain including HTAs (e.g., LLINs)
- Identification of immediate actions to unlock value
- Selection of key themes/products for long term development of TC reduction (e.g., viral load)

**Market Shaping Strategy**

---

¹ Total Cost approach is defined as "an estimate of all the direct and indirect costs involved in acquiring, shipping, operating and disposing of a product from the moment the demand is logged until the product has been delivered to the point of care"

Source: Team analysis
Our journey

What we have achieved

- Significant **value unlocked at unit price level**, e.g., 38% reduction in LLIN price since 2014

- **Ad hoc extension of analysis beyond unit price** to inform decision making, e.g., changed lab warranty agreement in an African country, which generated ~0.3 mn $ cartridge savings over 5 years

Where we want to get

- Unlock **additional value** through end-to-end total cost analysis and valuing enhanced specifications

- **Identification of value creation levers** through:
  - **Implementing innovative sourcing approaches**, e.g., improving supplier sourcing strategies and demand forecasting
  - **Capturing potential savings in the supply chain**, e.g., optimizing packaging and transports/logistics

Source: Team analysis
**A total cost approach could deliver benefits, incl. ~5% of product value**

<table>
<thead>
<tr>
<th>Examples of initiatives</th>
<th>Description</th>
<th>Case example</th>
<th>Examples of potentials benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve forecasting</td>
<td>▪ Predict future TGF demand (quantitative, qualitative, variations) to tailor supply accordingly</td>
<td>▪ A manufacturer of the highest volume product proposed to reduce its price by 10% if demand and supply were optimized (e.g., volume, freight)</td>
<td>▪ Negotiation power to discuss unit prices with suppliers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Potential 10% unit price reductions</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Up to 2-3% of product cost through more efficient freight</td>
</tr>
<tr>
<td>Optimize lab equipment selection and maintenance agreements</td>
<td>▪ Reduce total cost of test through decreased down time</td>
<td>▪ Changing warranty agreement for 1 type of lab machine in 1 African country generated 295,000 USD savings over 5 years</td>
<td>▪ Higher testing availability</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Decrease loss to follow-up</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Better informed treatment decisions</td>
</tr>
<tr>
<td>Optimize packaging and labelling</td>
<td>▪ Leverage bar-coding to drive efficiencies in the full supply chain</td>
<td>▪ A supplier of pharma products unlocked 20% of total shipping cost by increasing number of bottles per boxes (case study)</td>
<td>▪ Increase production/supply flexibility and responsiveness</td>
</tr>
<tr>
<td></td>
<td>▪ Use low cost / environment friendly materials for packaging; avoid unnecessary packaging</td>
<td></td>
<td>▪ Reduce quantity of paper/plastic used to decrease carbon footprint</td>
</tr>
<tr>
<td></td>
<td>▪ Leverage further multi-month packs and drive shelf life improvements</td>
<td></td>
<td>▪ Decrease freight cost equivalent to 2-3% of product cost (opportunity will increase with new ARV regiments)</td>
</tr>
<tr>
<td></td>
<td>▪ SKU standardization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sourcing closer to demand</td>
<td>▪ Locate strategic sourcing options close to demand</td>
<td>▪ Sites located in East Africa supplying ACTs and LLINs under framework agreements</td>
<td>▪ More responsive supply at no additional total cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>▪ Enabling of response to emergency orders due to short lead times (6 down to 2 weeks)</td>
</tr>
<tr>
<td>Optimize storage</td>
<td>▪ Minimize overall volume of stored product to reduce temporary warehouse volume</td>
<td>▪ Significant cost saved for 700 sq meter temporary warehouse</td>
<td>▪ Reduce overall volume of stored products</td>
</tr>
<tr>
<td></td>
<td>▪ Minimize cost of temporary warehouse solution (e.g., rental cost, number of warehouses in an area)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Team analysis
For the long term, there are 5 areas for the sourcing team to investigate:

<table>
<thead>
<tr>
<th>Area</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Improve demand forecasting in order to unlock value from the upstream supply chain as well as improve supply security and reduce lead time.</td>
</tr>
<tr>
<td>b</td>
<td>Employ lean management approach all along TGF end-to-end-value chain to continuously improve process efficiency at each step of the value chain while reducing cost.</td>
</tr>
<tr>
<td>c</td>
<td>Engage in relationship management with suppliers, especially working hand-in-hand to jointly co-create/generate product innovation.</td>
</tr>
<tr>
<td>d</td>
<td>Structure approaches to meet tradeoffs between multiple objectives, e.g., benefits through enhanced relationship with selected suppliers vs. protection of supply structures.</td>
</tr>
<tr>
<td>e</td>
<td><em>Push the boundaries: evaluate contract manufacturing</em> (long term, for discussion).</td>
</tr>
</tbody>
</table>

Source: Team analysis
Instructions for breakout

**Objective:** Identify Total Cost initiatives

**Instructions:**

1. On the poster are examples of **Total Cost initiatives**
2. Please write on post-its **how your organization could contribute to realizing the initiatives**. The color of the post-it signifies the level of impact you expect.
3. Stick your **post-its onto the poster**
4. If you have **ideas for additional initiatives**, please put them onto the “Others”-box on the bottom-right

- High impact
- Medium impact
- Low impact

Source: Team analysis
<table>
<thead>
<tr>
<th>Improve forecasting</th>
<th>Get sourcing closer to demand</th>
<th>Optimize packaging and labelling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consolidate demand over time</td>
<td>Optimize storage</td>
<td>Jointly generate innovation</td>
</tr>
<tr>
<td>Employ lean approach</td>
<td>Optimize lab equipment &amp; maintenance agreement</td>
<td>Others</td>
</tr>
<tr>
<td>Example of initiative</td>
<td>Definition</td>
<td>Initiative</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td>Improve forecasting</td>
<td>- Predict future demand (e.g., quantitative, qualitative, seasonal/ regional variations)</td>
<td>Get sourcing closer to demand</td>
</tr>
<tr>
<td>Consolidate demand over time</td>
<td>- Gather orders over a determined period of time to optimize mean of transport</td>
<td>Optimize packaging and labelling</td>
</tr>
<tr>
<td>Employ lean approach</td>
<td>- Employ lean management approach all along end to end value chain to improve process efficiency while reducing cost</td>
<td>Optimize lab equipment selection &amp; maintenance agreement</td>
</tr>
<tr>
<td>Optimize storage</td>
<td>- Minimize overall volume of stored product</td>
<td>Jointly generate innovation</td>
</tr>
</tbody>
</table>

