# Technical Evaluation Reference Group:

# Market Shaping Strategy Mid-Term Review

# Position Paper

December 2019

The Global Fund

# TERG Position Paper

## Executive Summary

### Context

The Global Fund Board approved the Market Shaping Strategy (MSS) in November 2015[1]. The Global Fund, in cooperation with countries and partners, is implementing the strategy to contribute to health outcomes by leveraging the Global Fund's position to facilitate healthier global markets for health products, today and in the future.

The Technical Evaluation Reference Group (TERG) commissioned a mid-term review of the Market Shaping Strategy, which was conducted from April to July 2019.

### Conclusions

A. To address the challenges identified, the Review provides four key prioritized actions, with suggestions as to how each action may be best implemented. The TERG agrees with these recommendations and provides four additional recommendations.

B. Significant progress from "smart procurement" towards "proactive market shaping" will require the Global Fund to: drive stronger health product management across all Global Fund-funded procurement; ensure internal teams and core partners align on issues, priorities and roles/accountabilities for specific product markets; and continue efforts to ensure the long-term sustainability of market-shaping successes. This would complement continuation of activities already underway, which drive value on the six MSS objectives.

### Input Received

The Review has been initiated and prepared with detailed and valuable contributions from the Global Fund Secretariat, particularly with extensive support from the Sourcing and Supply Chain Team.

[1] GF/B34/DP08

# Report

## What is the topic of this review?

1. The Market Shaping Strategy (MSS) 2016-2021[2] was approved by the Global Fund Board in November 2015. It defines how the Global Fund can contribute to improving health outcomes by leveraging its position to facilitate healthier global markets for health products, today and in the future. Strategic objectives of the MSS include: ensuring continued availability and affordability; promoting consistent quality standards; supporting efforts to stimulate innovation; accelerating the adoption of new and/or cost-effective products; preparing for country transition and long-term market viability; and strengthening key foundational elements for market shaping.

2. Annex I of the MSS states that a mid-term evaluation of the Strategy will be conducted by the TERG, which was performed from April to July 2019. The objective of this Market Shaping Strategy Mid-term Review was to permit an understanding of the status of delivering the Board-approved Strategy. More specifically, the objectives were to:
    a. Provide an independent view of **progress to date**;
    b. Provide an independent view of the **Secretariat's Roadmap** (developed in 2017) for implementing the 2nd phase of its current Market Shaping Strategy; and
    c. Provide an independent view of any **additional transformative value** that could be achieved through additional focused efforts (*e.g.*, on existing or new mechanisms and/or tools).

3. To meet these objectives, the Review included more than 60 key informant interviews, a literature review, quantitative analyses and five country case studies. An assessment of Global Drug Facility (GDF) activities beyond Global Fund-funded procurement was out-of-scope for this review.

## MSS Mid-Term Review Findings

4. The Review identified four key findings, summarized below in points A to D and in Figure 1.

    A. The Global Fund's Sourcing and Supply Chain team (SSC) conducts tenders and maintains long-term, performance-based framework agreements with suppliers for antiretroviral medicines (ARVs), antimalarial medicines and long-lasting insecticidal nets (LLINs). **SSC has driven strong improvements in the availability and affordability of products for which they have performance-based arrangements.**

    B. Limited centralized and real-time visibility into spend across channels likely leads to missed opportunities to drive availability, affordability, and quality:
        i. Due to **price & quality reporting (PQR) data incompleteness and delays in reporting**, there is limited real-time, centralized visibility into availability/affordability of products procured through non-PPM channels.

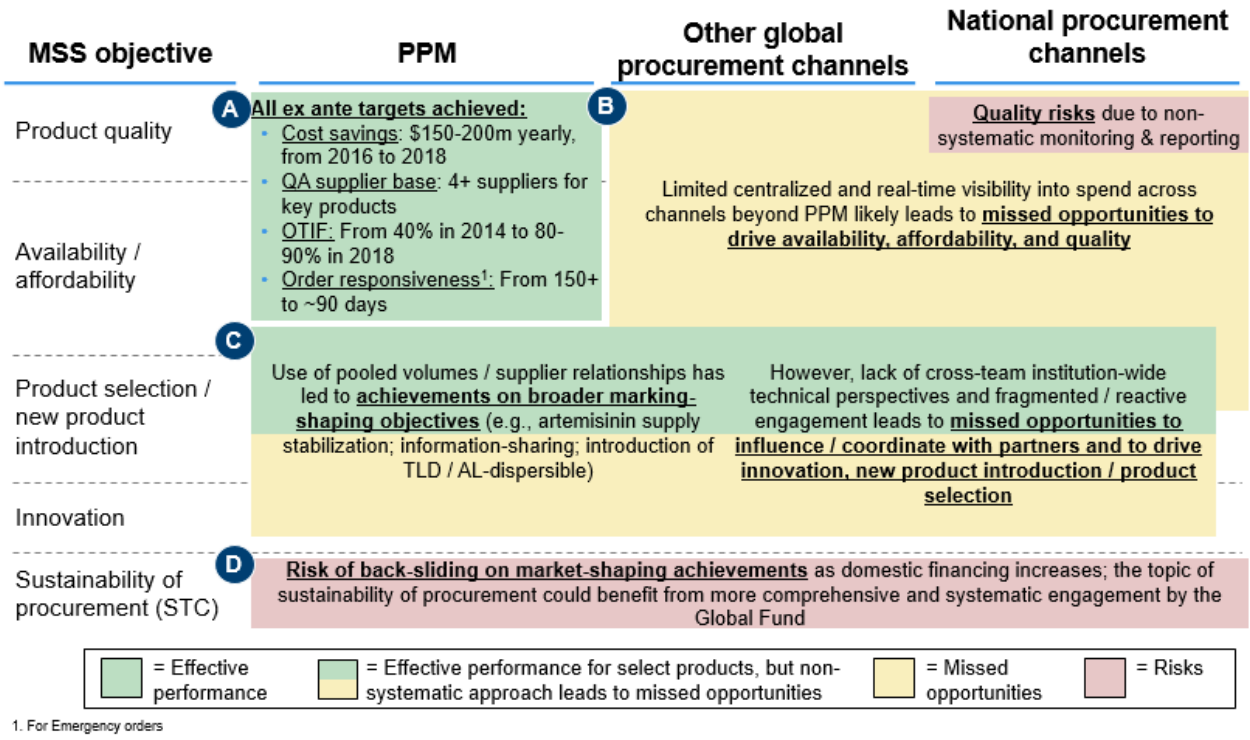
[2] https://www.theglobalfund.org/en/sourcing-management/market-shaping-strategy/

