The Global Fund Sourcing Strategic Review Meeting

16-17.10.2017

The Global Fund

Contents

Agenda Day 1

In small groups

Day 1 – 16th October

Time	Topic	Speaker
09.30 – 10.00	Welcome coffee	-
10.00 – 10.20	Welcome remarks	Patrik Latin
10.20 – 11.00	Market Shaping Strategy: Progress & Vision	Mariatou Tala Jallow
11.00 – 12.30	Category Highlights	Azizkhon Jafarov; Lin (Roger) Li; Martin Auton; Mathieu Courtois
12.30 – 13.30	Lunch	-
13.30 – 15.15	Breakout 1	Mariatou Tala Jallow; Lin (Roger) Li; Martin Auton; Melisse Murray; Nathan Vasher
15.15 – 15.30	Regrouping coffee	-
15.30 – 16.00	Responsible procurement	Nick Jackson; Lin (Roger) Li
16:00 – 18.00	Breakout 2	Mariatou Tala Jallow; Lin (Roger) Li; Martin Auton; Melisse Murray; Nathan Vasher
18.30 – 20.00	Cocktail, incl. day one closing	-

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

Agenda Day 2

In small groups

Day 2 – 17th October

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

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

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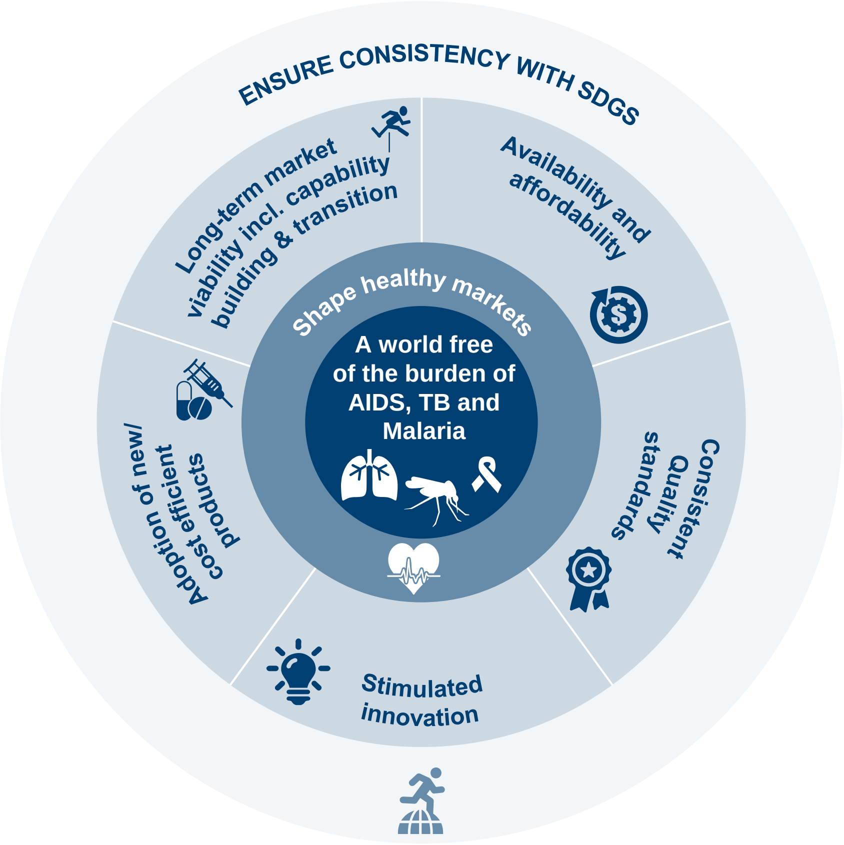
Market Shaping Strategy: Progress and Vision

Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Mariatou Tala Jallow

The Global Fund

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

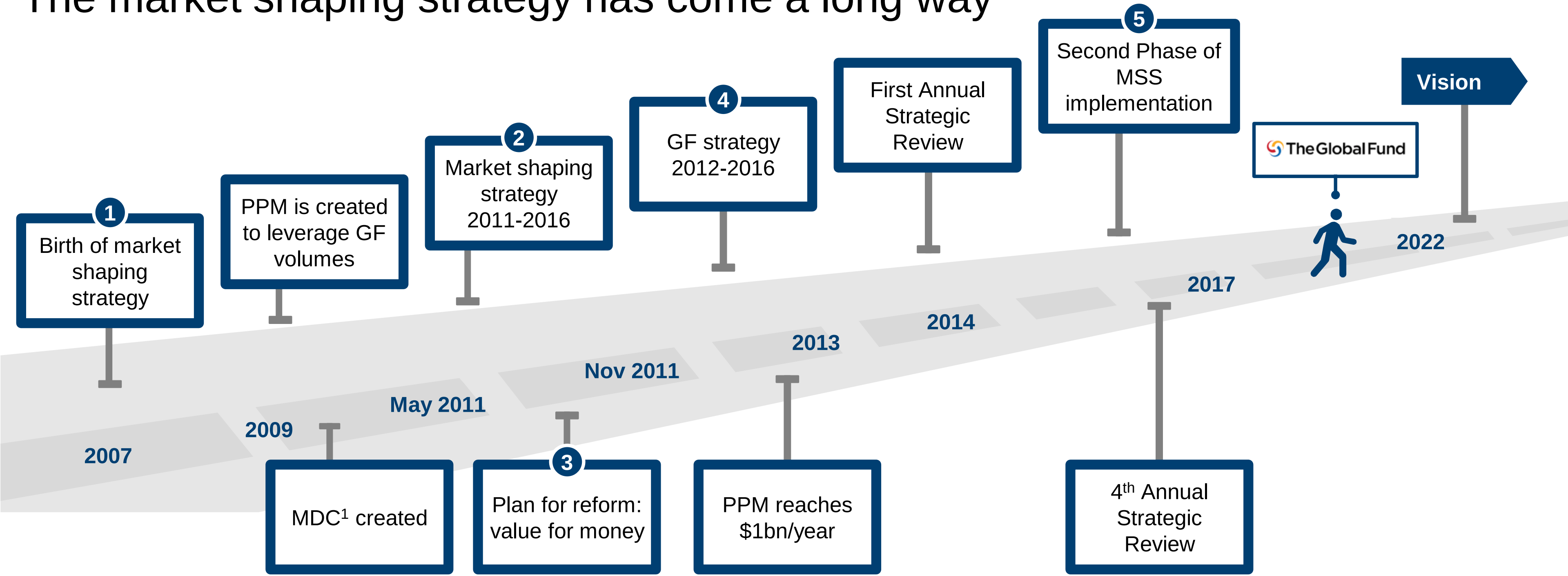
Source: Team analysis

Healthy markets have 6 characteristics

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

Source: Market Shaping Strategy, Annex 1 to GF/B4/17- Revision 1

The market shaping strategy has come a long way



1. Adoption of objective and guiding principle of market shaping
2. New market shaping strategy, incl. specific instructions for ARVs
3. Call to more proactively shape markets
4. Recognition of GF's abilities to influence market and call to extend toolkit
5. Reinforcement and development of market shaping objectives and toolkit

1 Market Dynamics Ad-hoc Committee

Source: Team analysis

Our efforts have borne fruit

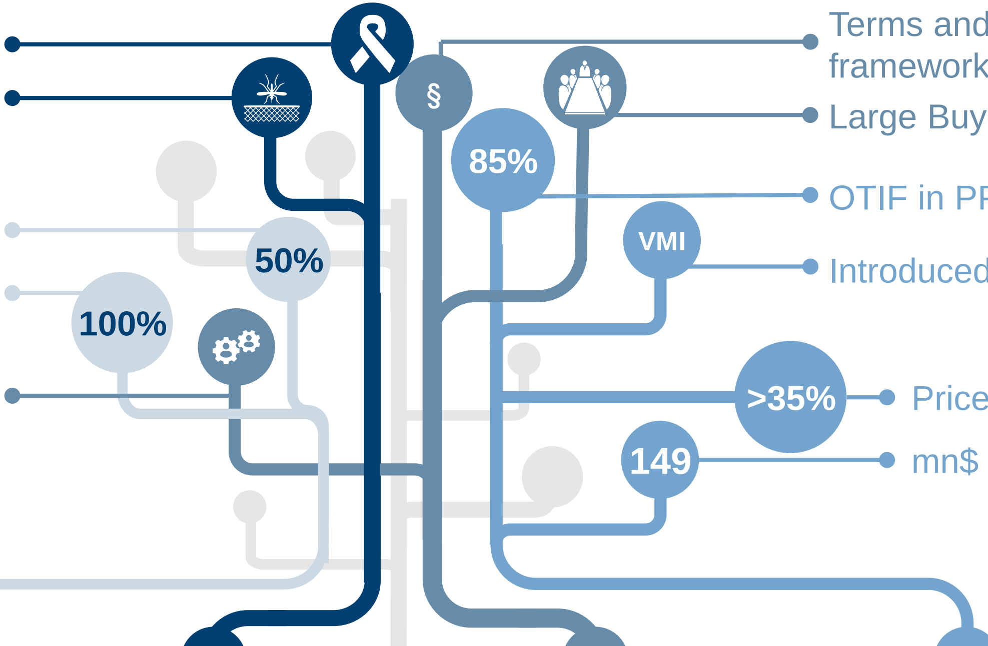
NOT EXHAUSTIVE

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

Reduction of scale-up time[2]

Tenders including innovation criteria

Collaboration and co-investment[3]



Terms and conditions of framework agreements extended[4]

Large Buyer Forum in ARV market

OTIF in PPM

Introduced to prevent stockouts

Price reductions LLIN/ARV[1]

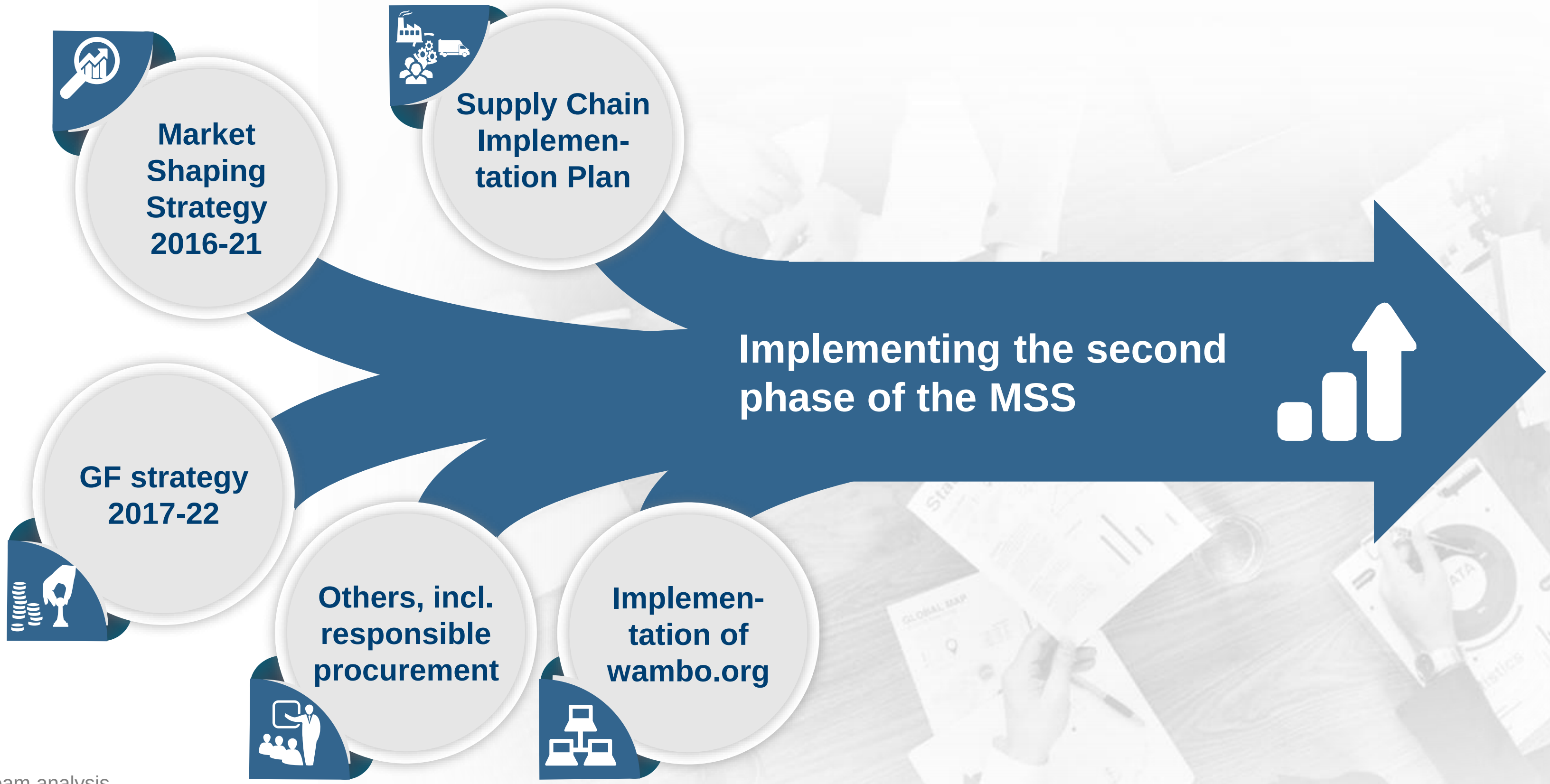
mn$ savings (2016)