Source: Team analysis
Breakout: New product introduction

Sourcing Strategic Review Meeting, Montreux, 16/17 October 2017

Martin Auton; Azizkhon Jafarov
## New product introduction at a glance

<table>
<thead>
<tr>
<th>What is this?</th>
<th>Fostering an environment that supports the development and accelerates the uptake of innovative/cost effective products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why this is relevant?</td>
<td>Innovation can help ensure fundamental long-term progress in disease mitigation and eradication, to which all of us can make a significant contribution</td>
</tr>
<tr>
<td>Where the challenge is?</td>
<td>Stakeholder collaboration is required to navigate the trade-offs between increasing access to superior health products and maintaining affordability</td>
</tr>
<tr>
<td>How it matters to partners?</td>
<td>Finding the optimal mode of collaboration, building on each partner’s mandate, value proposition, strengths and resources</td>
</tr>
</tbody>
</table>

Source: Team analysis
Our journey

### What we have achieved

- **Case-by-case support to innovators** focused on facilitation and engagement with partners under constraint not to commit volumes, e.g., DTG

- **Engaged cooperation of multiple internal stakeholders**, e.g., Sourcing, Grant Management, SIID and PRs

- **Organically evolving collaboration** with >18 partners leading to tangible impact (e.g., reduction of DTG introduction time from 10 to 5 years), heavy dependency on setup and context

### Where we want to get

- **End-to-end support**, employing comprehensive toolset of interventions and making full use of TGF’s unique position within its mandate in spirit of full collaboration

- **Full internal collaboration** with **clear delineation of responsibilities** and assignment of ownership (particularly on demand)

- **Principle-based, purposeful shaping of collaboration** ensuring smooth processes, incl. terms of engagement delineating roles/responsibilities and assigning ownership

- **Clear, communicated and recognized value proposition** of TGF facilitating realistic expectations

Source: Team analysis 1 Dolutegravic 2 Strategy, Investment and Impact Division
Engagement in product innovation requires collaboration

**Policy Development**

- Collaborate with partners in smooth product-introduction and scale-up
- Ensure adequate approval and endorsement of products by key authorities and guidelines (e.g., countries, WHO)
- Increase market transparency and decrease originator risk
- Fuel both fundamental and incremental innovation

**Product uptake**

- Support introduction and adoption of new products identified as high priorities from a public health perspective
- Foster environment that supports innovation with financing mechanisms, technical/development parties and countries
- Boost adoption of the most cost effective products, formulations, and presentations

**Insights**

- Encouraging and fostering innovation implies support before and after launch
- TGF’s engagement in innovation is a two way street in terms of information flow

**Objectives of support**

- Enable preparation for future uptake
- Give information on pipeline and upcoming developments

Source: Team analysis
<table>
<thead>
<tr>
<th>Key objectives</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incentivize and facilitate research and development</td>
<td>▪ Ensure adequate and timely pipeline of products</td>
</tr>
<tr>
<td></td>
<td>▪ Develop and harmonize policies</td>
</tr>
<tr>
<td>Develop, sustain, and secure supply</td>
<td></td>
</tr>
<tr>
<td>Foster adoption and uptake</td>
<td></td>
</tr>
<tr>
<td>Facilitate transition/switching</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Relevance along product lifecycle

<table>
<thead>
<tr>
<th>R&amp;D</th>
<th>Grow</th>
<th>Maturity</th>
<th>Decline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Significant impact has been achieved along the product lifecycle.

**Key partners**
- Unitaid
- FIND
- PATH
- DNDi
- MRC
- WHO
- USAID
- Win-Win Win-Win

**Activities**
- Early and proactive engagement together with partners
- "Being at table" and alignment of expectations
- Support with regulatory pass ways
- Successful support of innovation and launch of products without having to commit to volumes
- Acceleration of introduction
- Technical inputs
- Recommendations and commercial information
- Leveraging of relationships, incl. PRs
- Provision of negotiation support
- Extension of framework agreements
- Identification of potentially interested countries to induce demand
- Establishment of contact with countries
- Leveraging of volumes and relationships, incl. PRs
- Increase in access to formerly too expensive products
- Price reductions
- Support in development of exit strategies
- Sustenance and stabilization of supply structures

**Impact**

Source: Team analysis
A series of frequent challenges are faced as the global community aims to support new production introduction and development.

<table>
<thead>
<tr>
<th>Types of challenges</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Internal**        | - Objectives and priorities not fully aligned across different departments/divisions (GM, TAP, PSE, Sourcing, etc.) impeding adoption of new measures, e.g., trade-offs between generation of savings and investment in new products  
- Limited ability of **Sourcing to shape in country demand**  
- **No single point of contact** at TGF for key processes, e.g., demand aggregation |
| **External**        | - **Lack of demand visibility** driven by unclear funding availability inhibits investment decisions  
- Supply side **interventions that do not factor in future demand or procurement approaches**  
- Program **switching costs inhibit rapid scale-up** of new products  
- **Lengthy policy waterfalls and regulatory approvals** limit academic demand from becoming actualized |
| **Supply**          | - **Lack of end-to-end coordination** on ongoing interventions  
- **Sustainable procurement approaches** may not be utilized during intervention, design and implementation phases  
- **Misalignment of expectations for roles/responsibilities** for future interventions |
| **Demand**          | - **Lack of end-to-end coordination** on ongoing interventions  
- **Sustainable procurement approaches** may not be utilized during intervention, design and implementation phases  
- **Misalignment of expectations for roles/responsibilities** for future interventions |

Source: Team analysis
There are multiple opportunities along the product lifecycle to foster innovation.