ii. The **lack of standardized processes for reporting and closing quality incidents** poses a risk for the Global Fund, especially for products procured through national procurement channels, which present higher risks of non-compliance with requirements.

C. Although the use of pooled volumes and supplier relationships has led to achievements on broader market-shaping objectives, the **lack of institution-wide technical perspectives on market shaping, limited visibility into TB markets, and fragmented/reactive engagement** at times lead to missed opportunities to influence/coordinate with partners and to drive innovation, new product introduction, and product selection.

D. There is a **risk of backsliding on market-shaping achievements as domestic financing increases**; the topic of sustainability of procurement could benefit from more comprehensive and systematic engagement by the Global Fund.

***Figure 1: Summary of Global Fund performance related to MSS outcome objectives***



## MSS Mid-Term Review Recommendations and TERG's position

5. The Review recommended **four key actions** for the Global Fund to execute by the end of the MSS period (end 2021). These actions are based on the above key findings A to D and should allow significant progress from "smart procurement" towards "proactive market shaping". The recommendations below are direct quotations from the Review, with the emphasis in bold coming from the TERG.

   A. **SSC** should continue to drive value on availability, affordability, and quality by **using its strategic sourcing capabilities and leverage with suppliers**

      This involves continuing activities already underway by SSC, including ongoing supplier relationship management, and the implementation and execution of performance-based long-term agreements (LTAs). This will require maintaining the current level of resourcing for SSC.

   B. **SSC, Grant Management Division (GMD) and Technical Advice and Partnership Department (TAP) should drive stronger health product management across all Global Fund-funded procurement (not just pooled procurement mechanism) by strengthening metrics, tools, and systems that monitor health product spend**

      i. The Global Fund should **develop fit-for-purpose tools**, **master data**, and **standard operating procedures** to track health product spend, including demand forecasting, transaction management, and reporting/resolution of quality incidents.

      ii. The Global Fund should **expand its Strategic, Implementation, and Operational key performance indicators (KPIs)** to cover market-shaping objectives beyond availability and affordability, to cover spend channels beyond pooled procurement mechanism (PPM), and to include TB products. In particular, SSC, GMD, and TAP should introduce metrics to monitor: 1) new product introduction (i.e., product scale-up/phase-out rates, volumes, number of countries), 2) availability and affordability of non-PPM spend, and 3) operational KPIs on the severity level and closure rate for quality incidents.

   C. **The Global Fund should drive a stronger institution-wide effort to market shaping by ensuring that internal teams and core partners align on issues, priorities, and roles/accountabilities for specific product markets**

      i. For specific product categories, the Global Fund should **develop cross-team technical perspectives** (with input from partners) that articulate how market shaping will contribute to the fight against the three diseases. Evolving from "smart procurement" to "proactive market shaping" implies that the Global Fund develops and formalizes a broader perspective on products and market. These product-specific perspectives should span the entire product lifecycle, ensure accountability for market shaping across all teams (not just SSC), and help drive alignment with partners. These technical perspectives on product markets can also contribute to broader Global Fund technical perspectives

articulating the priorities in the fight against the three diseases. They would identify any market-shaping challenges impeding progress on these priorities.

a. While current **product category strategies** developed by SSC with inputs from TAP and GMD can serve as the basis for these perspectives on market shaping, **they will have to be expanded** to ensure comprehensiveness across the entire product lifecycle and accountability by teams outside SSC, and to link with other technical matters outside market shaping.
b. The roadmap developed by SSC in 2017 includes a proposal for **a biannual joint stock-take among SSC, GMD, TAP, and partners for new product introduction progress and bottlenecks**. Global Fund teams could pilot this approach to drive alignment on any product that faces market-shaping challenges (not only new products).
c. As mentioned, examples of product categories where this could drive value include HIV rapid diagnostic tests, LLINs, TB products and antimalarial medicines. For TB products, this should build on an assessment of TB markets, ideally developed jointly with Stop TB/GDF, USAID, Unitaid, and other key partners.