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



Source: Team analysis

A range of tools support the implementation of the MSS

To deliver on the objectives of the MSS…

- Availability and affordability
- Consistent quality standards
- Stimulated innovation
- Adoption of new/cost efficient products
- Country transition and long-term market viability
- Foundational elements

…there is a set of tools to support implementation

Tools	Description
Pooled procurement mechanism (PPM)	Consolidates recipient demand for health products, negotiates procurement, offers vehicle to deploy a variety of strategic procurement practices
The Global Fund's Quality Assurance policies	Covers pharmaceutical and diagnostic products and quality requirements for other health products (incl. Expert Review Panel)
Price and quality reporting mechanism (PQR)	Captures transaction-level procurement data on core health products financed by GF in public database
Revolving fund (catalytic fund)	Supports new product introduction
The Global Fund's guide to procurement and supply management (PSM) policies	Details the legal obligations that apply to GF-financed health products and other recommended best practices for PSM
Guidance provided by the grant management division's health product management specialists	Interfaces with PRs on PSM topics in grant-making and implementation process and monitors grant compliance with the procurement policies described above
Cost-effectiveness analysis (HTA)	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
wambo.org	Serves as "face" of PPM to increase country ownership and provides full visibility and a transparent and auditable process

Source: Annex 1 to GF/B34/17 – Revision 1

We identified 6 strategic priorities for which we wish to improve collaboration with partner organizations

To be discussed in breakouts

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

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

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Highlights: Antimalarials

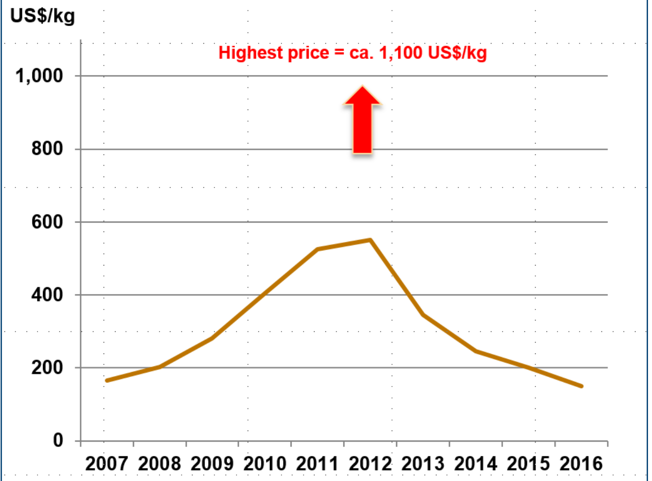
Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Lin (Roger) Li

The Global Fund

Responsible procurement in Antimalarials Medicine Sourcing Strategy 2018-20

Historical Average *Agricultural* Artemisinin Pricing[1]



Data Source: Agricultural Artemisinin price is based on Chinese export to India

Context

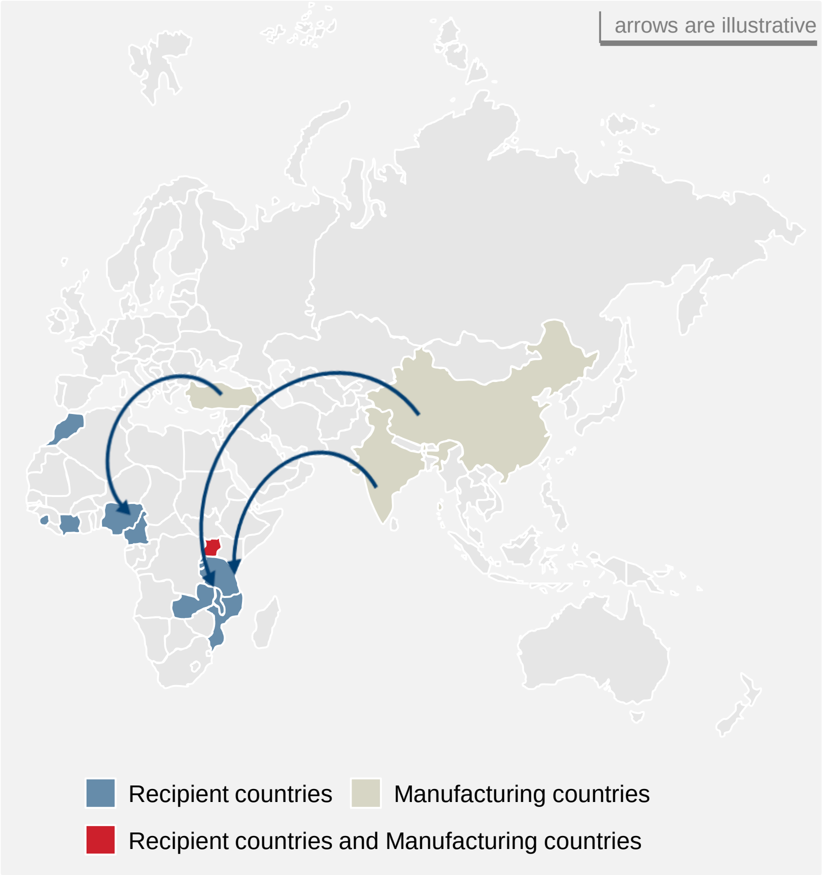
- **Agricultural Artemisinin prices are volatile** due to, e.g.,
  - Overproduction capacity because of low technical barriers to entry
  - Lack of harmonized quality standards
  - Inconsistent in-house EHS control
  - Lack of visibility of demand and long term agreement
- Agricultural Artemisinin price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



Source: GF

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

Highlights: LLINs

Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Aziz Jafarov

The Global Fund

LLIN sourcing has been evolved along 2 strategic rounds

Deep-dives on the next pages

	First round LLIN Sourcing Strategy 2014-2015	**Second round LLIN Sourcing Strategy** 2016-2017
Overarching objectives	▪ **Maximize investments** on LLINs within a dynamic and sustainable market environment ▪ Address **price volatility and standardization**	▪ 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

Targets of LLIN Sourcing Strategy 2014-2015

- 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

SOURCE: McKinsey

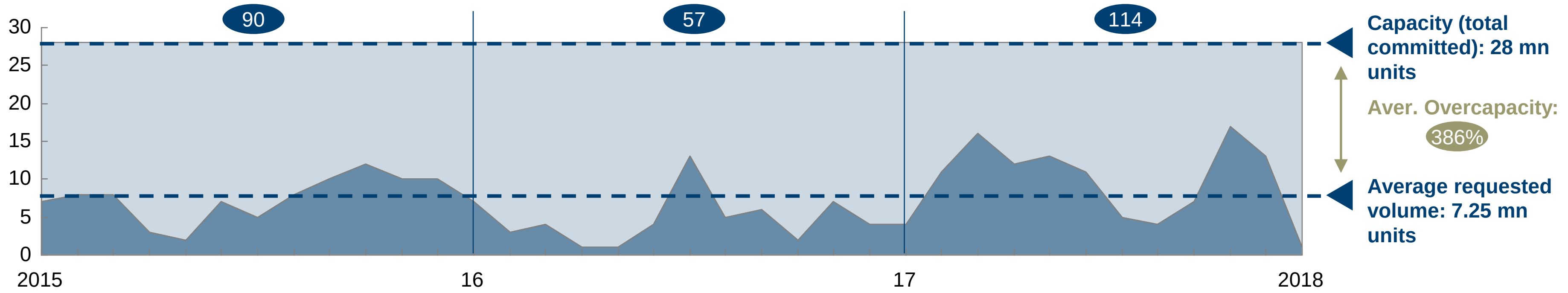
Also the second round enabled a leap forward, but there remain challenges to be addressed

Deep dive on the next page

	Although we achieved a lot…	… there remain challenges to be tackled
Impact	▪ 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**
Supply	▪ **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**	▪ 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**
Product and price	▪ 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

LLIN overcapacities

Deliveries to PPM PRs, mn units



Problem

- **10 out of 12 eligible LLIN manufacturers are selected as panel manufacturers** in GF 2014 tender for 2015 -2016 implementation[2]
- **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

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

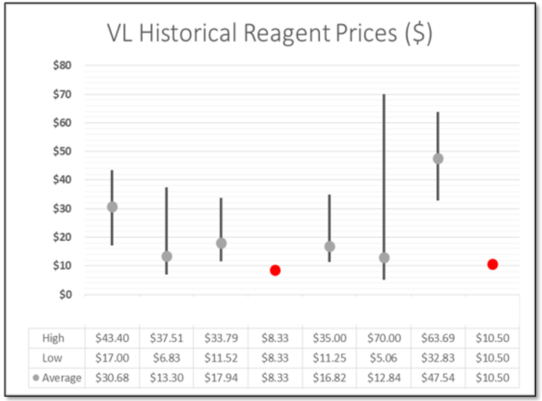
Aziz Jafarov

The Global Fund

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

Overall objective

- Provide **transparency in pricing, costs, acquisition, and contracting options**

Framework agreements

- 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

Selection process

- Provide inputs for **defined, competitive, and transparent selection** of viral load technologies by PRs

Volume allocations

- Potentially **include options for allocated or committed volumes based on aggregated forecast demand** across GF PRs[1]

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

Eligibility and Testing products

Supplier panel	Regulatory status	Technology approved
Abbott	WHO PQ	VL, EID
Alere	WHO PQ	EID
BCH BIOCENTRIC HEALTH, INC. ADVANCING SCIENCE FOR BETTER LIVING	CE mark	VL
BIOMÉRIEUX PIONEERING DIAGNOSTICS	WHO PQ	VL
Cepheid. A better way.	CE mark/WHO PQ	VL, EID
DRW	CE mark	VL, EID
HOLOGIC The Science of Sure	CE mark	VL
QIAGEN	CE mark	VL
Roche	WHO PQ	VL, EID









GF targets a range of credible, cost-effective, competitive options with more transparent pricing and contracting, which are broadly accessible to all

	Achievements
Leveraged volumes	▪ Enabled **volumes to be leveraged** and **promoted maximum up-time** and **throughput**
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

Country scenario	Programming & funding	RFP process/ outcomes	Platform / technology selection	Pricing options	Contracting option
Plan to scale-up	Implementa-tion plans	RFP objectives and process	Supplier panel	Total Cost of Ownership explanation	Comparison between options
Exploit new arrange-ments	Funding requests	RFP outcomes	Supplier information	VL – comparison	Supplier options
Procure and implement	Other guidance	Commercial results	Technical summary	EID – comparison	Key principles