**Focus of today**
- Address long lead-time and poor delivery performance
  - Early engagement
    - Lack of clarity for investment
  - Competitive cost
    - Recover from investment and growth
  - Deliver sustainability: mitigate price volatility and secure supply
    - Brutal competition
    - Ethical exit plan

**Potential levers**
- Leverage future demand
- Reward innovators
- Share commercial information / forecasting / scenario perspective with originators
- Counsel product development partnerships (PDP) and other partners
- Engage with partners/PDP to include supplier metrics early in pipeline
- Leverage relationships with partners and PRs to support pick-up of demand

**Manufacturers**
- Leverage volumes to reduce price (and price volatility) as well as secure supply and stabilize supply structures
- Help originators / suppliers forecast sales erosion and foresee market development
- Leverage supplier relationships, partners and recipients to smoothen exit and stabilize supply structures

**Buyers**
- Leverage future demand
- Reward innovators
- Share commercial information / forecasting / scenario perspective with originators
- Counsel product development partnerships (PDP) and other partners
- Engage with partners/PDP to include supplier metrics early in pipeline
- Leverage relationships with partners and PRs to support pick-up of demand

Source: Team analysis
Instructions for exercise: improving collaboration

**Objective:** Identify opportunities to improve collaboration to support new innovative product development/uptake

**Instructions:**

1. Please put on the first column of the poster **pain-points you have experienced regarding collaboration** to support introduction and uptake of new, innovative products.

2. We will **discuss the pain points together**. Subsequently, please put on the second column **opportunities you see for your specific organization to engage and relieve** any of the pain points:

   - **High impact**
   - **Medium impact**
   - **Low impact**

Source: Team analysis
Exercise: How can we improve collaboration

<table>
<thead>
<tr>
<th>Product development</th>
<th>Opportunities for your organization to collaborate and relieve pain points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy development</td>
<td></td>
</tr>
<tr>
<td>Demand generation</td>
<td></td>
</tr>
<tr>
<td>Supply development</td>
<td></td>
</tr>
</tbody>
</table>

Source: Team analysis
GF has identified a set of success factors for collaboration

<table>
<thead>
<tr>
<th></th>
<th>For pilot launch</th>
<th>For scale-up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product development</strong></td>
<td>▪ Early and proactive engagement together with partners&lt;br&gt;▪ “Being at table” and align expectations&lt;br&gt;▪ Sharing of technical inputs&lt;br&gt;▪ Sharing of recommendations</td>
<td>▪ Sharing of technical inputs&lt;br&gt;▪ Sharing of recommendations and commercial information&lt;br&gt;▪ “Being at table” and align expectations</td>
</tr>
<tr>
<td><strong>Policy development</strong></td>
<td>▪ Support with regulatory pass-ways</td>
<td>tbd</td>
</tr>
<tr>
<td><strong>Demand generation</strong></td>
<td>▪ Leveraging of relationship pool, incl. PRs&lt;br&gt;▪ “Being at table” and align expectations</td>
<td>▪ Leveraging of relationship pools, incl. PRs&lt;br&gt;▪ “Being at table” and align expectations&lt;br&gt;▪ Rewarding of innovative products</td>
</tr>
<tr>
<td><strong>Supply development</strong></td>
<td>▪ Early and proactive engagement together with partners&lt;br&gt;▪ “Being at table” and align expectations&lt;br&gt;▪ Sharing of technical inputs</td>
<td>▪ Sharing of recommendations and commercial information&lt;br&gt;▪ Rewarding of innovative products&lt;br&gt;▪ Engagement with partners/PDPs to include supplier metrics early in pipeline</td>
</tr>
</tbody>
</table>

Source: Team analysis
Contents

- Welcoming and introductory remarks
- Market Shaping Strategy: Vision and Progress
- Category Highlights
- Responsible Procurement
- Provision of Market Information
- Quality Assurance
- Tuberculosis Market
- Material for breakouts

- Wrap-up
Playback of breakout-sessions

1. Leveraging Impact
2. New Product Introduction
3. Total Cost Approach
## Leveraging impact: we want to move towards a smarter collaboration

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples of opportunities for collaboration</th>
</tr>
</thead>
</table>
| Information sharing       | - Extend joint forecasting across all categories  
- Define purpose of different types of forecasting (e.g., short vs long term, funded vs non-funded)  
- Develop/align on transparent forecasting methods  
- Align on nomenclature                                                                                                                                                          |
| Capability/capacity building | - Build in country data capability with aligned approach  
- Jointly ensure long term strategy (including support of regional/sub-regional mechanisms)                                                                                             |
| Supplier mgmt approach    | - Jointly publish and align tender schedules for more products categories  
- Harmonize regulations (e.g., QA) across organizations/countries where feasible                                                                                                                                                        |
| Mechanisms and contracts  | - Expand reach/scope of tenders:  
  - Fully align strategic principles/tender requirements (especially key categories)  
  - Explore joint tenders where feasible  
- Create tenders for small volume high impact products  
- Expand reach of existing tools (e.g., wambo.org)                                                                                                                                 |
| Other ideas               | - Explicitly define needs for collaboration per topic area (e.g., product categories, cross-cutting themes like data capability building) and map partners and existing committees against these needs                                                                                           |

Source: Output of breakouts; team analysis
### Situation

- Fostering product development and uptake is a key ambition of multiple partners and stakeholders.
- There is significant willingness, readiness and a large stock of ideas to increase collaboration and engage among the partnership.
- Each partner has a unique mandate, value proposition and strengths that collectively and complementarily enable the partnership to provide end-to-end support for innovation.

### Challenges

- There is a “web” of partners, product regulation policies and requirements, as well as innovators/innovations that is:
  - Difficult to navigate up- and downstream for developers/producers both in terms of how to introduce a product and what regulatory pathways exist, hindering development of supply.
  - Limits country visibility downstream, curbing full development of demand.
- The benefits/support generated by the partnership fall short of potential since they are not fully complimentarily aligned and adequately conveyed to developers/producers.

### Action points for GF

- Collaborate to “untangle the web”, e.g., by co-developing the two-way “needs” at each stage of the lifecycle to prepare for scale and navigate regulatory pathways.
- Align and join support with partners to fully and complimentarily leverage and communicate support, with clear delineation of roles and responsibilities depending on focus/mandate.
- Fully leverage GF’s mandate and position to support innovation, especially close to scale-up and to sustain supply in mature/declining markets, if needed.