ii. In parallel to developing these product-specific technical perspectives, the Global Fund should also **clarify the governance/accountability between SSC, GMD, and TAP** for activities which require input and decision-making on country-level, technical, and sourcing topics. If this effort results in any new accountabilities for Global Fund Secretariat teams (*e.g.,* for SSC, Country Teams, or TAP), these accountabilities should be formally documented and possibly included in teams' performance metrics.

a. **Influencing partners on innovation**: Developing clear perspectives on innovation requirements will help the Global Fund influence partner R&D priorities, target product profiles, evidence generation, and other upstream activities in the product lifecycle.
b. **Coordinating with Unitaid on early adoption/scale-up**: For Unitaid projects where the Global Fund may be expected to scale the intervention/associated products, the Global Fund and Unitaid should align on the definition of success and quantified conditions for scale up. The Global Fund should provide systematic input into the design of Unitaid grants, including on grant KPIs if that is identified as a limitation to the strength of the proof of concept. (…) One should note that the recently developed Unitaid Mid-Term Strategy Review also highlights coordination with scale-up partners such as the Global Fund as a priority area.
c. **Providing guidance to PRs on product selection**: When gaps exist from partners on guidance for product selection, especially for cost-effectiveness analysis, the Global Fund should fill these gaps either by developing internal guidance for grantees based on existing evidence, or by commissioning necessary research for specific product categories and/or for specific contexts. (…)

D. **Key Global Fund teams (*e.g.*, GMD, SSC, and TAP) should help ensure long-term sustainability of market-shaping successes and reduce the likelihood of backsliding on progress by developing a comprehensive approach to address risks associated with increased domestic financing.** A proposal to address these risks would include:

i. Benchmarking information (new or already existing) to assess risks/bottlenecks and prioritize solutions associated with countries' abilities to conduct key procurement and regulatory functions.
ii. A proposal for how to organize Global Fund functions to address these issues. This should address questions including whether the Global Fund should use only existing grant funds versus adding a new strategic initiative; whether to develop new expertise in RSSH team or leverage existing SSC team to provide TA; how best to incorporate activities into grant objectives where Country Teams can influence but not control outcomes; and how to coordinate among SSC, GMD, and other teams to address these topics.
iii. A plan to expand the Wambo pilot granting access to LTAs for domestically financed procurement. (…) A long-term strategy would consider topics like Wambo's potential impact on country-level procurement systems, its impact on global markets for health products, and its value proposition for countries and suppliers as compared with other global/pooled procurement channels. (…)

6. Priority for the Global Fund in the coming years is to address the limitations and proposed actions described above. **At a later stage and possibly for the next MSS**, the Review recommends that Global Fund consider expanding its role into:
   i. New stages of the product lifecycle (*e.g.*, innovation, new product introduction/product selection) for current product categories by taking additional ownership for outcomes in these stages
   ii. New product categories within the three diseases (*e.g.*, Indoor Residual Spray for malaria) or new diseases (*e.g.*, sexual and reproductive health)
   iii. New market-shaping objectives (*e.g.*, economic development of countries through local manufacturing or quality testing)

## TERG's position

7. **The TERG agrees with the four key prioritized actions**, accompanied by recommendations as to how the actions may be best implemented, **with two qualifications/additions**. First, the TERG suggests considering expansion of the MSS-related KPIs in the context of the development of the next Global Fund Strategy. Secondly, as an addition to Recommendation C.ii. above, the TERG suggests increasing coordination with Global Drug Facility (GDF), enhancing the visibility of TB product procurement by requesting GDF to share procurement information related to product selection and pricing, and implementing joint decision making on new product introductions.

8. **In addition, the TERG recommends the following**:
   i. **The Global Fund should consider broadening the SSC's approach to market shaping along the lines of the approach taken by Gavi** ('Healthy Market Framework'), which adopts a more comprehensive perspective towards market problems and solutions.
   ii. **The current MSS period should be extended by one year to the end of year 2022** to align the timing of the following MSS with the next post-2022 Strategy period, while also allowing time to instill ownership of the market-shaping objectives across the Secretariat.

iii. **The Global Fund should consider piloting cost-effectiveness analysis for selected health products and interventions.** This could be carried out more efficiently and effectively in collaboration with Unitaid, GDF and/or Gavi. Many national health systems have cost-effectiveness analysis as a standard procedure, which has led to revisions of the commodities and interventions that are provided. The fact that much of what the Global Fund finances has not been assessed for cost-effectiveness implies that impact can be further maximized.

iv. **The Global Fund should aim to ensure that transitioning countries benefit from progress in implementation of all aspects of the MSS,** so that in-country capacity is built to retain access to affordable, quality-assured health products, one of the objectives of the MSS identified by the Review as a risk (see Figure1). This should include access to the lowest sustainable prices and key market-shaping tools (*e.g.*, reference pricing or other information related to pooled procurement), even when procurement is with domestic finances, to ensure sustainable domestic procurement after transition from Global Fund support. A recent TERG review on the Sustainability, Transition and Co-financing Policy also recommended continuing to create and ensure access to Global Public Goods in key areas, especially market shaping for key drugs, diagnostics and commodities, including post-transition (GF/SC10/04).

## TERG's position on next steps and lessons for the future

9. The TERG is currently initiating its Strategy Review 2020 (SR2020)[3], which will assess the operationalization and implementation of the Strategy 2017-2022 at its mid-term and will aim to inform the development of the post-2022 Global Fund Strategy. Among the indicative evaluation questions of SR2020 are the extent to which the Global Fund's procurement mechanisms and market-shaping efforts are contributing to the value for money of Global Fund investments, and the likelihood that any economies and efficiencies realized through these efforts will be sustained post-transition. Addressing these questions may yield relevant findings and recommendations for future implementation of the MSS.