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

Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

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

Reduces market complexity and need for intermediaries

Select desired specifications, order terms **and place order**

Decreases administrative burden; for PPM PRs, automates PPM ordering

Track and trace requisition, direct payment

Acceleration of the procurement process

Easy reporting, allowing for better, more **specific forecasting**

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

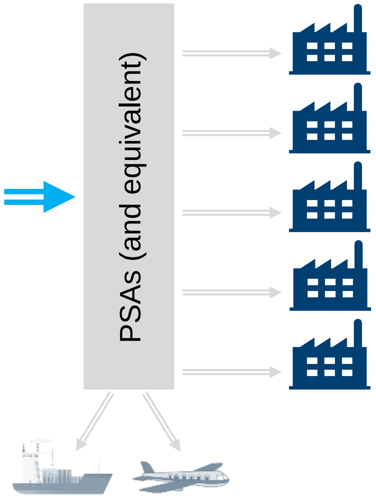
wambo.org

e-RFQs direct to manufacturers *soon!*

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

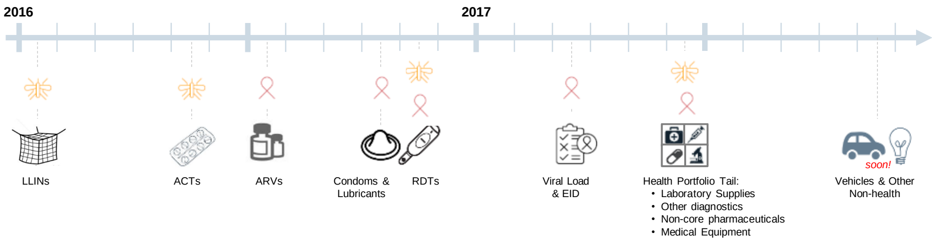
wambo.org



*PSA: Procurement Services Agent

All PPM transactions are now flowing through wambo.org

Launch of product categories



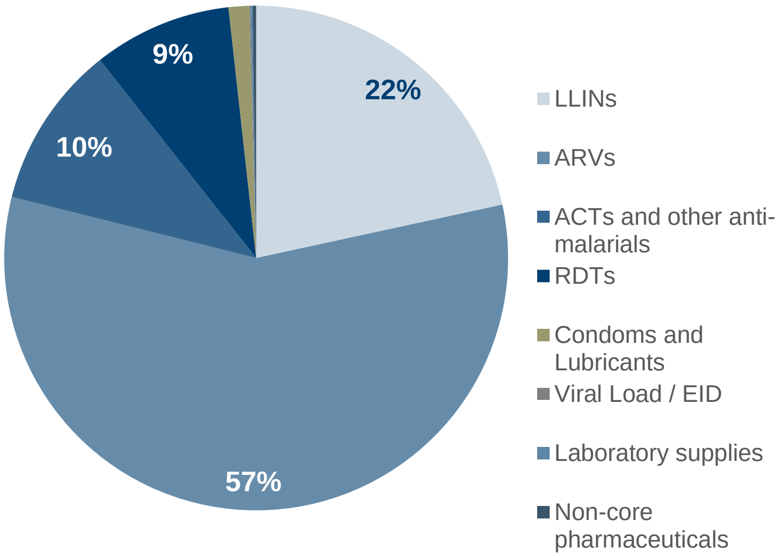
wambo.org has launched all of the product categories available to PRs through PPM at a careful pace and is now looking to expand to non-health through the **UNOPS** MoU and TB through the **GDF** MoU.

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*



*excludes impact of logistics costs, data January 2016 – September 2017

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

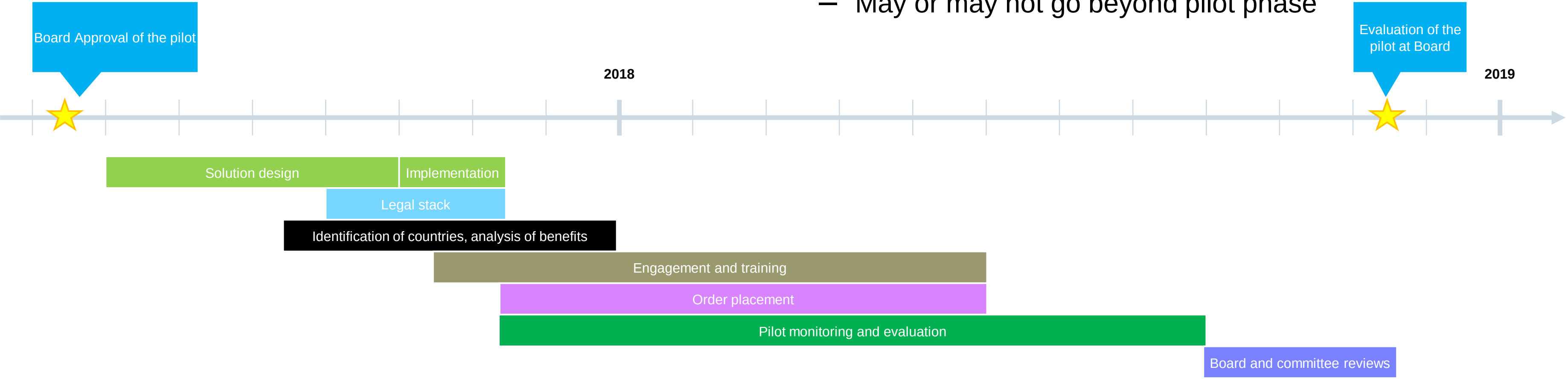
The Global Fund is taking wambo.org to the next stage and piloting the use of domestic funds

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

Sourcing Strategic Review Meeting, Montreux
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Nick Jackson, Lin (Roger) Li

The Global Fund

Partners, donors and other stakeholders expect GF to deliver a responsible procurement approach that supports the Sustainable Development Goals

ILLUSTRATIVE

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

DEEP DIVES FOLLOW

Dimensions	What we have achieved	What we want to attain
Approach	GF addressed responsible procurement reactively through specific ad hoc cases	GF proactively employs a respon-sible procurement approach tailored to its end-to-end value chain with 4 dimensions: economy, ecology, society and business practices
Guidelines	Guidelines created by initiative in specific cases (e.g., Artemisinin; Supplier Code of Conduct) but not holistic codification	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

Dimen-sions

	Description
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

Society | Ecology | Economy | Business practices

Dimension addressed	Case examples	Issue	Solution
Ecology, Society, Economy	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
Ecology, Economy	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 artemisimin producers: – GF conducted agricultural artemisinin manufacturer qualification through 3rd party – GF incentivized best practices among manufacturers by offering 3 years allocation
Ecology, Business practices	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

2009

- GF introduces the supplier code of conduct

2013

DFID Department for International Development

- DFID raised concerns about LLINs misuse

2014

- GF addresses LLIN ecological concerns through its anti-malaria strategy
- GF starts risk assessment per product category

2015

- GF sign contribution agreement with Norway on eco-footprint

- GF appoints its first ethics officer
- GF signed the Joint Intergagency Statement for sustainable procurement

2016

- GF joined the SPHS[1] task team on sustainable procurement

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

SOURCE: Team analysis

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Provision of Market Information

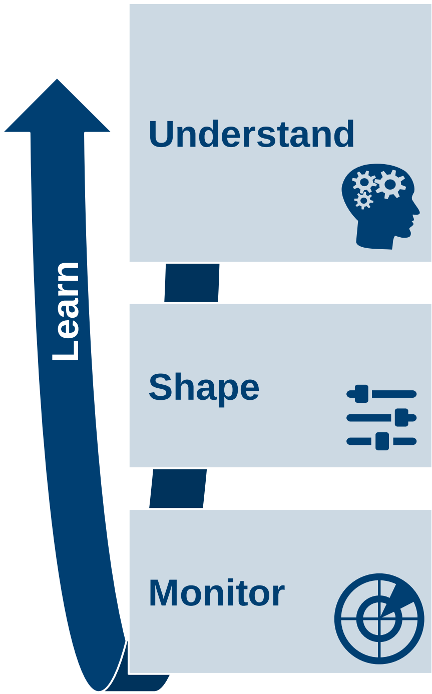
Sourcing Strategic Review Meeting, Montreux
16-17.10.2017

Nick Jackson, Rod Carlton (Freshfields)

The Global Fund

WHY: Sharing information is critical to building healthy markets

Market shaping process



Importance of mutual information sharing

- Use data for **operational and strategic decision-making**
- Enable **diagnosing market dynamics** challenges and identifying opportunities for improvement

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- 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"*
>
> **GF Board**

> *"Disclosure of information (…) is a **matter of principle and will facilitate a process leading to lower prices**"*
>
> **GF Board**

WHAT: GF aims to share with each recipient data that is crucial to them

Deep dive on the next page

WORK IN PROGRESS

Recipients of market information

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

Key channels Selected	Status quo – Description	Status quo – Benefits	Mid-term opportunities	Long-term vision
PQR	▪ Public **database** ▪ **Transaction-level** procurement data	▪ Sharing of price data, benchmarks, and forecasting ▪ Potential identification of "value for money" opportunities	▪ Refine value proposition for the needs of 2017 ▪ Extend quality stan-dards to full data set	▪ Create fully transparent markets to generate healthy structures and fierce competition
Standard market intelligence	▪ Set of regularly updated, **standardized reports**, e.g., tender outcomes, strategy documents, and reference prices	▪ Broad spectrum of high-level market intelligence ▪ Benefits for large scope of interested stakeholders ▪ Formalized and established market conditions	▪ Collaborate with partners to provide broader perspective ▪ Establish needs and interests of different stakeholders and further tailor reports	▪ Provide pre-processed market intelligence to cater for a variety of needs and increase visibility and awareness for the broader public
On demand	▪ **Solicited information** sharing ▪ Provision based on **legitimate needs**	▪ Needs-based in-depth provision of information ▪ High relevance due to tailoring to specific context/circumstances	▪ Define clear principles for evaluating requests ▪ Develop joint platform/ mechanism to institutionalize sharing	▪ Enable partners by ensuring that market shaping never fails due to the inaccessibility of available information

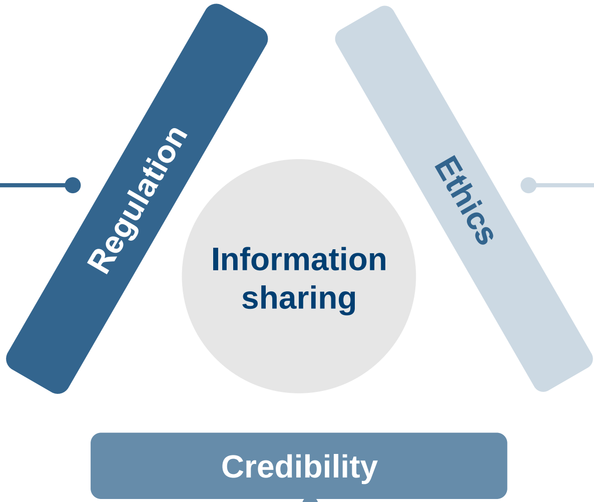
SOURCE: Team analysis

CONSTRAINTS: Information sharing is constrained from 3 angles

EXAMPLES ON NEXT PAGE

- 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

Ensure rigorous compliance with applicable regulations and obligations



- 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

Uphold high ethical standards

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

SOURCE: Team analysis

A set of key principles aims to maintain GF's integrity and credibility

Deep-dive in the following

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

SOURCE: Team analysis

Key principles that GF will need to bear in mind

Key principles	Considerations
Whether exchanging information is permissible will depend upon the type of information requested	▪ Public/confidential? ▪ Historic/forward-looking? ▪ Aggregated/anonymised? ▪ Relating to prices/volumes?
It is important that GF consider how and why information has been disclosed to them	▪ What was the purpose of the information disclosure? ▪ Was the information solicited? (NOTE: There is a presumption of usage) ▪ Is the information confidential? Is there an NDA?
GF should also consider why this information has been requested, and by whom	▪ What is the purpose of the request? ▪ Are safeguards necessary to protect the data? ▪ Was the information requested during a tender process? ▪ Could a hub-and-spoke arrangement be in operation?