Source: Output of breakouts; team analysis.
## New Product Introduction: Pain points and opportunities (1/2)

### Pain points

<table>
<thead>
<tr>
<th>Product development</th>
</tr>
</thead>
<tbody>
<tr>
<td>- There are limited “upstream signals”, leading to, e.g., slow and bothersome navigation of market entry process (incl., guidelines, PQ etc.)</td>
</tr>
<tr>
<td>- Visibility of early-stage development pipeline for TGF is limited</td>
</tr>
<tr>
<td>- Grants do not necessarily contain optimal products</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Policy development</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Health product regulation policies and requirements are not harmonized enough and there is lacking visibility for producers/developers, be it on a SRA level, on country level</td>
</tr>
<tr>
<td>- Assessment of value beyond unit price is not mature for innovative products</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Demand generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Countries have limited visibility on product pipeline, benefits of new products, as well as general innovation-related information</td>
</tr>
<tr>
<td>- Lacking involvement of communities/patients in product design characteristics and generating downstream demand</td>
</tr>
</tbody>
</table>

### Takeaways going forward

<table>
<thead>
<tr>
<th>Product development</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Specify approach to be flexible per category</td>
</tr>
<tr>
<td>- Introduce cross-secretariat/partner biannual stock-take on uptake progress and bottlenecks for new products meeting criteria for success</td>
</tr>
<tr>
<td>- Deliberately evaluate the inclusion of products with fundamental innovation in funding technical review or grant making</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Policy development</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Collaborate to pool resources/information, leverage stakeholder relationships and increase visibility on process and decision points for clinical recommendations and regulatory approvals</td>
</tr>
<tr>
<td>- Consider valuing participation in regional / WHO collaborative registration in tenders</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Demand generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Collaborate to pool resources/information, leverage stakeholder relationships and increase visibility on innovation landscape and developments in the market</td>
</tr>
<tr>
<td>- As partnership, increase user and program acceptance to improve chances of successful uptake</td>
</tr>
</tbody>
</table>

---

Source: Output of breakouts
## New Product Introduction: Pain points and opportunities (2/2)

### Pain points

- **Messaging towards suppliers conveys image of lacking ROI / unattractiveness and misses to communicate benefits provided by partnership (e.g., reduction of transaction cost, procurement/negotiation support)**
- Lacking end-to-end support not fully utilizing momentum of benefits/support provided by different partners
- Limited support to sustain declining products (if needed)

### Takeaways going forward

- Articulate clear position statement to support business case developments: market entry and how the GF recognizes innovation in procurement and can minimize some risks
- Establish the two-way “needs” at each stage of the lifecycle to prepare for scale; identification and filling of gaps
- Structured periodic engagements on upstream developments from partners and industry to ensure “needs” for scale are incorporated; Sourcing advice where valued to support future scale
- Intensify dialogue to identify complementary levers with partners, especially close to scale-up in order to sustain support post-donors and before scaled demand
- **Fully leverage strong downstream position of GF to sustain products until countries are ready for new products / new products are available**

- **Collaborate to “untangle the web”, to show how to scale-up products, navigate regulatory pathways, and depicting innovation landscapes adequately**

### Source:
Team analysis, Output of breakouts

---

**NOT EXHAUSTIVE**
In the Total Cost approach break-out, numerous ideas were raised that can enable collaboration

### Improve forecasting
- UNIDO can help show how improving forecasting can reduces risk for manufacturer
- USAID to investigate how to give more certainty in forecasts
- UNFPA pushes to improve forecasting of condoms between with the GF and USAID

### Get sourcing closer to demand
- UNIDO can help show how improving forecasting can reduces risk for manufacturer
- USAID to investigate how to give more certainty in forecasts
- UNFPA pushes to improve forecasting of condoms between with the GF and USAID

### Optimize packaging and labelling
- DFID offers to connect with NHS teams to understand how reduced packaging costs
- MPP works closely with generics manufacturers to make sure the integrate recommendations
- USAID drive to encourage packaging improvement and co-ordinate to SKU standardisation and barcoding

### Consolidate demand over time
- DFID is co-funding the global visibility and analytics network – to investigate how this improves country demand and providing inbound inventory visibility

### Optimize lab equipment & maintenance agreement
- GDF is keen to align/co-ordinate approach to negotiating prices on service/maintenance
- Gates Foundation exploring how to contract for maintenance for both dx and medical equipment
- UNITAID/USAID also support leveraging the Integrated Diagnostics Procurement Consortium

### Optimize storage
- Investigate collaboration with NSCIP in Nigeria and also Malawi

### Employ lean approach
- GDF and UNITAID support workstream to look into end-to-end chain involved in key procurement processes
- UNIDO supports lean manufacturing approach to value chain processes (experience in Kenya)

### Jointly generate innovation
- FIND and Gates Foundation can collaborate with manufacturers
- MPP also offers collaboration with manufacturers and stakeholders to drive innovation in making novel generic products

### Others
- USAID + Communities Delegation to GF Board support to include programmatic costs not included in direct supply chain (i.e. outside TGF)
- GIZ – connect supply chain experts with GF team working on supply chain (East Africa)

---

Source: Output of breakouts
Tuberculosis Market-Shaping Strategy: Overview, Updates & Priority Issues from Stop TB’s Global Drug Facility

Dr Brenda Waning
Chief, Global Drug Facility, Stop TB Partnership
17 October, 2017
Montreux, Switzerland
Session Outline

1. GDF Overview
2. TB Medicines Market Evolution
3. Update on GDF 2015-2020 Strategy
4. Priority Issues & Challenges in TB Markets
5. GDF Next Steps, Conclusion
1. GDF Overview

- Established in 2001
- Initiative within the Stop TB Partnership
- Hosted by UNOPS
- Original mandate: pooled procurement mechanism to facilitate access to QA FLDs; subsequent expansion of products & services
- Clients: Governments with domestic funds, Global Fund PRs, NTPs w/other donor grants
- Web-based order system
- Funded largely by USAID
- ISO 9001 certified in 2008
GDF Procurement of TB Products: Historical Timeline

- Grants (USAID, Canada, UNITAID, etc.) were key to catalyzing TB medicines & diagnostics markets
- Global Fund funding was key to market maturation, scale-up, and expanded access
GDF Procurement Evolution: to Improve Efficiency & Shape Markets

New operating models and tools to continuously improve GDF’s performance, optimize market efficiency

✓ End 2015, switch from contracted procurement agent to **GDF in-house procurement & supply TB Diagnostics**
✓ 2017 launch of **new SRS for SLDs** to dramatically decrease delivery lead time & smoothen production cycles
✓ Establishment of **flexible procurement fund** - bridge procurement costs when funds not readily available
2. Tuberculosis Medicines Markets Evolution

The power of GDF pooled procurement & market interventions (1)

SLDs: Significant increase in the number of GDF quality-assured suppliers & formulations

- **2009**: start of GDF dedicated SLD sourcing
- **July 2010**: GDF QA policy harmonized with The Global Fund and partners