10. As the post-2022 Global Fund Strategy would require the revisiting of KPIs, the TERG suggests that market shaping KPIs be more accurately described in future to avoid potential misinterpretation. For example, at present the methodology for KPI 12b, "Annual savings achieved through PPM on total cost of product delivery…", does not control for general market trends, which would have occurred even without intervention by the Global Fund Secretariat. This obscures the extent to which reductions are *genuinely* achieved by Global Fund Secretariat actions. Such instances may be more amenable to instructive case studies than to measurement by KPIs.

[3] https://www.theglobalfund.org/en/updates/other-updates/2019-09-09-global-fund-strategic-review-2020/

## Annexes

The following items can be found in Annex:

- Annex 1: Relevant Past Board Decisions
- Annex 2: Relevant Past Documents & Reference Materials
- Annex 3: List of Abbreviations

# Annex 1 – Relevant Past Board Decisions

| Relevant past Decision Point | Summary and Impact |
|---|---|
| **GF/B34/EDP07: Enhanced Governance Structure (January 2016 and effective as of the conclusion of the 35th Board Meeting held on 26 – 27 April 2016)** [4] | The Board approved the charter of the Strategy Committee to include an oversight role on the overall impact and effectiveness of Global Fund investments in health, including its market shaping strategy, partnerships and strategic funding decisions. |
| **GF/B35/DP04: The Global Fund Strategy 2017 – 2022: Investing to End Epidemics (April 2016)** [5] | The Board approved the Global Fund Strategy 2017 – 2022. Its fourth Strategic Objective and related sub-objectives (c) and (d) outlines how market shaping efforts support delivery of the Global Fund Market Shaping Strategy by increasing access to affordable, quality assured key medicines and technologies and by stimulating innovation and scale up cost-effective health technologies and implementation models. |
| **GF/B34/DP08: Approval of the amended and restated Market Shaping Strategy (November 2015)** [6] | The Board acknowledged the significant role the Global Fund plays in global markets for health products related to HIV/AIDS, tuberculosis and malaria and as per prior direction, requested the Global Fund to continue to play an active, deliberate and strategic role in shaping markets to maximize access to health products and improve health outcomes for people living with HIV/AIDS, tuberculosis and malaria. The revised strategy puts forth a set of strategic objectives that leverage the Global Fund's position over the period from 2016 – 2022. This decision superseded the Market Shaping Strategy approved in 2011 (GF/B23/DP21). |
| **GF/B23/DP21: Global Fund Market Shaping Strategy and Market Shaping Interventions for ARVs (May 2011)**[7] | The Board acknowledged the Global Fund's critical role in shaping markets to maximize global access to health products and further emphasized its desire for the Global Fund to more actively shape markets for health products to optimize price, quality, design and sustainable supply. The Board approved the market shaping strategy recommended by the Market Dynamics Committee, including a set of specific interventions for anti-retroviral medicines (ARVs). This strategy superseded the Market Shaping Strategy approved in 2007 (GF/B15/DP15). Approval of the decision point presented in the current paper will supersede GF/B23/DP21 and the Market Shaping Strategy approved under it. |

[4] https://www.theglobalfund.org/board-decisions/b34-edp07/
[5] https://www.theglobalfund.org/board-decisions/b35-dp04/
[6] https://www.theglobalfund.org/board-decisions/b34-dp08/
[7] https://www.theglobalfund.org/board-decisions/b23-dp21/

## Annex 2 – Relevant Past Documents & Reference Materials

- TERG Thematic Review on Sustainability, Transition and Co-financing Policy (STC Policy), GF/SC10/04
- Market Shaping Strategy Update GF/SC04/07
- Market Shaping Strategy GF/B34/17
- Market Shaping Strategy: Annex 1 GF/B34/17
- TERG Thematic Review on the Market Shaping Strategy GF/SIIC16/04

## Annex 3 – List of Abbreviations

| | |
|---|---|
| AL | Artemether-Lumefantrine |
| ARVs | Antiretroviral medicines |
| GDF | Global Drug Facility |
| GMD | Grant Management Division |
| HRDT | HIV Rapid Diagnostic Test |
| KPI | Key Performance Indicator |
| LLIN | Long-Lasting Insecticidal Net |
| LTA | Long-Term Agreements |
| MSS | Market-Shaping Strategy |
| OTIF | On-Time, In-Full |
| QA | Quality Assurance/quality-assured |
| RFP | Request for Proposal |
| SR | Strategic Review |
| SSC | Sourcing and Supply Chain Team |
| TAP | Technical Advice and Partnerships |
| TB | Tuberculosis |
| TERG | Technical Evaluation Reference Group |
| TLD | Tenofovir Disoproxil Fumarate/Lamivudine/Dolutegravir |
| USAID | United States Agency for International Development |

# Secretariat management response to TERG evaluation

Market Shaping Strategy Mid-Term Review

December 2019

## Introduction

The Technical Evaluation Reference Group (TERG) is a critical component of the Global Fund Partnership, providing independent evaluations of the Global Fund's business model, investments and impact to the Global Fund Board through its Strategy Committee. The Global Fund values transparency and publishes TERG reports according to the TERG Documents Procedure approved by the Strategy Committee.