SOURCE: Team analysis

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

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

Focus of today's presentation

Guidance by market shaping strategy

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 inter-nationally-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

NOT EXHAUSTIVE

Focus of the next pages

	What we have done	What we have achieved	What opportunities remain
Scope of activities	▪ Evolved QA policies to shape market ▪ Managed ERP[2] process with partners	▪ Increased and refined toolkit[1] ▪ Accelerate access to >40 innovative products	▪ Play more (pro-)active role in Quality Assurance
Intelli-gence on quality	▪ Refined understanding of marketed products ▪ Improved visibility on patients' safety (incl. better and more timely information)	▪ Improved ability to identify and act upon signals from the market	▪ Facilitate sharing of information ▪ Integrate multiple stakeholder approaches
Risk of quality issues	▪ Mitigated risk of quality issues	▪ Actively managed quality risks	▪ Refine and act upon own QA risk appetite

1 E.g., PSM guide

2 Expert Review Panels

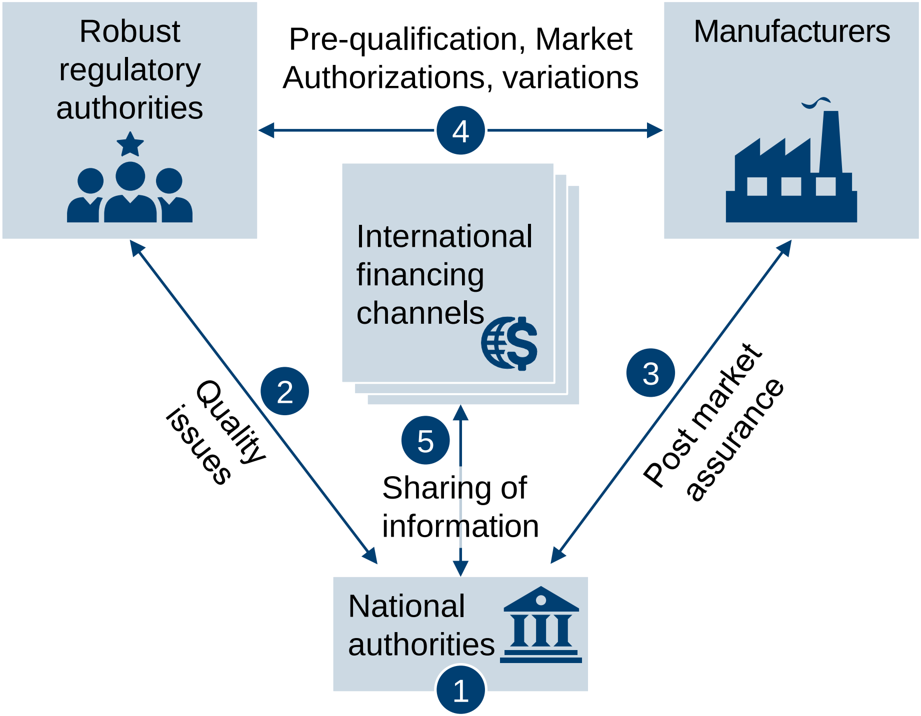
Source: GF

Further reducing patient risk is impeded by different challenges observed in the Quality Assurance ecosystem

x Mitigation levers on the next page

↔ Quality related interaction

Quality assurance ecosystem



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

X See underlying challenges on previous page

Nature of GFs involvement	Potential levers
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 4 **Extend rigorous information loop** to all national authorities, facilitate information flow
Engage (pro-) actively	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 5 **Pool and leverage resources, knowledge, and data** of GF and other organizations by **sharing of regulatory data** with key stakeholders (e.g., PRs)

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

Contents

Contents

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

The Global Fund

Leveraging impact at a glance

What is this?	**SMART[1] and effective collaboration**, including leveraging volumes between TGF, international financing partners and public health bodies
Why this is relevant?	Collaboration can enable significant additional impact on the journey **to create healthy markets**
Where the challenge is?	Identify, prioritize and seize **opportunities for collaboration** while maintaining focus and respecting resource constraints
How it matters to partners?	**SMART coordination** offers the opportunity to **get the most of existing resources,** incl. leveraging TGF's benefits

Source: Team analysis

1 Specific Measurable Achievable Realistic Timebound

Our journey

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

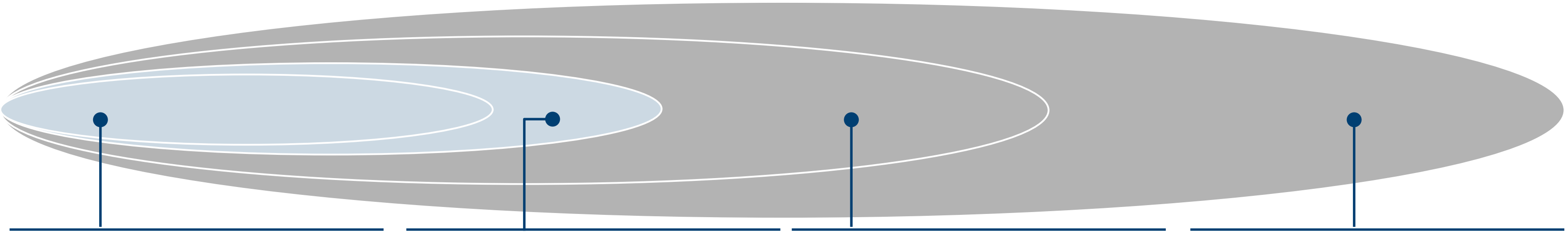
Source: Team analysis

Through collaboration we can unlock significant benefits and deliver on the Market Shaping Strategy

ESTIMATES

TGF internal volumes | TGF external volumes

Bubble size: $ health product funding on HIV/TB/Malaria



TGF influence → Unleveraged impact

	TGF - PPM 1.1 $bn	**TGF-** total PR grants +0.9 $bn	**International financing** +2-4 $bn spend of partners	**Total public health spend** +5-7 $bn, incl. country spend
Descrip-tion	▪ HIV/TB/Malaria health product expenditure run through PPM	▪ *See to the left* + grants by TGF for HIV/TB/Malaria health products not run through PPM	▪ *See to the left* + spend of financing partners on HIV/TB/Malaria health products	▪ *See to the left* + country and other (e.g., technical partners) spend on HIV/TB/Malaria
Benefits towards MSS	▪ Increase leverage and buying power through volume ▪ Provide access to competitive market prices, eliminate procurement delays, support timely grant expenditure, and ensure quality	▪ Extend benefits through synergies and economies of scale in order to increase impact through collaborative initiatives ▪ Build experience and refine tools/processes ▪ Gain stakeholder recognition	▪ Build market power and capture synergies / economies of scale ▪ Attain resource relief by spreading disease burden further ▪ Coordinating procurement of low volume ARVs	▪ Locally embed and enforce impact and align with policies and initiatives ▪ Achieve trickle-down effects on overall health system ▪ Ensure legitimization and support

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

Mutual impact leveraging ecosystem | Sharing institutions | Intermediary beneficiary | Eventual beneficiary

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

Level of collaboration	Strategic priorities	Examples
	1 Gain visibility on procurement practice and planning	*See below*
	2 Coordinate tender cycle and timeline	▪ LLIN: UNICEF, PMI ▪ ARV: PEPFAR, South Africa
	3 Align principles of performance-based procurement approach	▪ ARV: E.g., Kenya/ Ethiopia/UNDP and other non-PPM country procurement
	4 Join/pool procurement practice	▪ ARV: PAHO

Insights

- **Depending on the stage of the market** in terms of level of collaboration, different levers have the potential to increase impact
- Both degree and focus of collaboration/mutual impact leveraging should be **tailored to specific level of collaboration**
- TGF seeks to collaborate with the **right partners at the right point in time** to achieve optimal results

Source: Team analysis

Strategic initiatives and activities

Partners		Examples of initiatives
TGF	PPM	▪ Continue to drive the **extension of framework agreements** to further categories ▪ Advance **direct engagement and sharing of information uniformly with suppliers**
	Non-PPM	▪ Drive **visibility into current demand and procurement practices** ▪ **Coordinate approach**, e.g., when to tender, go-to-market timings ▪ Encourage and facilitate **sharing of best practices** ▪ Enter into **joint procurement** ▪ Improve **access to innovative products through procurement solutions**, i.e., generate visibility on demand, identify demand levers, explore procurement solutions (e.g., bundling, catalytic funding, leveraging existing supplier relationships)
International financing		▪ Improve **visibility into current demand and procurement practices** ▪ **Coordinate approach,** e.g., when to tender, go-to-market timings ▪ Facilitate **development of strategic sourcing**, e.g., further drive initiatives to improve OTIF and quality metrics ▪ **Secure supply and mitigate price volatility** on emerging, declining and low volume/fragmented products ▪ **Coordinate with other major buyers** on provision of upstream demand forecasts in order to generate secure supply and minimize price volatility ▪ Continue to **promote product standardization and quality** as part of Innovation to Impact, e.g., establish clear normative guidelines on policy, co-ordinate buyers to streamline inputs to suppliers

Initiatives broken down to:

- Disease areas (Malaria, HIV, TB)
- Stakeholders (e.g., PRs, partners)

Source: Team analysis

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

		Disease area	
Category	Examples	Disease specific	Cross-diseases
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

Exercise: Opportunities for collaboration

Category	Examples	Disease area: Disease specific		Disease area: Cross-diseases	
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

The Global Fund

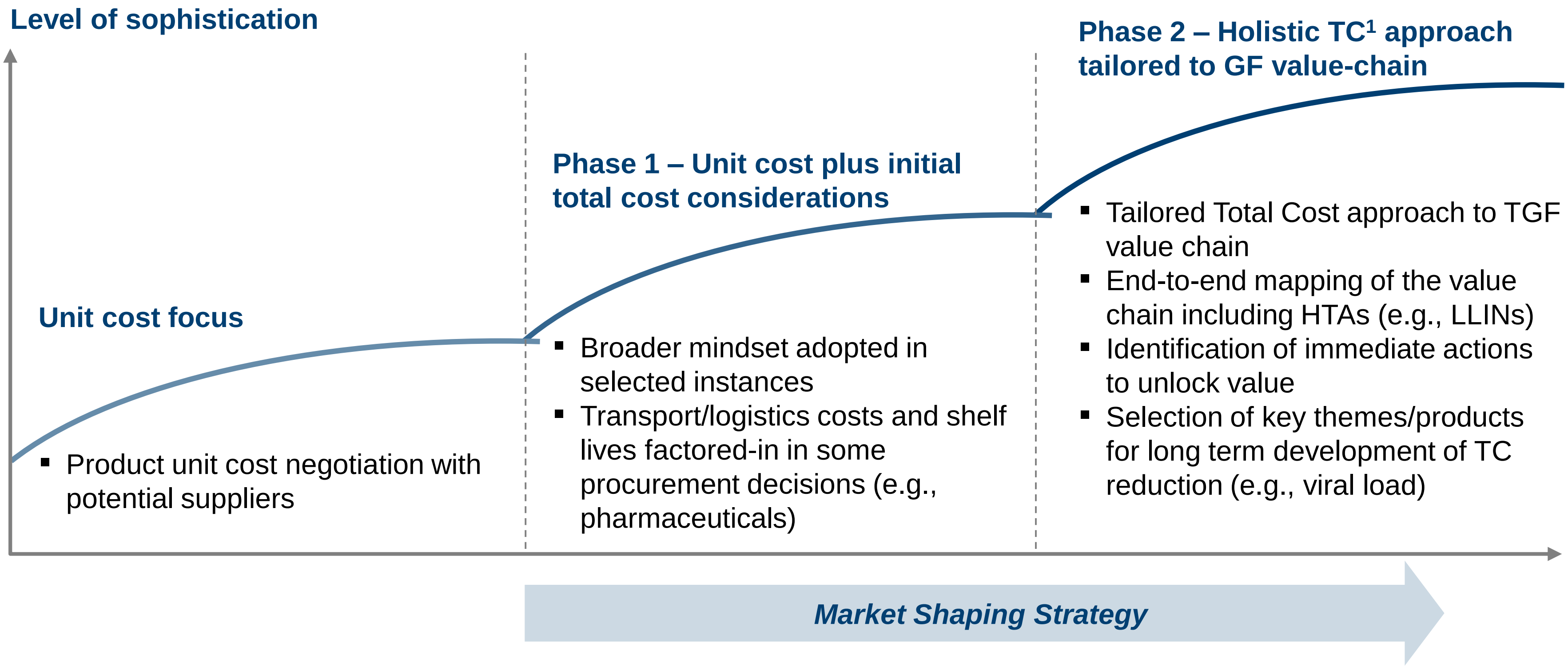
Total Cost approach at a glance

What is this?	An estimate of **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
Why this is relevant?	Looking systematically at all cost buckets at each stage of the end-to-end value chain will **generate significant benefits** (incl. **savings, supply chain, social, environmental** benefits) that will empower country capability and enable achievement of SDGs
Where the challenge is?	Allocation and optimization of each cost bucket for each product and stage of the value chain requires **SMART[1] coordination with partner organizations** to generate highest benefits while maintaining highest product quality
How it matters to partners?	**SMART coordination** and sharing of information among partners is needed to **maximize savings/supply chain/environmental/social benefits for all partners**

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



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	Where we want to get
Unit cost approach	▪ Significant **value unlocked at unit price level**, e.g., 38% reduction in LLIN price since 2014	▪ Unlock **additional value** through end-to-end total cost analysis and valuing enhanced specifications
Evolving towards a Total Cost approach	▪ **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	▪ **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