<table>
<thead>
<tr>
<th>Year</th>
<th>Suppliers</th>
<th>Formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>2013</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>24</td>
<td>117</td>
</tr>
</tbody>
</table>

94.5% average supplier performance (Jan-June 2017)
The power of GDF pooled procurement & market interventions (2)

Dramatic decrease in GDF SLDs prices for MDR-TB regimens

2012/2016 Regimen costs: Mid regimen 8 Z Km Lfx Eto Cs / 12 Z Lfx Eto Cs

- 43.5 %
The power of GDF pooled procurement & market interventions (3)

Lower prices means more SLDs purchased with less money

Value*/volume of SLDs orders (as 30 Sept 2017)

*All costs included

26.2 M savings

Jan-Sept 2017
GDF Facts and figures (2001 through 30 Sep, 2017):

2001 through 30 Sep, 2017:
- Supplied medicines to 138 countries
  - 28 Mn adult FLD treatments
  - 277,100 adult SLD treatments
  - 1.9Mn pedi FLD treatments
- Supplied diagnostics to 86 countries
  - $183Mn worth of diagnostics

Jan – Sep 2017:
- $270Mn TB products ordered
- $195 Mn TB products delivered
  - 1.5Mn adult FLD treatments; 92% OTIF
  - 37,800 adult SLD treatments; 83% OTIF
  - SRS lead time* 57 days

*from order placed date to actual arrival date
3. GDF Strategy 2015-2020

**Strategic Objective 1 – Apply Market Intelligence**
- Improved market coordination, global policy
- Improved supply security
- Lowest possible sustainable prices
- Facilitated production planning

**Strategic Objective 2 - Strengthen Procurement & Global Supply Systems**
- Quality-assured products
- Shorter lead times
- Improved On Time In Full (OTIF)
- Improved forecasts

**Strategic Objective 3 - Facilitate Uptake of New TB Tools**
- Expedited uptake of new TB regimens, medicines, formulations and diagnostics
SO1: Apply Market Intelligence: GDF Role in Market Coordination (1)

Creation of the **TB Procurement & Market-Shaping Action Team (TPMAT)**
- Composed of procurers, donors, implementers, international organizations & civil society
- Aim to address existing challenges of TB medicines and diagnostics markets in a coordinated manner
- Focus areas: diagnostics, new medicines, harmonization & prioritization
- **Interventions to Date**
  - WHO PQ Annual Fee Waivers for At-Risk TB Medicines – Done
  - Policy Guidance to Accelerate Uptake of New Medicines/Regimens Introduction
    - GF Guidance on Medicines Policy Wastage (pedi FDCs, STRs) - done
    - WHO Guidance on Importance of Pedi FDCs – done
    - Global Fund ERP EOI Prioritization – Awaiting approval & implementation

- **Future areas of work**
  - WHO Guidelines, PQ EOI, EML, GF ERP EOI, GDF Catalog harmonization
  - TB Medicines Formulary to consolidate market around fewest # formulations
  - Revision to WHO 75% Remaining Shelf Life Guidance
  - Global Fund Sustainability, Co-Financing, and Transition m&e, policy development
SO1: Apply Market Intelligence: GDF Role in Market Coordination (2)

- Active participation in DR-TB STAT
  - Monthly procurement updates; link to programmatic challenges w/ introduction
- GDF – Global Fund MoU for procurement & market shaping
- GDF–UNDP MoU for SLD procurement
- GDF–MSF MoU for delamanid procurement
- GDF–FIND–MSF–UNDP negotiations w/BD (expand access pricing for MGIT diagnostic)
- GDF participation in HIV POC Working Group
- Ongoing coordination around missions and TA
- GDF Support to new UNITAID TB projects
  - EGPAF pedi TB
  - Aurum latent TB
## Accelerated uptake of STR with GDF (and other partner) assistance in priority countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Original Transition Date</th>
<th>Accelerated Transition Date</th>
<th>Value of Old stock to be removed (USD)</th>
<th>Value of New Drugs ordered 2017/2018 (USD)</th>
<th>Operational cost saving</th>
<th>GF status</th>
<th>Number of patients benefited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>Dec 2017 (all at once)</td>
<td>All eligibles in Oct/Nov 2017</td>
<td>143,000</td>
<td>68,000</td>
<td>500,000</td>
<td>GF approved NTP to implement</td>
<td>200</td>
</tr>
<tr>
<td>Indonesia</td>
<td>July 2017 to Dec 2018 (phased approach)</td>
<td>All eligibles in July 2017</td>
<td>2,610,052</td>
<td>NTP has enough stock</td>
<td>Not calculated</td>
<td>GF approved NTP to implement</td>
<td>7,888</td>
</tr>
<tr>
<td>Malawi</td>
<td>June 2018</td>
<td>Q1 2018</td>
<td>0</td>
<td>31,312</td>
<td>Not calculated</td>
<td>GF approved NTP to implement</td>
<td>42</td>
</tr>
</tbody>
</table>
# GDF 2016 Sales of PQ products Compared to Annual PQ Fees

<table>
<thead>
<tr>
<th>Annual GDF Sales</th>
<th>Number of Products</th>
<th>% of GDF Portfolio</th>
<th>WHO PQ Annual Fee</th>
<th>Estimated 2016 Profit (Assuming 10% Profit x 2016 Sales)</th>
<th>Annual WHO PQ Fee as % of 2016 Estimated Annual Profit</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;$20,000</td>
<td>6</td>
<td>11%</td>
<td>$20,000</td>
<td>$2,000</td>
<td>Fee exceeds profit</td>
</tr>
<tr>
<td>$20,000-$100,000</td>
<td>6</td>
<td>11%</td>
<td>$20,000</td>
<td>$2,000-$10,000</td>
<td>Fee exceeds profit</td>
</tr>
<tr>
<td>$100,001-$200,00</td>
<td>9</td>
<td>17%</td>
<td>$20,000</td>
<td>$10,000-$20,000</td>
<td>Fee exceeds or = profit</td>
</tr>
<tr>
<td>$200,001-$500,000</td>
<td>7</td>
<td>13%</td>
<td>$20,000</td>
<td>$20,000-$50,000</td>
<td>41-99%</td>
</tr>
<tr>
<td>$500,001-$1 Mn</td>
<td>5</td>
<td>9%</td>
<td>$20,000</td>
<td>$50,000-$100,000</td>
<td>21-40%</td>
</tr>
<tr>
<td>$1,000,001 - $3 Mn</td>
<td>11</td>
<td>20%</td>
<td>$20,000</td>
<td>$100,000-$300,000</td>
<td>8-20%</td>
</tr>
<tr>
<td>$3,000,001 - $5 Mn</td>
<td>1</td>
<td>2%</td>
<td>$20,000</td>
<td>$300,000-$500,000</td>
<td>5-7%</td>
</tr>
<tr>
<td>$5,000,001- $10 Mn</td>
<td>7</td>
<td>13%</td>
<td>$20,000</td>
<td>$500,000-$1Mn</td>
<td>2-4%</td>
</tr>
<tr>
<td>&gt;$10 Mn</td>
<td>1</td>
<td>2%</td>
<td>$20,000</td>
<td>&gt;$1Mn</td>
<td>&lt;2%</td>
</tr>
</tbody>
</table>