The Global Fund Secretariat welcomes the Market Shaping Strategy Mid-Term Review conducted by the TERG and agrees with many of the findings and recommendations. We support the review's recognition of the value delivered to date through implementation of the Market Shaping Strategy and the highest priority recommendation for the Secretariat to continue its work to drive value through strategic sourcing. The Secretariat also values the caution made against diverting resources from ongoing activities which could put them at risk.

## Areas of agreement

The Secretariat appreciates the TERG's recognition of the strong value delivered through effective execution and oversight of the Global Fund's Pooled Procurement Mechanism. The mechanism drives the availability of affordable and quality health products by leveraging the close to US$ 1 billion of health products purchased each year. The Secretariat also appreciates the prioritized recommendation to ensure continuity of its strategic sourcing work, including implementation of long-term performance-based agreements with suppliers as a core market shaping tool.

To improve visibility into Global Fund-funded procurement channels outside of the Pooled Procurement Mechanism, the Secretariat will analyze the possibility of rolling-out improvements to the Price and Quality Reporting platform over time to improve it for today's needs. This includes enabling access to more timely information and being more user-friendly, both for data entry and analytics. The vision is to evolve the tool to better leverage impact through sharing of key market intelligence, beyond price information.

Regarding strengthened collaborative efforts, particularly for innovation and new product scale-up, the Secretariat is operationalizing its Memorandum of Understanding signed with UNITAID earlier this year and has initiated joint efforts towards a common framework to estimate the costs and benefits of newer products to support product selection decisions. A more formalized approach to collaboration

across departments within the Secretariat (e.g., Supply Operations and Technical Advice and Partnerships) has also already progressed.

The Secretariat agrees on the importance of ensuring that countries continue to access the right products at the right price and quality when purchasing health products with domestic funding. The Board's recent decision to permit an expansion of the wambo.org pilot will enable helpful learning to be generated towards that end.

The Secretariat agrees with the importance of aligning the period of the Market Shaping Strategy with the Global Fund's and will ensure harmonization of strategy development for the next period (beyond 2022).

**Other recommendations**

One recommendation requiring further analysis refers to better understanding partners' frameworks and analytical approaches to identify market problems and solutions, including partners like GAVI. The Secretariat recognizes important differences between the supply environments of vaccines and those in which the Global Fund operates, with diverse and numerous health products. A potential analysis will allow the Secretariat to discern whether there is additional value-add in further broadening its approach. Both the analysis and expansion in approach would require additional resources.

**Next steps**

The Secretariat will continue to advance the objectives of the Market Shaping Strategy and identify and reduce potential missed opportunities as recommended by the review. As the review notes, most recommendations will require additional resources, which may not be immediately available to allow full implementation. New activities to address recommendations will be prioritized after analysis of resource requirements and potential value-add. Considering resource limitations, trade-offs will be necessary without detriment to on-going activities.

The Secretariat will resume annual strategic market shaping reviews with key partners and stakeholders and will provide a progress update on strategy implementation to the Strategy Committee before the end of 2020.

We thank the TERG for our continued partnership to strengthen the impact of Global Fund investments together.

# TERG Market-Shaping Strategy Mid-Term Review
# Final Report

July 31, 2019

RFP TGF-19-004

Submitted by Boston Consulting Group

Boston Consulting Group – 24-26 rue Saint-Dominique, 75007 Paris, France

## Acknowledgments

This report was produced by Boston Consulting Group. The consulting team responsible for the production of the report included:

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The authors acknowledge with gratitude the cooperation and participation of the many key informants who were interviewed or shared critical documentation for this report. We also express appreciation for the support provided for this review by members of the Global Fund Secretariat. In particular, the Sourcing and Supply Chain Team provided extensive support in data collection and in responding to the consulting team questions. We especially thank Ryuichi Komatsu, Sylvie Olifson, Dan Whitaker, Beatriz Ayala-Ostram, Kenneth Castro, Luisa Frescura, and Erin Eckert as well as other members of the TERG and TERG Secretariat, for the assistance and guidance they provided during the review. We also would like to thank global health partners and other organizations for providing input throughout this project.