Supply Chain opportunity

NOT EXHAUSTIVE

Examples of initiatives	Description	Case example	Examples of potentials benefits
Improve forecasting	▪ Predict future TGF demand (quantitative, qualitative, variations) to tailor supply accordingly	▪ A manufacturer of the highest volume product proposed to reduce its price by 10% if demand and supply were optimized (e.g., volume, freight)	▪ **Negotiation power** to discuss unit prices with suppliers ▪ Potential **10% unit price** reductions ▪ Up to **2-3% of product cost** through more efficient freight
Optimize lab equipment selection and maintenance agreements	▪ Reduce total cost of test through decreased down time	▪ Changing warranty agreement for 1 type of lab machine in 1 African country generated 295.000 USD savings over 5 years	▪ **Higher testing availability** ▪ Decrease **loss to follow-up** ▪ Better informed **treatment decisions**
Optimize packaging and labelling	▪ Leverage bar-coding to drive efficiencies in the full supply chain ▪ Use low cost / environment friendly materials for packaging; avoid unnecessary packaging ▪ Leverage further multi-month packs and drive shelf life improvements ▪ SKU standardization	▪ A supplier of pharma products unlocked 20% of total shipping cost by increasing number of bottles per boxes (case study)	▪ Increase **production/supply flexibility and responsiveness** ▪ Reduce **quantity of paper/plastic** used to decrease carbon footprint ▪ Decrease **freight cost equivalent to 2-3%** of product cost (opportunity will increase with new ARV regiments)
Sourcing closer to demand	▪ Locate strategic sourcing options close to demand	▪ Sites located in East Africa supplying ACTs and LLINs under framework agreements	▪ More **responsive supply** at no additional total cost ▪ **Enabling of response to emergency orders** due to short lead times (6 down to 2 weeks)
Optimize storage	▪ Minimize overall volume of stored product to reduce temporary warehouse volume ▪ Minimize cost of temporary warehouse solution (e.g., rental cost, number of warehouses in an area)	▪ Significant cost saved for 700 sq meter temporary warehouse	▪ **Reduce overall volume** of stored products

Source: Team analysis

For the long term, there are 5 areas for the sourcing team to investigate

a **Improve demand forecasting in order to unlock value from the upstream supply chain** as well as improve supply security and reduce lead time

b **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

c Engage in relationship management with suppliers, especially working hand-in-hand to **jointly co-create/generate product innovation**

d **Structure approaches to meet tradeoffs between multiple objectives**, e.g., benefits through enhanced relationship with selected suppliers vs. protection of supply structures

e ***Push the boundaries:* evaluate contract manufacturing** (long term, for discussion)

Source: Team analysis

Instructions for breakout

Objective: Identify Total Cost initiatives

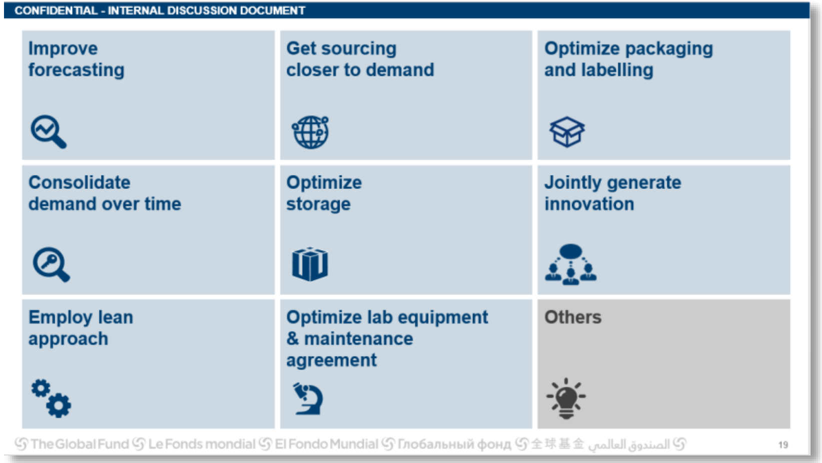
Instructions:

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

Improve forecasting

Get sourcing closer to demand

Optimize packaging and labelling

Consolidate demand over time

Optimize storage

Jointly generate innovation

Employ lean approach

Optimize lab equipment & maintenance agreement

Others

Example of initiative	Definition
Improve forecasting	▪ **Predict future demand** (e.g., quantitative, qualitative, seasonal/ regional variations)
Consolidate demand over time	▪ **Gather orders over a determined period of time** to optimize mean of transport
Employ lean approach	▪ Employ **lean management approach** all along end to end value chain to improve process efficiency while reducing cost
Optimize storage	▪ Minimize **overall volume of stored product**

Initiative	Definition
Get sourcing closer to demand	▪ Locate strategic **sourcing options closer to demand**
Optimize packaging and labelling	▪ **SKUs standardization** ▪ Use **low cost/environment friendly materials; Avoid unnecessary packaging** ▪ Leverage **bar-coding**
Optimize lab equip-ment selection & maintenance agreement	▪ Reduce total cost of test by **decreasing equipment down time**
Jointly generate innovation	▪ Work hand-in-hand with suppliers to **jointly co-create/ generate innovation**

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

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

Source: Team analysis

Our journey

	What we have achieved	Where we want to get
Leveraging TGF's position	▪ Case-by-case support to innovators focused on facilitation and engagement with partners under constraint not to commit volumes, e.g., DTG[1]	▪ **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
	▪ Engaged cooperation of multiple internal stakeholders, e.g., Sourcing, Grant Management, SIID[2] and PRs	▪ Full internal collaboration with **clear de-lineation of responsibilities** and assign-ment of ownership (particularly on demand)
Collaborating with partners	▪ 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	▪ 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

Launch

Sustainably available and affordable new/ cost efficient product

Policy | **Development** | **Product uptake** | **Insights**

Objectives of support

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

Stake-holder interde-pendency

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

Information-flow between key stakeholders

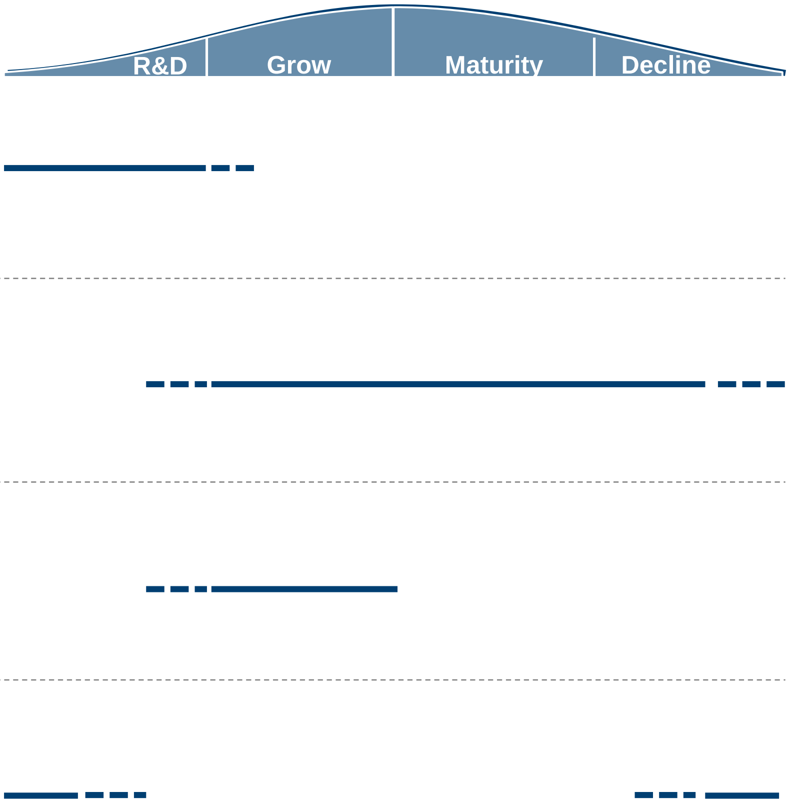
- Enable forecast of future uptake and commercial case
- Decrease risk of innovation through smooth entry and scale-up

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**

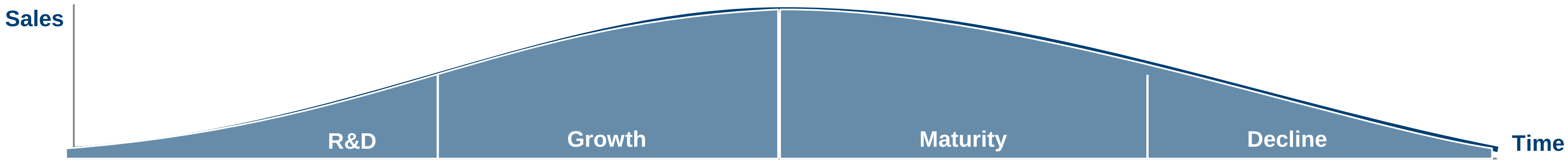
Source: Team analysis

Relevance along product lifecycle



Key objectives	Description
Incentivize and facilitate research and development	▪ Ensure adequate and timely pipeline of products ▪ Develop and harmonize policies
Develop, sustain, and secure supply	
Foster adoption and uptake	
Facilitate transition/ switching	

nificant impact has been achieved along the product lifecycle



	R&D	Growth	Maturity	Decline
Key partners	Unitaid, FIND, Médecins Sans Frontières, World Health Organization, Bill & Melinda Gates Foundation, TB Alliance, PATH, Clinton Health Access Initiative, PMI, DNDi, Stop TB Partnership Global Drug Facility, Medicines for Malaria Venture	Unitaid, World Health Organization, Stop TB Partnership Global Drug Facility, Bill & Melinda Gates Foundation, PATH, PMI, Clinton Health Access Initiative	PMI, Stop TB Partnership Global Drug Facility, psi, Clinton Health Access Initiative, unicef, PATH, DFID, World Health Organization	Stop TB Partnership Global Drug Facility, PMI, World Health Organization, PATH, psi, Clinton Health Access Initiative
Activities	▪ Early and proactive engagement together with partners ▪ “Being at table” and alignment of expectations ▪ Support with regulatory pass ways	▪ Technical inputs ▪ Recommendations and commercial information ▪ Leveraging of relationships, incl. PRs	▪ Leveraging of volumes and relationships, incl. PRs	▪ Support in development of exit strategies
Impact	▪ Successful support of innovation and launch of products without having to commit to volumes ▪ Acceleration of introduction	▪ Provision of negotiation support ▪ Extension of framework agreements ▪ Identification of potentially interested countries to induce demand ▪ Establishment of contact with countries	▪ Increase in access to formerly too expensive products ▪ Price reductions	▪ Sustenance and stabilization of supply structures

Source: Team analysis

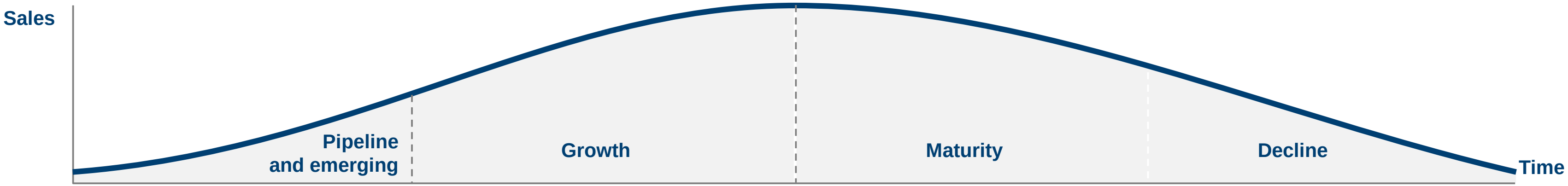
A series of frequent challenges are faced as the global community aims to support new production introduction and development

Types of challenges		Description
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	Supply	▪ **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**
	Demand	▪ Program **switching costs inhibit rapid scale-up** of new products ▪ **Lengthy policy waterfalls and regulatory approvals** limit academic demand from becoming actualized
	Approach/ coordination	▪ **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



Buyers

Address long lead-time and poor delivery performance

Pipeline and emerging	Growth	Maturity	Decline
Early engagement	Competitive cost	Deliver sustainability: mitigate price volatility and secure supply	

Manu-facturers

Pipeline and emerging	Growth	Maturity	Decline
▪ Lack of clarity for investment	▪ Recover from investment and growth	▪ Brutal competition	▪ Ethical exit plan

Potential levers

Buying power	**Leverage future demand**		**Leverage volumes to reduce price (and price volatility) as well as secure supply and stabilize supply structures**
	Reward innovators		
Informa-tion	**Share commercial information / forecasting / scenario perspective with originators**		**Help originators / suppliers forecast sales erosion and foresee market development**
	Counsel product development partnerships (PDP) and other partners		
Influ-ence	**Engage with partners/PDP to include supplier metrics early in pipeline**	**Leverage relationships with partners and PRs to support pick-up of demand**	**Leverage supplier relationships, partners and recipients to smoothen exit and stabilize supply structures**