For 21 (39%) of products, fee = or exceeds profit

For 23 (42%) of products, fee accts large % of profit

46 (81%) products at risk
## SO2: Strengthen Procurement & Global Supply Systems
Cost-savings of GDF Interventions with country orders (q1-q3 2017)

<table>
<thead>
<tr>
<th>Type of Intervention</th>
<th>Action</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order cancellation (waste averted)</td>
<td>Proactive analysis of country data and order adjustment</td>
<td>Saved US$ 3,232,648</td>
</tr>
<tr>
<td>Order reallocation (waste averted)</td>
<td>Orders that cannot be cancelled were relocated to other clients</td>
<td>Saved US$ 1,264,548</td>
</tr>
<tr>
<td>Order postponement (waste averted)</td>
<td>Proactive analysis of country data and order rescheduling</td>
<td>Saved US$ 2,572,868</td>
</tr>
<tr>
<td>Pre-order modification of quantity (stock-outs averted)</td>
<td>Proactive analysis of quantification data and quantity adjustments to prevent potential stock outs</td>
<td>Avoided treatment interruption of 1607 DR-TB cases</td>
</tr>
</tbody>
</table>

>$7 Million in Savings from Jan to Sep 2017
The Case for a Strategic Rotating Stockpile for SLDs

Value of SLDs delivered from 2013 to 2016 (Except India)

Unpredictable purchase patterns; high peaks and severe lows complicate production & supply planning. Results in order-specific production & long lead times.
The new SRS: an innovative logistic solution

GDF has created a new Strategic Rotating Stockpile (SRS) to supply SLDs to countries with the aim to dramatically decrease delivery lead time and smooth supplier’s production cycles.

The new SRS is an innovative logistic solution that aims to:

- Improve GDF service to clients:
  - Decrease lead time by serving country orders from SRS (target <3 months); 57 days in 2017
  - Flexibility of supply in case of overstocking or stock-out situations (postponement/cancellation of orders or emergency orders)

- Improve GDF forecasts/order planning to be a client of choice for suppliers:
  - Provide more reliable forecasts
  - Improve the GDF order cycle by a better scheduling of orders to suppliers
  - Adapt replenishment orders & supplier’s production capacity to smooth peaks in the GDF ordering

New IT systems/tools developed to operationalize new SRS: replenishment tool & dynamic batch allocation tool
SO3: Facilitate Uptake of New Tools

Bedaquiline: Procurement Status (donations & purchases)

Bedaquiline delivered to 55 countries; 10 addtl countries with orders in process;
GDF support aDSM, adherence WHO Guidelines; GDF overs transport costs of BDQ donation when ordered separately

<table>
<thead>
<tr>
<th>Treatments* in early stage of order process</th>
<th>2015</th>
<th>2016</th>
<th>Jan-Sep 2017</th>
<th>Total 2015-Sept 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatments* in late stage of order process</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatments* Delivered</td>
<td>1,001</td>
<td>1,474</td>
<td>4,303</td>
<td>6,778</td>
</tr>
<tr>
<td>Total</td>
<td>1,001</td>
<td>1,474</td>
<td>13,540</td>
<td>16,015</td>
</tr>
</tbody>
</table>

In 2017, India accounts for 3,500 treatments (660 delivered & 2,840 in process)

Delivered:
- Afghanistan
- Armenia
- Azerbaijan
- Bangladesh
- Belarus
- Benin
- Bolivia
- Burkina Faso
- Cambodia
- Cameroon
- Chile
- Cote d’Ivoire
- DPRK
- DRC
- Djibouti
- Dom Republic
- Eq. Guinea
- Ethiopia
- Georgia
- Guinea
- Haiti
- India
- Indonesia
- Jordan
- Kazakhstan
- Kenya
- Kyrgyzstan
- Lebanon
- Lesotho
- Liberia
- Mali
- Mongolia
- Mozambique
- Myanmar
- Namibia
- Niger
- Nigeria
- Pakistan
- Papua New Guinea
- Peru
- Philippines
- Rep. Moldova
- Senegal
- Sri Lanka
- Sudan
- Swaziland
- Tajikistan
- Thailand
- Turkmenistan
- Uganda
- Ukraine
- Un. Rep Tanzania
- Uzbekistan
- Viet Nam
- Zimbabwe

In-process:
- China
- Ecuador
- Iraq
- Kosovo
- Malawi
- Nepal
- Rwanda
- Sierra Leone
- Somalia
- Zambia

GDF support aDSM, adherence WHO Guidelines; GDF overs transport costs of BDQ donation when ordered separately.
Delamanid Procurement Status

Delamanid delivered to 26 countries; 14 addtl countries w/ orders in process;
Support aDSM, adherence WHO Guidelines

<table>
<thead>
<tr>
<th>Country/Status</th>
<th>2016</th>
<th>Jan-Sep 2017</th>
<th>Total 2016–Sep 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatments* in early stage of order process</td>
<td></td>
<td>1,053</td>
<td>1,053</td>
</tr>
<tr>
<td>Treatments* in late stage of order process</td>
<td></td>
<td>1,227</td>
<td>1,227</td>
</tr>
<tr>
<td>Treatments* Delivered</td>
<td>620</td>
<td>970</td>
<td>1,590</td>
</tr>
<tr>
<td>Total</td>
<td>620</td>
<td>3,250</td>
<td>3,870</td>
</tr>
</tbody>
</table>

Would not have been possible w/o SRS (many orders <5 tx)

MSF EndTB accounts for ~50% orders in 2016, ~30% in 2017

Delivered: Afghanistan Armenia Bangladesh Belarus Cameroon Cote d’Ivoire DPRK Dom Republic Ethiopia Georgia India Jordan Kazakhstan