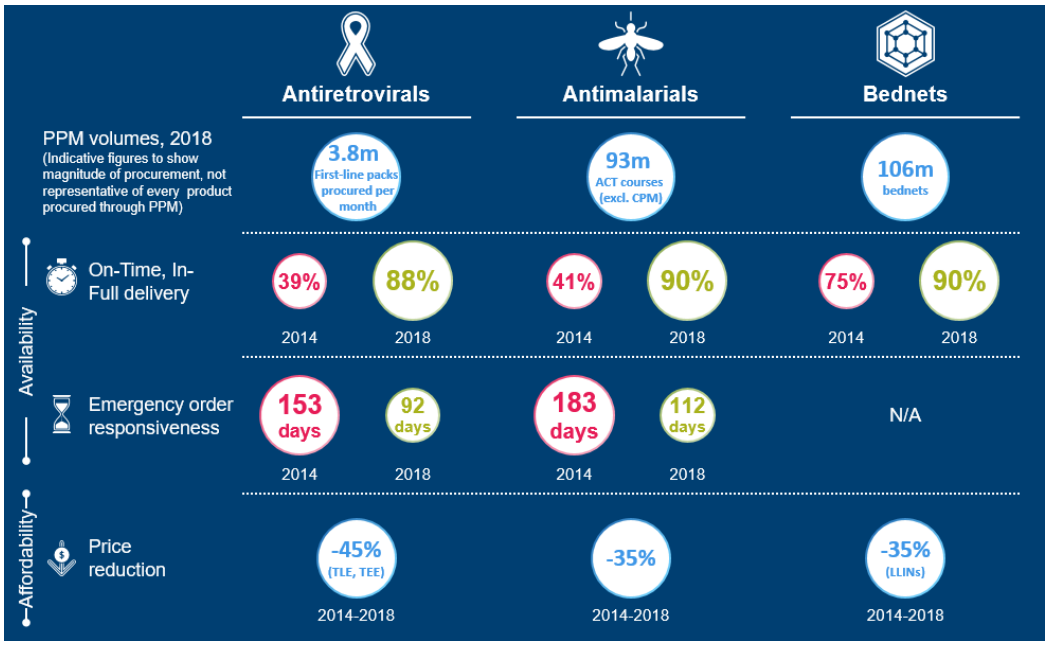
## Contents

## Overview

The Global Fund's 2016-2021 Market-Shaping Strategy (MSS) focuses on eight product categories - (Antiretrovirals [ARVs], Antimalarials [ANTMs], Long-Lasting Insecticidal Nets [LLINs], Viral Load – Early Infant Diagnosis [VL-EID], HIV Rapid Diagnostic Tests [HRDTs], Malaria Rapid Diagnostic Tests [MRDTs], and TB medicines/diagnostics). It includes a focus on foundational elements, plus five key outcome objectives: 1) Availability and affordability; 2) Quality; 3) Innovation; 4) New product introduction/product selection; and 5) Sustainability of health product procurement.

The goal of this mid-term review is to assess Global Fund's performance for these eight products on these six objectives. The review covers Global Fund-funded procurement through all procurement channels: Pooled Procurement Mechanism (PPM), other global pooled channels (e.g. UN agencies procuring health products), and domestic procurement channels. The MSS report does not address all available health product interventions used for HIV, TB and malaria programs, as some are not currently permitted to be funded with Global Fund resources (e.g., BCG vaccine given at birth to prevent severe forms of TB). The Stop TB Global Drug Facility (GDF) serves as the global lead for both market-shaping and global pooled procurement of TB medicines and diagnostics, and an assessment of GDF activities beyond Global Fund-funded procurement is out-of-scope for this review. The review is based on extensive quantitative analyses, a literature review, case studies, and 60+ interviews with stakeholders (Global Fund Secretariat, global health partners, and suppliers).

The Global Fund's Sourcing and Supply Chain team (SSC) conducts tenders and maintains long-term, performance-based framework agreements with suppliers for ARVs, ANTMs, LLINs. SSC has driven strong improvements in availability and affordability of products for which they have these performance-based arrangements (see Figure below for a summary for ARVs, ANTMs, and bednets). SSC is currently conducting a tender to begin this process for RDTs, and they have also conducted a tender for VL-EID products.



In addition to the improvements in availability and affordability, the Global Fund, with SSC in a leading role, has also driven broader market-shaping successes across product categories. These include stabilization of the artemisinin market, introduction a new contracting model for VL-EID ("rental reagent"), and introduction of new and/or more cost-effective products (TLD, AL-dispersible) at prices comparable to those of products being replaced/phased out.

Despite these successes, the Global Fund faces several key missed opportunities and risks to address in the remaining period of the MSS (through 2020). These include:

- Limited centralized and real-time visibility into spend across channels likely leads to missed opportunities to drive availability, affordability, and quality
    - Due to PQR data incompleteness and delays in reporting, there is limited real-time, centralized visibility into availability/affordability of products procured through non-PPM channels
    - The lack of standardized processes for reporting and closing quality incidents poses a risk for the Global Fund, especially for products procured through national procurement channels, which present higher risks of non-compliance with requirements.
- Although the use of pooled volumes and supplier relationships has led to achievements on broader market-shaping objectives, the lack of institution-wide technical perspectives on market-shaping, limited visibility into TB markets, and fragmented/reactive engagement leads to missed opportunities to influence/coordinate with partners and to drive innovation, new product introduction, and product selection
- There is a risk of backsliding on market-shaping achievements as domestic financing increases; the topic of sustainability of procurement could benefit from more comprehensive and systematic engagement by the Global Fund

Addressing these missed opportunities and risks could drive value in several ways. First, increasing visibility into all spend would allow the Global Fund to identify and address opportunities in availability, affordability, and quality across all procurement channels, potentially leading to cost savings or improvements in grant performance. Second, driving agreement, accountability, and responsibility across Global Fund teams and with core partners on market-shaping priorities would help lead to more effective collective action. In particular, more systematically defining issues, priorities, and roles would help increase the likelihood of fully addressing these issues, especially for objectives related to innovation and product introduction/selection, where multiple Global Fund teams beyond SSC, and core partners, have important roles to play. Examples of products where this approach could have driven value and could still drive value going forward include RDTs, LLINs, TB products, and certain ANTMs. Lastly, more comprehensively and systematically addressing sustainability of procurement as domestic financing increases would help ensure that countries and the global health system maintain market-shaping successes achieved to date by the Global Fund and partners. Unlocking this additional value means that the Global Fund needs to move fully from procurement activities focused on availability/affordability/quality of PPM spend to "proactive market-shaping" activities across all MSS outcome objectives, including using leverage from PPM spend and other market-shaping tools to drive performance on these outcomes.