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

	Pain points	Opportunities for your organization to collaborate and relieve pain points
Product development		
Policy development		
Demand generation		
Supply development		

Source: Team analysis

GF has identified a set of success factors for collaboration

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

Sustainable commercial production for procurement

Source: Team analysis

Contents

Playback of breakout-sessions

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

1 Leveraging impact: we want to move towards a smarter collaboration

NOT EXHAUSTIVE

Category	Examples of opportunities for collaboration
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 fore 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

2 New Product Introduction: We want to "untangle the web"

NOT EXHAUSTIVE

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

2 New Product Introduction: Pain points and opportunities (1/2)

NOT EXHAUSTIVE

	Pain points	Takeaways going forward
Product develop-ment	▪ There are limited "upstream signals", leading to, e.g., slow and bothersome navigation of market entry process (incl., guidelines, PQ etc.) ▪ Visibility of early-stage development pipeline for TGF is limited ▪ Grants do not necessarily contain optimal products	▪ Specify approach to be flexible per category ▪ **Introduce cross-secretariat/partner biannual stock-take on uptake progress and bottlenecks for new products meeting criteria for success** ▪ Deliberately evaluate the inclusion of products with fundamental innovation in funding technical review or grant making
Policy develop-ment	▪ 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 ▪ Assessment of value beyond unit price is not mature for innovative products	▪ Collaborate to pool resources/information, leverage stakeholder relationships and increase visibility on process and decision points for clinical recommendations and regulatory approvals ▪ Consider valuing participation in regional / WHO collaborative registration in tenders
Demand generation	▪ Countries have limited visibility on product pipeline, benefits of new products, as well as general innovation-related information ▪ **Lacking involvement of communities/patients in product design characteristics and generating downstream demand**	▪ Collaborate to pool resources/information, leverage stakeholder relationships and increase visibility on innovation landscape and developments in the market ▪ As partnership, increase user and program acceptance to improve chances of successful uptake

Source: Output of breakouts

2 New Product Introduction: Pain points and opportunities (2/2)

NOT EXHAUSTIVE

	Pain points	Takeaways going forward
Supply develop-ment	▪ **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)	▪ 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**
Over-arching	▪ There is **a "web"** of partners, product regulation policies and requirements, as well as innovators/innovations that is difficult to navigate for demand/supply	▪ **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

3 In the Total Cost approach break-out, numerous ideas were raised that can enable collaboration

NOT EXHAUSTIVE

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

- GIZ: encourage African manufacturers in “Access to Medicines” to participate in GF survey
- Utilize DFID country networks/market shaping team to promote local production/manufacturing
- USAID can collaborate on local manufacturing initiatives and analyses

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 storage

- Investigate collaboration with NSCIP in Nigeria and also Malawi

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

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)

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

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

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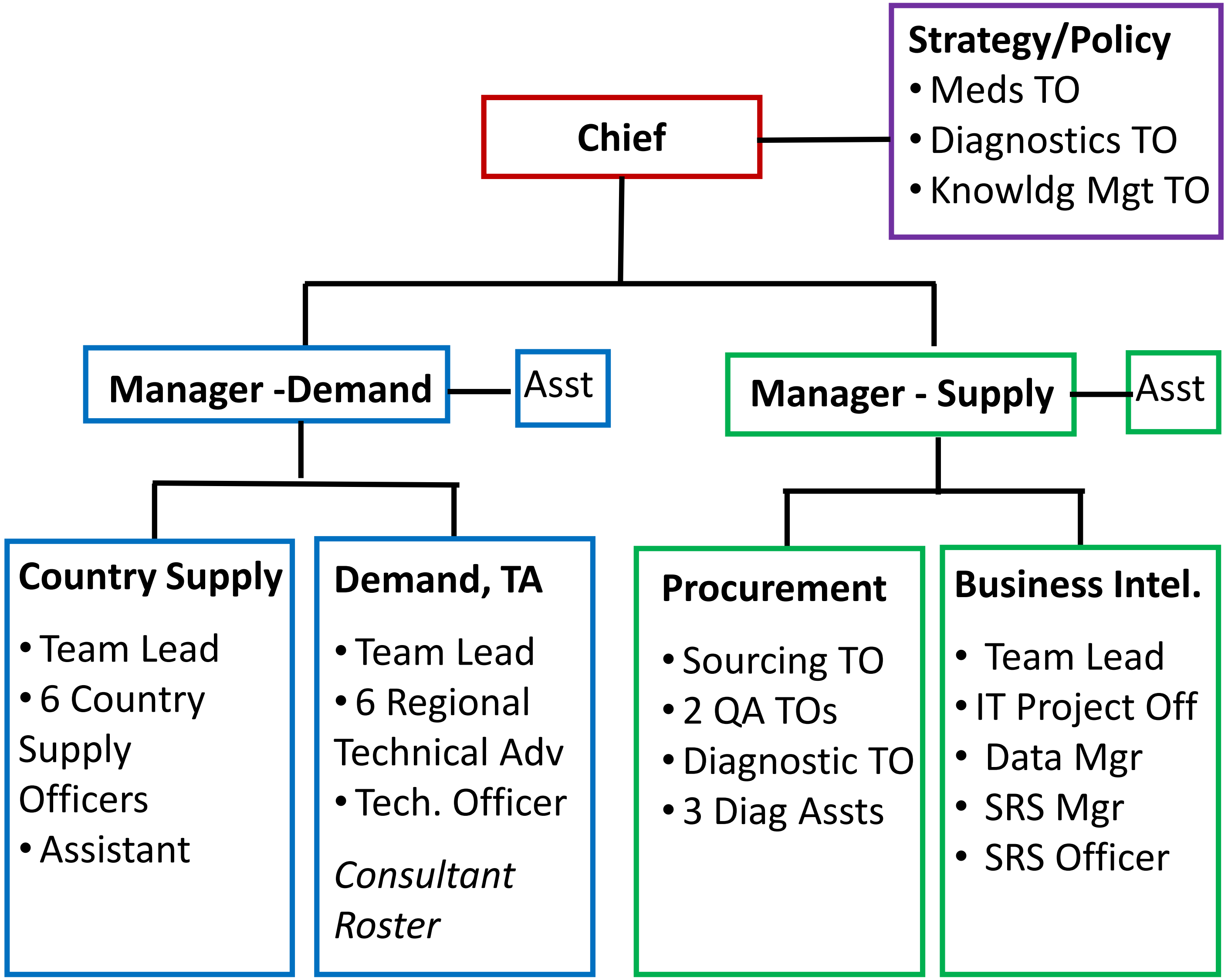
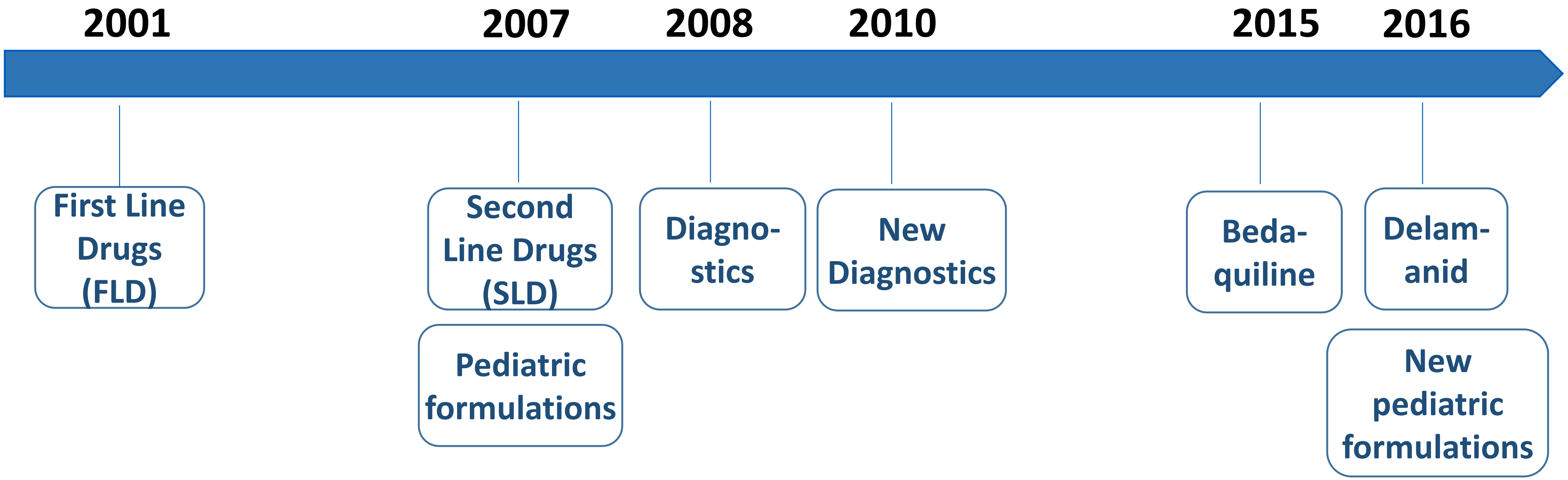
1. GDF Overview

- 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

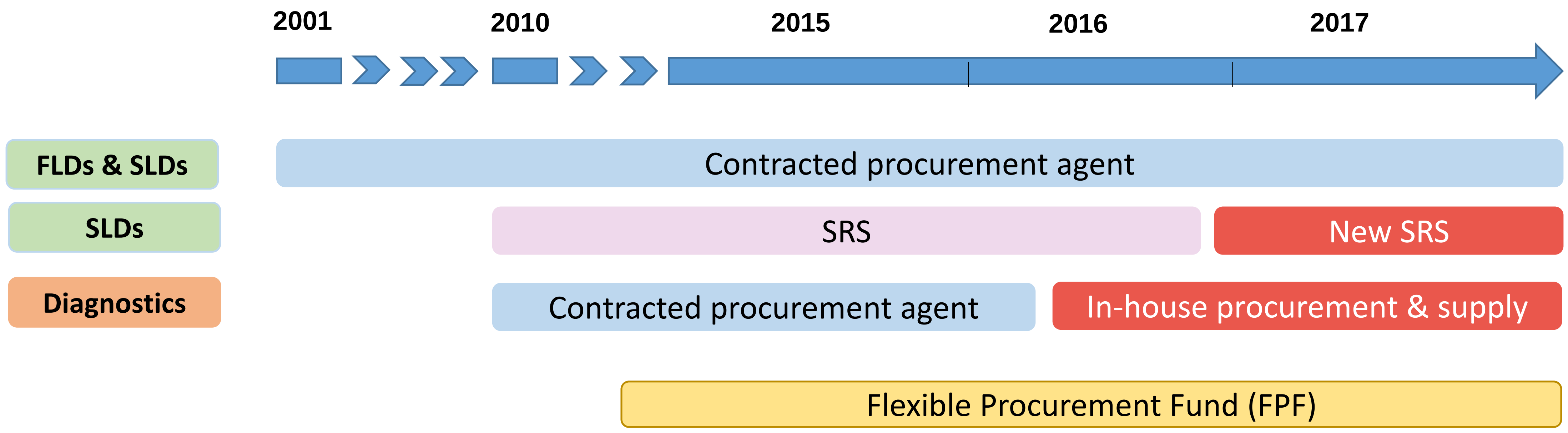
- Grants (USAID, Canada, UNITAID, etc.) were key to catalyzing TB medicines & diagnostics markets
- Global Fund funding was key to market maturation, scale-up, and expanded access