Delivered:
Kenya Kyrgyzstan Mali Morocco Mozambique Myanmar Nigeria Papua New Guinea Peru Russia South Africa Sri Lanka Swaziland

In-process:
Azerbaijan DRC Indonesia Malawi Nigeria Pakistan Philippines

In-process:
Rep. Moldova Rwanda Sierra Leone Turkmenistan Un. Rep Tanzania Uzbekistan Zimbabwe

2016 Jan-Sep 2017 2016–Sep 2017
1,053 1,053
1,227 1,227
620 970 1,590
620 3,250 3,870

Delamanid delivered to 26 countries; 14 addtl countries w/ orders in process; Support aDSM, adherence WHO Guidelines

Would not have been possible w/o SRS (many orders <5 tx)

MSF EndTB accounts for ~50% orders in 2016, ~30% in 2017
## Uptake of STRs with GDF (and other partner) assistance in priority countries

Out of the Tier 1 countries (n=25):
- 10 countries have implemented as of 30-Sept-2017
- 8 countries will be implementing by the end of 2017
- 7 countries will be implementing by June 2018

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
<th>Timeline/Plan</th>
<th>Country</th>
<th>Status</th>
<th>Timeline/Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afghanistan</td>
<td>Plan</td>
<td>Q1 2018</td>
<td>Nigeria</td>
<td>Started</td>
<td>Q2 2017</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>Started</td>
<td>April 2017</td>
<td>Pakistan</td>
<td>Plan</td>
<td>Q1 2018</td>
</tr>
<tr>
<td>Cambodia</td>
<td>Plan</td>
<td>Nov 2017</td>
<td>Philippines</td>
<td>Started</td>
<td>July 2015 (trial)/Q1 2017 (scale-up)</td>
</tr>
<tr>
<td>DR Congo</td>
<td>Started</td>
<td>2013-2015, 2016 (scale-up)</td>
<td>South Sudan</td>
<td>Started</td>
<td>Q2 2017</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Plan</td>
<td>Q1 2018</td>
<td>Tajikistan</td>
<td>Started</td>
<td>Q2 2017</td>
</tr>
<tr>
<td>India</td>
<td>Plan</td>
<td>Jan 2018</td>
<td>Tanzania</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Started</td>
<td>Sept 2017</td>
<td>Uganda</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Kazakhstan</td>
<td>Plan</td>
<td>Q4 2017</td>
<td>Ukraine</td>
<td>Plan</td>
<td>Q3 2018</td>
</tr>
<tr>
<td>Kenya</td>
<td>Started</td>
<td>Q3 2017</td>
<td>Uzbekistan</td>
<td>Plan</td>
<td>Q1 2018</td>
</tr>
<tr>
<td>Kyrgyzstan</td>
<td>Started</td>
<td>Q1 2017</td>
<td>Vietnam</td>
<td>Started</td>
<td>April 2016</td>
</tr>
<tr>
<td>Malawi</td>
<td>Plan</td>
<td>Q1-2 2018</td>
<td>Zambia</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Plan</td>
<td>2016 (trial)/Q4 2017 (scale up)</td>
<td>Zimbabwe</td>
<td>Plan</td>
<td>Q4 2017</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Plan</td>
<td>Oct 2017</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Countries that have Ordered New Paediatric FDCs from GDF


68 Countries have ordered ~500,000 treatment courses* of new paediatric FDCs as of end Aug 2017

- 59 countries have had FDCs delivered (~410,000 treatments); 9 countries in ordering process

Practically no pedi FDC procurement outside of GDF

*Treatment course estimated for children in the third weight band [3 tablets daily] with 2 months of intensive phase and 4 months continuation phase
GDF outcomes on diagnostic orders over the years (2):

Significant increase of Xpert MTB/RIF Cartridges ordered by GDF

2015 and 2016 actual procurement

- 6.2 million

2017 forecasted procurement

- 6.9 million
- Rest of world: +27 to 53%
- GDF-supplied NTPs: +53%
- India (via GDF): +190%
- South Africa: 0%

2017 forecasted procurement

- 10-11 million

GDF now largest single purchaser of Xpert

2017 data: South Africa NHLS, GDF data (India, 42 other countries), NTPs from Kenya, Philippines; estimated 27-53% growth for remaining 77 countries

Inadequate forecasting, quantification, order management

• **Aspirational forecasts**
  • Forecasts in concept notes sometimes aspirational; set to meet unrealistic treatment targets
  • If orders placed against over-ambitious targets, result is over-ordering
  • End-year, end-grant disbursement pressure can also lead to over-ordering
  • Over-ordering often leads to requests for postponements & cancellations

• **Inaccurate forecasts**
  • Result in under- over-ordering
  • Methods/Numbers don’t match across CN, PSM, GDF mission quantification, Orders
  • New DR-TB drugs, shorter regimens complicating quantification
    • Need eligibility estimates
    • Need access to enrollment plans & actual enrollment (e.g., BDQ experience)
Global Fund Sustainability, Transition, and Co-Financing Policy

What the 2016 Policy includes:
• Requires all countries progressively absorb the costs of key program components, including procurement of essential drugs and commodities

What the 2016 Policy doesn’t include:
• Explicit goal to ensure markets created by Global Fund are sustained
• Risk management plan to protect markets and access
• Clear m&e of procurement practices & outcomes

• Implementation observations to date:
  • Guidance differs country to country
  • “Bottom-up” approach not connected to a “top-down” market strategy
  • Many countries advised to first absorb smaller cost products- such as pediatric TB medicines
    • Approach runs counter to a market-shaping approach which would aim to keep procurement of low-volume medicines centralized
GDF Observations of National Tenders w/ Co-financing, Transition

As countries co-finance or transition, national laws, rules & regulations dictate procurement practices

Observed outcomes on national procurement:

• **Protracted tendering and contracting** processes
• **Failed tenders:** no bids submitted, bid prices too high, service terms unacceptable
• **Delays** in allocation of government funds to pay which delays ordering & deliveries
• **Poor service:** distributors, agents, suppliers fail to meet delivery times & volumes
• **Lack of clarity on roles & payor:** customs clearance, import duties, in-country transport
• **Inability to access concessional pricing** for certain products (Xpert MTB/RIF Cartridges)
• **Increased prices** charged by global & local suppliers/distributors

• Countries pop in and out of the GDF/International QA market over time
  • Analyses to date show no clear trends
  • Order a product from GDF once or twice, go away, then order again years later
  • Unknown why - perhaps addressing some of the problems above? Others?