Based on these findings, we recommend four actions for the Global Fund to execute. These actions should be completed by the end of the MSS (2021). The Global Fund should provide adequate resourcing for all necessary activities and avoid diverting resources away from ongoing activities to undertake new activities in any way that could put ongoing activities at risk.

- A. SSC should continue to drive value on availability, affordability, and quality by using its strategic sourcing capabilities and leverage with suppliers. This involves continuing activities already underway by SSC, including ongoing supplier relationship management, and the implementation and execution of performance-based LTAs. This will require maintaining the current level of resourcing for SSC.
- B. SSC, GMD, and TAP should drive stronger health product management across all Global Fund-funded procurement (not just PPM) by strengthening metrics, tools, and systems that monitor health product spend
    i. The Global Fund should develop fit-for-purpose tools, master data, and standard operating procedures to track health product spend, including demand forecasting, transaction management, and reporting/resolution of quality incidents.
    ii. The Global Fund should expand its Strategic, Implementation, and Operational KPIs to cover market-shaping objectives beyond availability and affordability, to cover spend channels beyond PPM, and to include TB products.
- C. The Global Fund should drive a stronger institution-wide effort to market-shaping by ensuring that internal teams and core partners align on issues, priorities, and roles/accountabilities for specific product markets
    i. For specific product categories, the Global Fund should develop cross-team technical perspectives (with input from partners) that articulate how market shaping will contribute to the fight against the three diseases. For TB products, this should begin with an assessment of the current state of TB markets, ideally jointly with key partners such as USAID, Stop TB, Unitaid, and others.
    ii. In parallel to developing these product-specific technical perspectives, the Global Fund should also clarify the governance/accountability between SSC, GMD, and TAP for activities which require input and decision-making on country-level, technical, and sourcing topics. If this effort results in any new accountabilities for teams (e.g. for SSC, Country Teams, or TAP), these accountabilities should be formally documented and possibly included in teams' performance metrics.
- D. Key Global Fund teams (e.g., GMD, SSC, and TAP) should help ensure long-term sustainability of market-shaping successes and reduce the likelihood of backsliding on progress by developing a comprehensive approach to address risks associated with increased domestic financing. A proposal to address these risks would include: benchmarking to assess risks/bottlenecks, a proposal for how to organize Global Fund response to these risks across various teams (e.g. SSC, GMD, and TAP), and a plan to expand and conduct a formal evaluation of the Wambo pilot.

Delivering impact on channels and objectives outside of PPM will likely require process and resourcing adjustments (since current processes are tailored to availability/affordability and quality of PPM). In particular, actions B.i, C.i (especially for TB products), and D will likely require incremental resourcing to execute.

We believe that the priority for the Global Fund in the next couple of years is to address the limitations and proposed actions described above. At a later stage and possibly for the next MSS, the Global Fund could consider expanding its role into:

- New stages of the product lifecycle (e.g. innovation, new product introduction/product selection) for current product categories by taking additional ownership for outcomes in these stages
- New product categories within the three diseases (e.g. Indoor Residual Spray for malaria) or new diseases (e.g. sexual and reproductive health)
- New market-shaping objectives (e.g., economic development of countries through local manufacturing or quality testing)

## Executive Summary

The Global Fund's 2016-2021 Market-Shaping Strategy (MSS) defines an approach to use its position in global health to influence product markets. The MSS applies to eight product categories (Antiretrovirals [ARVs], Antimalarials [ANTMs], Long-Lasting Insecticidal Nets [LLINs], Viral Load – Early Infant Diagnosis [VL-EID], HIV Rapid Diagnostic Tests [HRDTs], Malaria Rapid Diagnostic Tests [MRDTs], and TB medicines/diagnostics), as well as other health products procured by the Global Fund. It applies to the entire product lifecycle, and all procurement channels (Pooled Procurement Mechanism [PPM] and non-PPM). The MSS spans multiple Global Fund teams (e.g., Grant Management Division [GMD], Technical Advice & Partnerships [TAP]), with Sourcing and Supply Chain (SSC) in a leading role.

Commissioned by the TERG, this Mid-Term Review of the MSS has three objectives:

- Assess the Global Fund's performance on the MSS to date on foundational elements, plus five key outcome objectives listed in the MSS: 1) Availability and affordability; 2) Quality; 3) Innovation; 4) New product introduction/product selection; 5) Sustainability of health product procurement
- Assess the Secretariat's plans for implementing "Phase 2" of its current Market-Shaping Strategy, developed in 2017 to provide concrete actions for achieving market-shaping objectives
- Provide recommendations for additional focused efforts to consider to achieve transformative value

The review included 60+ key informant interviews, literature review, quantitative analyses, and case studies.

Three key topics fall outside the scope of this review:

- Assessment of market-shaping performance by partner organizations (the assessment of the Global Fund's engagement with these partners on market-shaping is in scope; any assessment of "other global procurement channels" refers to the Global Fund's engagement with these channels, not performance by other market-shaping institutions)
- In-country supply chain, distribution, and logistics
- Assessment of Wambo as a technology platform (the assessment of pooled procurement and transactions flowing through Wambo are in scope)

### What is the Global Fund's current performance on its market-shaping objectives?

Foundational elements: The Global Fund has effective foundational elements to drive availability, affordability, and quality of products procured through PPM (~$1.1 billion annually), which we refer to as "smart procurement." These include: category-specific strategies developed by the SSC team, in consultation with others, to guide sourcing and market-shaping activities; tenders and implementation of long-term framework agreements (LTAs) using a performance-based approach to manage suppliers; clearly defined and reported metrics for PPM spend; comprehensive transaction data, and; partnerships with other major procurers. SSC has clear accountability for driving availability and affordability of PPM spend. For a summary of results using "smart procurement" for PPM spend for certain product categories, see the Figure A below.