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



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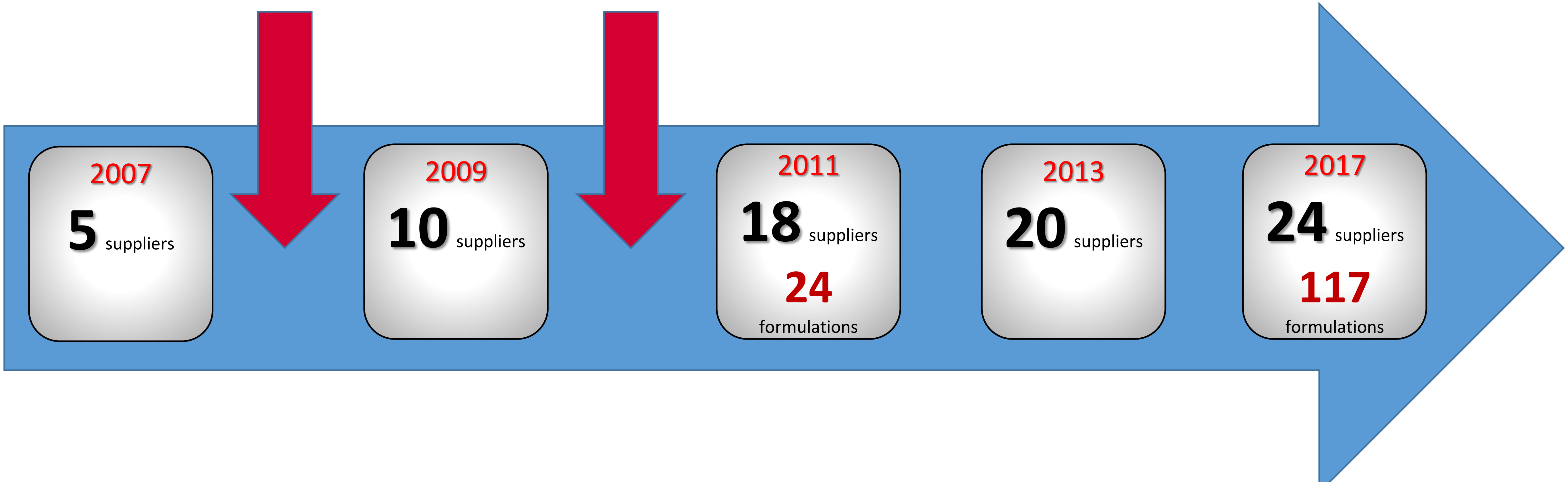
2. Tuberculosis Medicines Markets Evolution

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

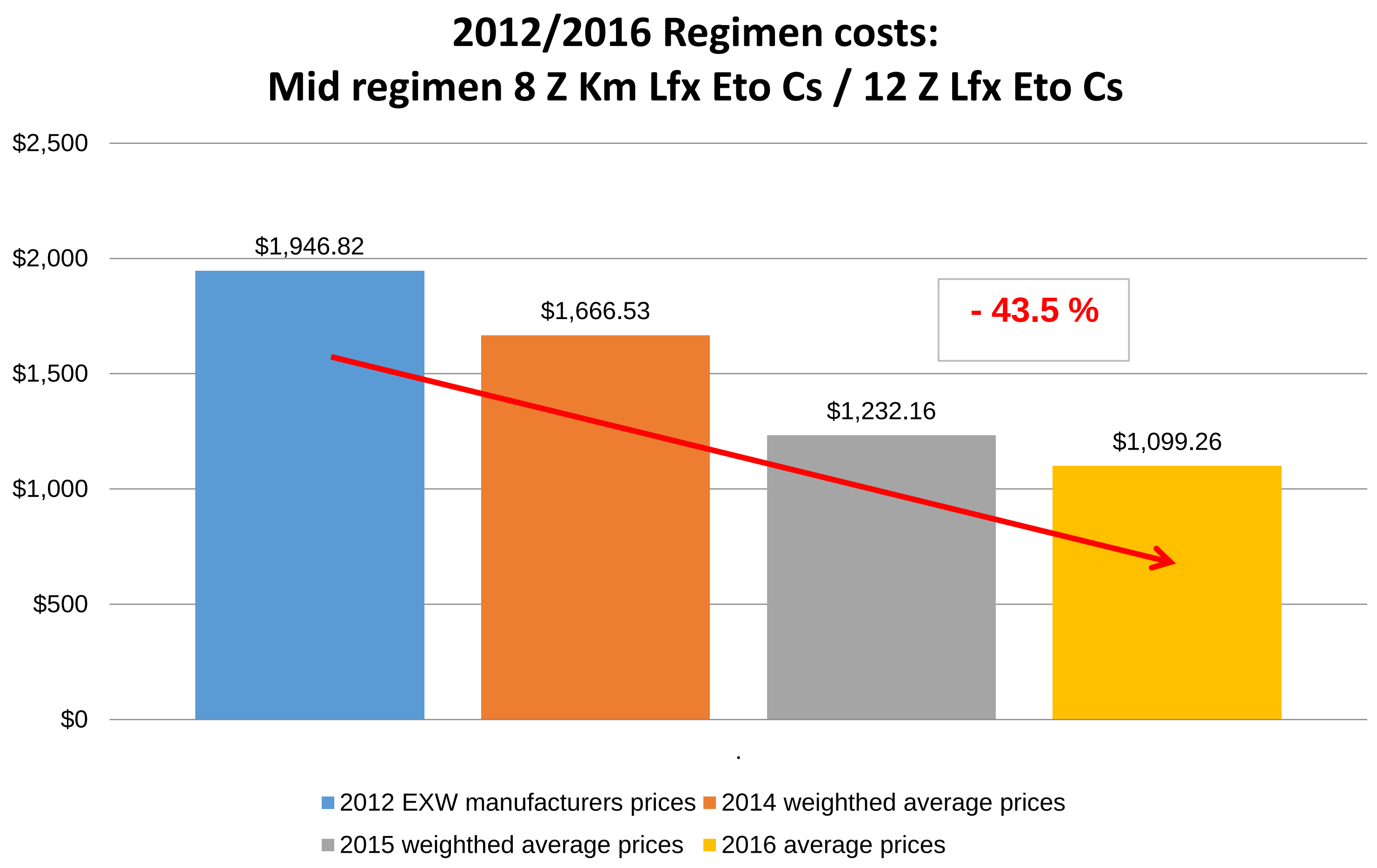
July 2010: GDF QA policy harmonized with The Global Fund and partners



94.5% average supplier performance (Jan-June 2017)

The power of GDF pooled procurement & market interventions (2)

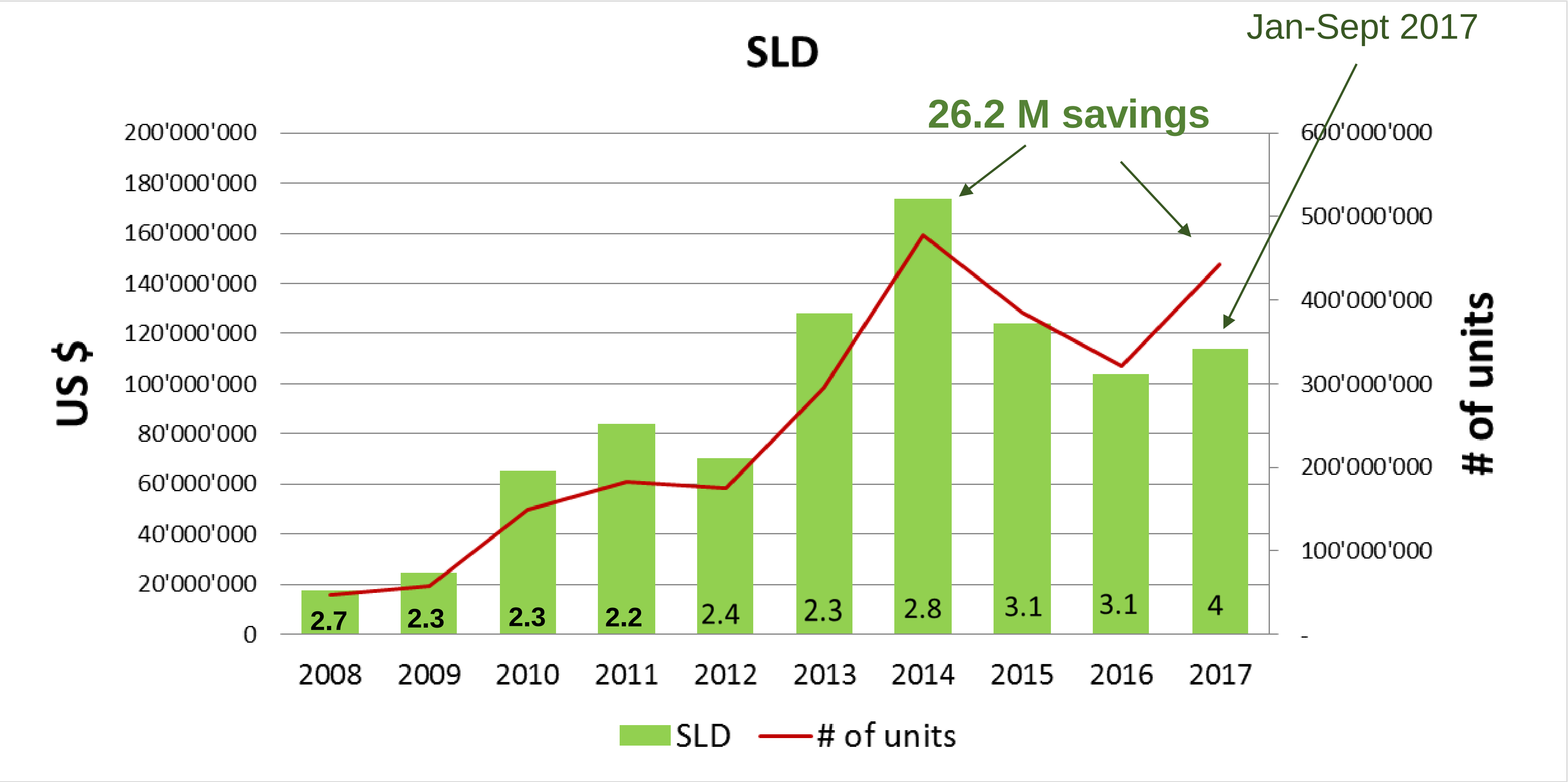
Dramatic decrease in GDF SLDs prices for MDR-TB regimens



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

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

Country	Original Transition Date	Accelerated Transition Date	Value of Old stock to be removed (USD)	Value of New Drugs ordered 2017/2018 (USD)	Operational cost saving	GF status	Number of patients benefited
Cambodia	**Dec 2017 (all at once)**	**All eligibles in Oct/Nov 2017**	143,000	68,000	500,000	GF approved NTP to implement	**200**
Indonesia	**July 2017 to Dec 2018 (phased approach)**	**All eligibles in July 2017**	2,610,052	NTP has enough stock	Not calculated	GF approved NTP to implement	**7,888**
Malawi	**June 2018**	**Q1 2018**	0	31,312	Not calculated	GF approved NTP to implement	**42**

GDF 2016 Sales of PQ products Compared to Annual PQ Fees

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

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

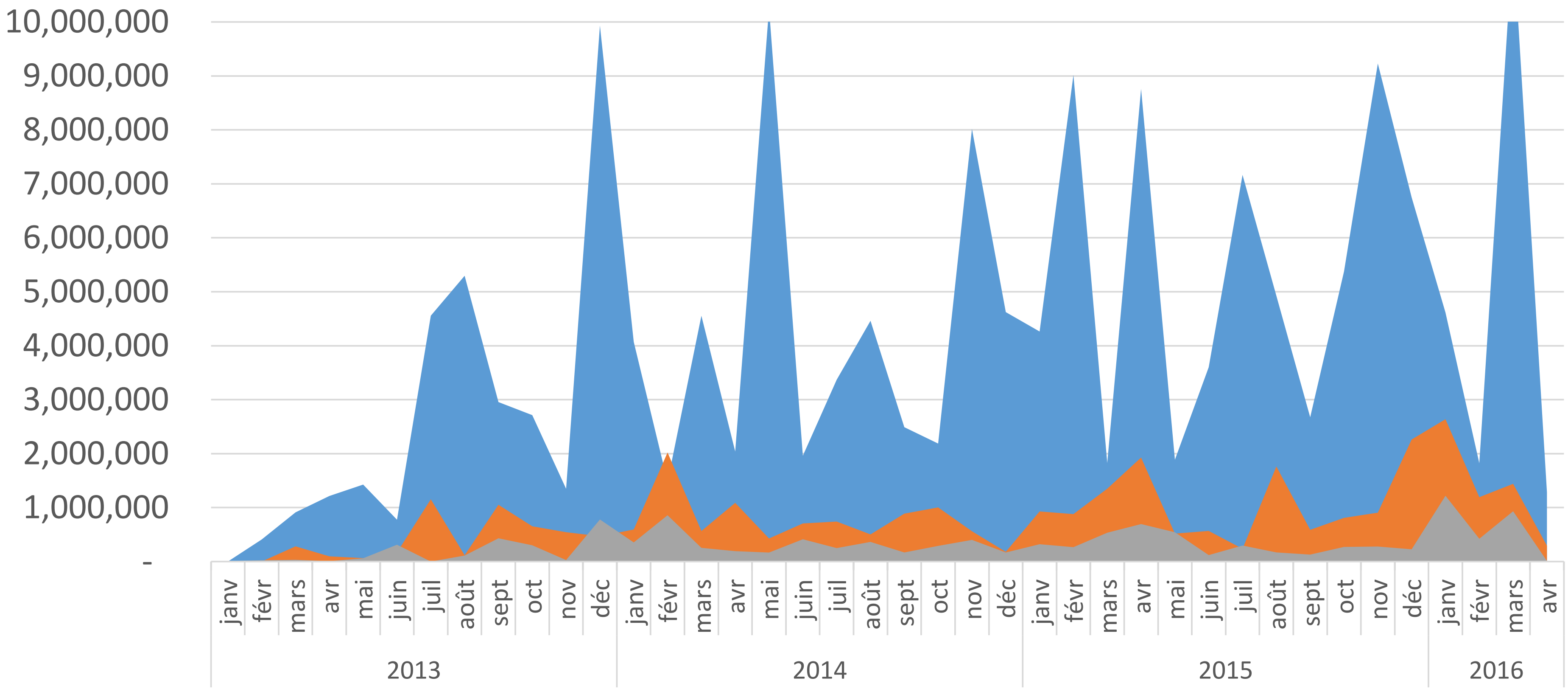
Cost-savings of GDF Interventions with country orders (q1-q3 2017)