Result in shortages, stockouts
## Observations on WHAT countries buy: Will NTPs Revert to Pre-GF Practices? (Meds)

<table>
<thead>
<tr>
<th>Pre-Global Fund</th>
<th>Global Fund</th>
<th>Co-Financing/Transition</th>
</tr>
</thead>
</table>
| ![Multiple, single tablets and injections Not optimized, not user-friendly](image1) | ![Fixed-dose combinations Optimized, user-friendly](image2) | Continue using FDCs  
*Or,*  
Go back to multiple tablets, irrational regimens |
| ![Unknown quality status](image3) | ![Quality-assured products](image4) | Continue to use Quality-Assured Products  
*Or,*  
Revert to products of unknown quality |
| ![Expensive second line treatment (>$5000 per treatment course)](image5) | ![Large Price decreases ($800 for shorter MDR regimens)](image6) | Continue to use optimized regimens at low prices via some type of pooled procurement  
*Or,*  
Pay higher prices as a single buyer |
## Observations on WHAT countries buy: Will NTPs Revert to Pre-GF Practices? (Dx)

<table>
<thead>
<tr>
<th>Pre-GLOBAL FUND</th>
<th>DURING GLOBAL FUND</th>
<th>CO-FINANCING/TRANSITION</th>
</tr>
</thead>
</table>
| **Solid culture TB diagnosis & DST** | **Automated liquid culture TB diagnosis & DST (MGIT)** | • Countries may reduce amount of liquid culture performed, reverting to solid culture for testing of patient groups of lesser priority  
• National/regional distributors of Becton Dickinson sometimes significantly mark-up prices |
| • Slower, less sensitive  
• Inexpensive, materials sourced locally | • Faster, more sensitive  
• Expensive, sole source, reliable provider  
• (Becton Dickinson) | |
| **Microscopy** | **Xpert MTB/RIF** | • Countries may revert to microscopy, or reduce amount Xpert performed  
• Countries may not be able to access concessional prices when national regulations require payment in local currency upon delivery; national distributors known to mark-up 50%-800% |
| • Low sensitivity  
• Does not provide information on drug resistance  
• US$ 1-2 / test, sourced locally | • High sensitivity  
• Provides information on drug (rifampicin) resistance  
• US$ 9.98/test, sole source provider (Danaher/Cepheid), USA) offering concessional prices when paid in US$ upfront | |
GeneXpert service and maintenance: background

- Cepheid’s standard warranty is widely considered by TB stakeholders to be inadequate & overpriced
  - Does not cover in-country travel for module swapping, repairs
  - Refurbished modules do not arrive in country in a timely manner
  - Warranty cost of US$ 2,898 / year
  - Many countries are not buying the warranty, resulting in even more machine downtime

- In selected countries (including South Africa, Pakistan, Uganda, Kenya), Cepheid or their distributor has proposed cartridge surcharges for “enhanced” or “comprehensive” maintenance, as a replacement for warranties
  - Services offered vary but generally include in-country travel for swapping, repairs, maintenance
  - Terms and conditions of proposed contracts are vague
  - No reporting that would allow for monitoring of performance of service provider
  - Surcharge prices are not clearly based on cartridge volumes or subject to annual revision
  - Included in Concept Notes under a separate funding line from machine & cartridge procurement
GeneXpert service and maintenance: proposed path forward

- GDF and MSF developed model Service Level Agreement (SLA)
  - Shared with and supported by TB and HIV stakeholders (POC Consortium)
  - Model SLA includes a comprehensive list of clearly described minimum services, terms and conditions (countries may add additional activities as desired)
  - Model SLA includes standard reporting requirements that would allow for monitoring of performance of service providers by country, procurement agent and GF
- Targets have been proposed that can be used to refine payments or introduce penalties
5. GDF Next Steps

• **SO1: Apply Market Intelligence (via TPMAT)**
  - Harmonization: WHO Guidelines, WHO EML, WHO PQ EOI, GF ERP EOI, GDF Catalog harmonization
  - Consolidation: TB Formulary
  - Revision of WHO Guidance on 75% Remaining Shelf Life
  - Systematic analyses, modeling procurement with co-financing, transition; policy guidance, as needed

• **SO2: Strengthen Procurement & Global Supply Systems**
  - Increase procurement frequency of NTPs to 2x/year; increase # orders through SRS
  - Implement new data warehouse & ERP system – on-line dashboard; link to Wambo
  - Explore new SCM activities, roles; explore track & trace package options
  - Improve Cepheid terms on service & maintenance
  - Work with GF on improved quantification, order planning; potential joint negotiations

• **SO3: Facilitate the Uptake of New TB Tools**
  - **Ongoing:** pedi FDCs, BDQ, DLM – implications of new VLs, STRs, Xpert
  - **New:** LAM diagnostic; portable X-ray; rifapentine; new pedi MDR-TB formulations
Conclusions

• The Global Fund & other donors have together made incredible progress to build TB medicines markets that have undoubtedly contributed to increased access to quality TB care

• GDF’s pooled procurement, Strategic Rotating Stockpile (SRS) for SLDs, and other org’s interventions have facilitated price reduction, dramatically lower lead times, development of optimized formulations, emergency response, and new product introduction

• Despite this progress, most TB markets are fragile at best. Many are failed markets
  • For many TB medicines, there is actually an absence of market – remove supports propping the “market” & the products will likely disappear

• Dynamic global policy envt. Many threats to TB markets that will decrease volumes, increase costs, decrease availability
  • Changes in financing & procurement, new WHO guidances ,PQ fees, natl registration fees and other policies
  • Proactive stakeholder engagement & risk management must be done before new policies are implemented
  • If TB medicines volumes decrease, unclear how long the QA market can be held together

• Global community – including donors need to decide if sustaining QA markets created by GF (and others) is a priority
  • If yes, market sustainability must be an explicit goal of all policies & practices to ensure long-term access to quality-assured, optimized, affordable products
Thank you

Brenda Waning

brendaw@stoptb.org
# GROWTH FUND SOURCING STRATEGIC REVIEW MEETING
# 16th & 17th OCTOBER 2017
# PARTICIPANTS LIST, EXTERNAL AND INTERNAL

<table>
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<tr>
<th>Organization</th>
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