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

>$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

	2015	2016	Jan-Sep 2017	Total 2015-Sep 2017
Treatments* in early stage of order process			3,098	3,098
Treatments* in late stage of order process			6,139	6,139
Treatments* Delivered	1,001	1,474	4,303	**6,778**
Total	**1,001**	**1,474**	**13,540**	**16,015**

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

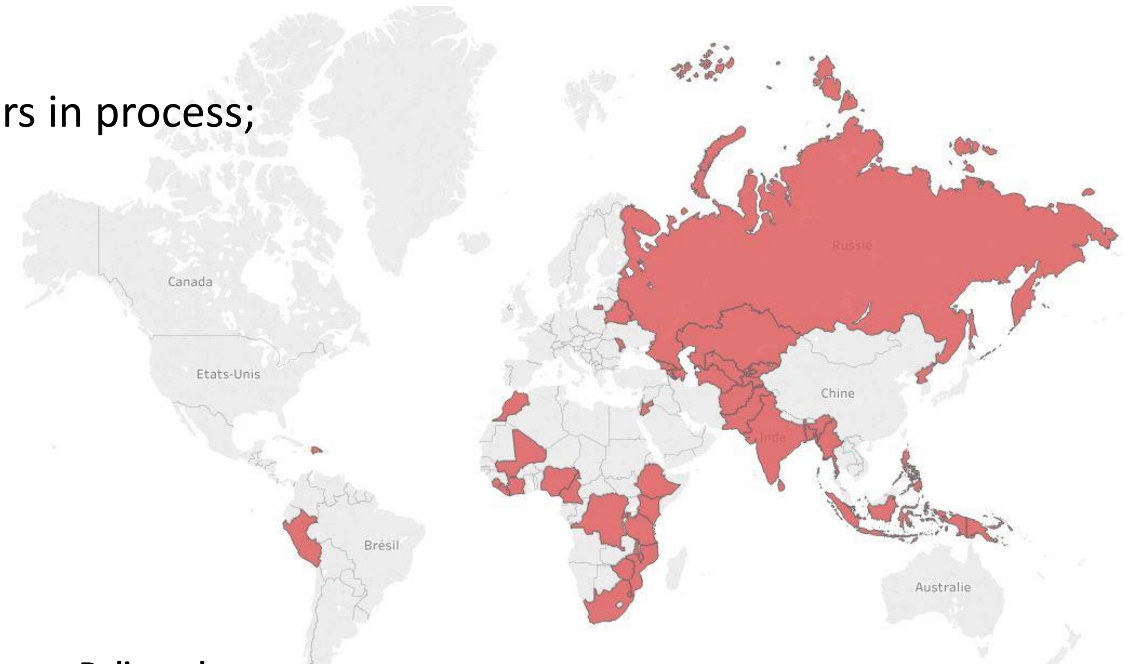
Delamanid Procurement Status

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

	2016	Jan-Sep 2017	Total 2016 – Sep 2017
Treatments* in early stage of order process		1,053	1,053
Treatments* in late stage of order process		1,227	1,227
Treatments* Delivered	620	970	**1,590**
Total	**620**	**3,250**	**3,870**

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

In-process:

Azerbaijan
DRC
Indoneisa
Malawi
Nigeria
Pakistan
Philippines
Rep. Moldova
Rwanda
Sierra Leone
Turkmenistan
Un. Rep Tanzania
Uzbekistan
Zimbabwe

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

Country	Status	Timeline/Plan	Country	Status	Timeline/Plan
Afghanistan	Plan	Q1 2018	Nigeria	Started	Q2 2017
Bangladesh	Started	April 2017	Pakistan	Plan	Q1 2018
Cambodia	Plan	Nov 2017	Philippines	Started	July 2015 (trial) /Q1 2017 (scale-up)
DR Congo	Started	2013-2015, 2016 (scale-up)	South Sudan	Started	Q2 2017
Ethiopia	Plan	Q1 2018	Tajikistan	Started	Q2 2017
India	Plan	Jan 2018	Tanzania	Plan	Q4 2017
Indonesia	Started	Sept 2017	Uganda	Plan	Q4 2017
Kazakhstan	Plan	Q4 2017	Ukraine	Plan	Q3 2018
Kenya	Started	Q3 2017	Uzbekistan	Plan	Q1 2018
Kyrgyzstan	Started	Q1 2017	Vietnam	Started	April 2016
Malawi	Plan	Q1-2 2018	Zambia	Plan	Q4 2017
Mozambique	Plan	2016 (trial)/ Q4 2017 (scale up)	Zimbabwe	Plan	Q4 2017
Myanmar	Plan	Oct 2017			

Countries that have Ordered New Paediatric FDCs from GDF

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Afghanistan	Ghana	Pakistan
Bangladesh	Guinea	Papua New Guinea
Benin	Guinea-Bissau	Philippines
Bhutan	Haiti	Rwanda
Burkina Faso	India	Samoa
Burundi	Jordan	Sao Tome and Principe
Cambodia	Kazakhstan	Senegal
Cameroon	Kiribati	Sierra Leone
Central Africa Republic	Kyrgyzstan	Solomon Islands
Chad	Lao	Somalia
China	Lebanon	Sri Lanka
Congo	Lesotho	Sudan
Cote d'Ivoire	Liberia	Swaziland
DPRK	Madagascar	Syria
DRC	Malawi	Tajikistan
DR Timor-Leste	Maldives	Togo
Djibouti	Marshal Islands	Tuvalu
Ecuador	Mauritania	Uganda
Egypt	Mozambique	Un. Rep. Tanzania
Eq Guinea	Myanmar	Uruguay
Ethiopia	Nepal	Viet Nam
Gambia	Niger	Zambia
	Nigeria	Zimbabwe

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

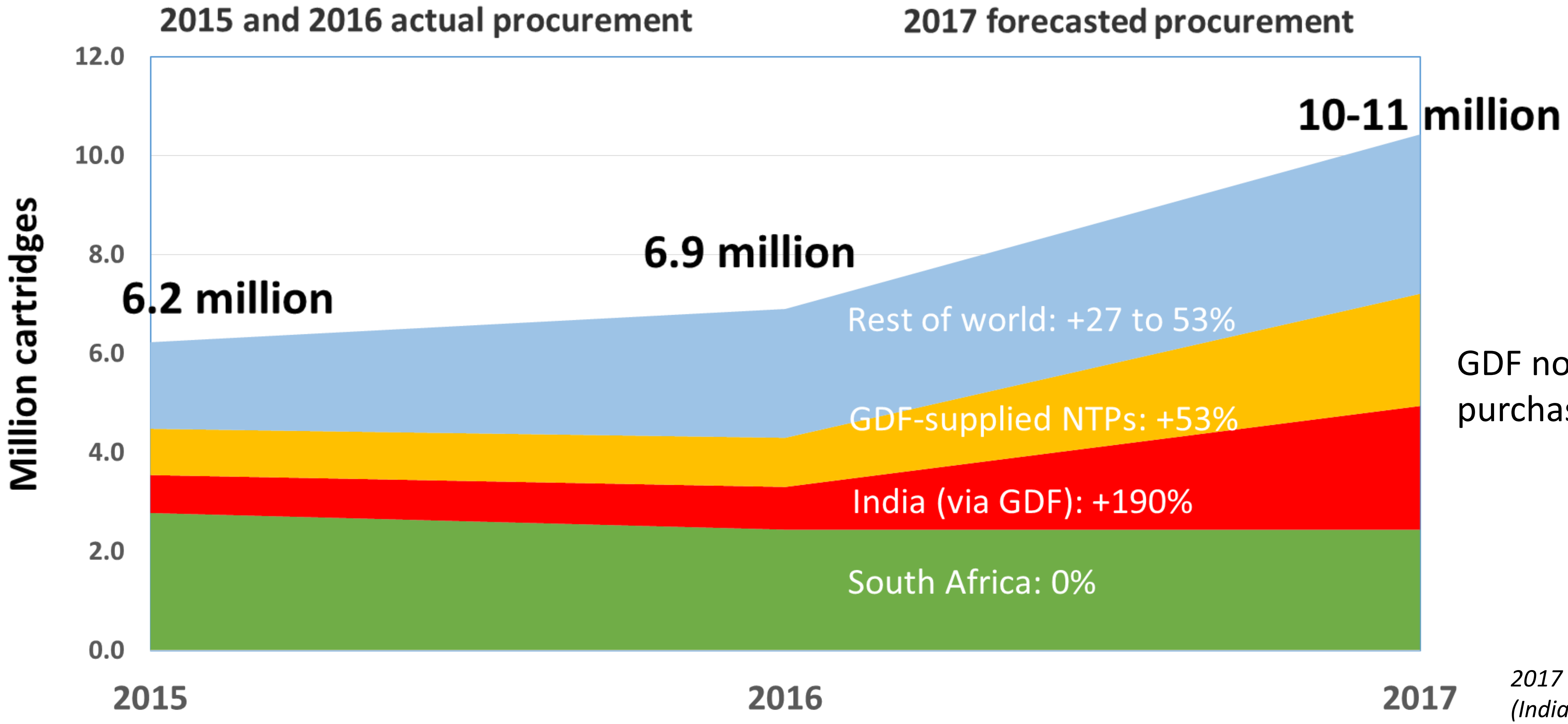
- 59 countries have had FDCs delivered (~410,000 treatments); 9 countries in ordering process

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



2015-2016 data: Cepheid

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

4. Priority Issues & Challenges in TB Markets: Forecasting, GF Co-financing, Xpert

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

35th Board Meeting

The Global Fund Sustainability, Transition and Co-financing Policy

GF/B35/04 – Revision 1
Board Decision

PURPOSE: This paper presents the Sustainability, Transition and Co-financing Policy that the Strategy, Investment and Impact Committee recommends for Board approval.

The Global Fund

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

Result in shortages, stockouts

- 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?

Observations on WHAT countries buy: Will NTPs Revert to Pre-GF Practices? (Meds)

Pre-Global Fund	Global Fund	Co-Financing/Transition
 Multiple, single tablets and injections Not optimized, not user-friendly	 Fixed-dose combinations Optimized, user-friendly	Continue using FDCs ***Or,*** Go back to multiple tablets, irrational regimens
 Unknown quality status	World Health Organization Quality-assured products	Continue to use Quality-Assured Products ***Or,*** Revert to products of unknown quality
$ Expensive second line treatment (>$5000 per treatment course)	$ Large Price decreases ($800 for shorter MDR regimens)	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)

Pre-Global Fund	During Global Fund	Co-financing/Transition
Solid culture TB diagnosis & DST • Slower, less sensitive • Inexpensive, materials sourced locally 	**Automated liquid culture TB diagnosis & DST (MGIT)** • Faster, more sensitive • Expensive, sole source, reliable provider • (Becton Dickinson) 	• 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
Microscopy • Low sensitivity • Does not provide information on drug resistance • US$ 1-2 / test, sourced locally 	**Xpert MTB/RIF** • 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 	• 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%

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

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The Global Fund

GLOBAL FUND SOURCING STRATEGIC REVIEW MEETING

16th & 17th OCTOBER 2017

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