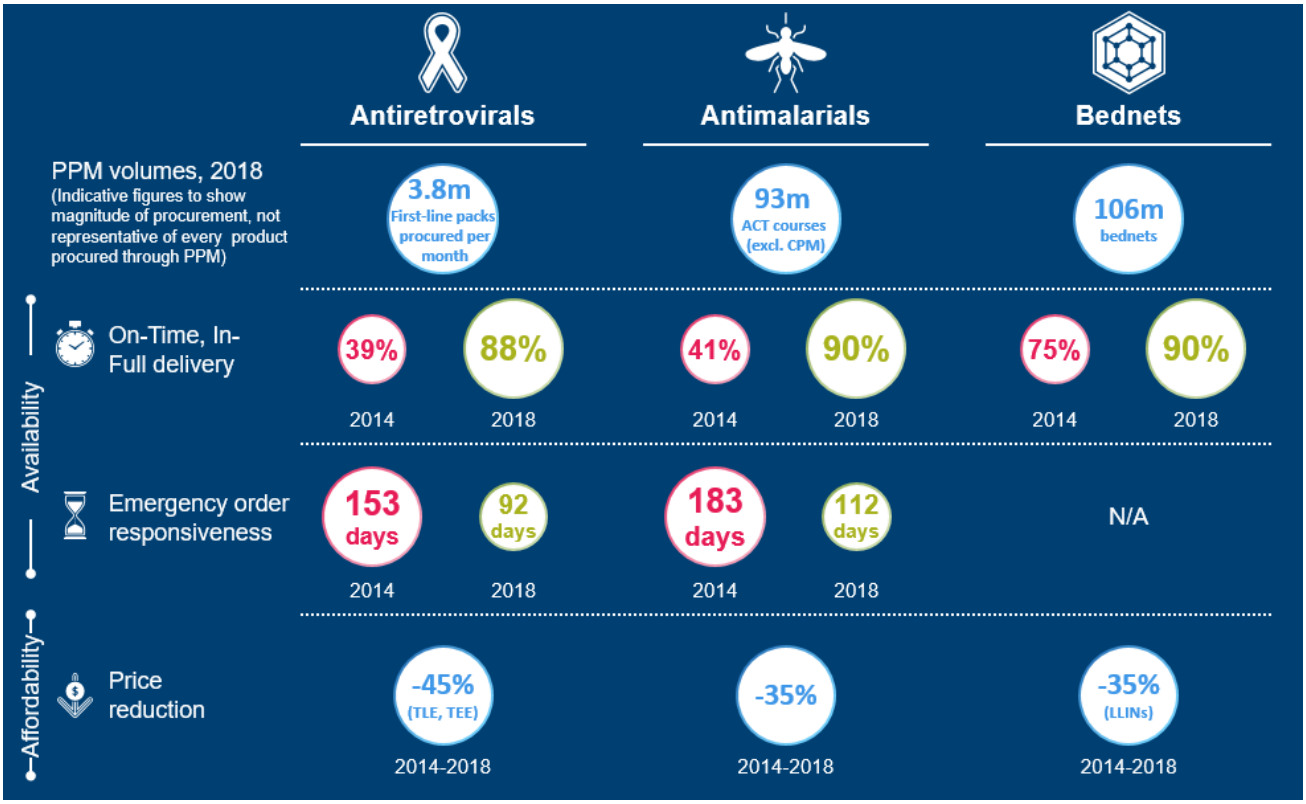



Figure A – Key market-shaping achievements *Source: PPM Transaction files*

Outside of these strengths, the Global Fund faces key limitations in its current foundational elements, which limit its ability to conduct "proactive market-shaping" across all objectives and channels:

- Strategies: The MSS did not include any targets, metrics, or KPIs. (The overall Global Fund Strategy introduced Board-level KPIs on availability/affordability one year later. However, there are no KPIs for the other MSS objectives). Product-specific market-shaping strategies developed by SSC in consultation with other teams and partners do not clearly define or ensure accountability for market-shaping activities by other Global Fund teams (e.g., GMD, TAP) or roles for core partners. The Global Fund has no formally defined, institution-wide strategy for market-shaping related to TB products.
- Roles/accountabilities: There are various levels of cross-Secretariat engagement on market-shaping by Global Fund teams outside SSC. Taking certain decisions or developing institution-wide Global Fund perspectives on certain topics – especially those related to innovation, new production introduction, product selection, and sustainability of procurement – require country-level, technical, and sourcing inputs. Because this expertise is split across three teams (GMD, TAP, and SSC, respectively), the governance for executing these activities is unclear.
- Tools and systems: The Price & Quality Reporting tool (PQR) data is incomplete, limiting centralized, real-time visibility into non-PPM spend (approximately 40% of total product spend). While it has achieved some success in increasing price transparency, PQR is not a fit-for-purpose tool for comprehensive visibility into and management of health products. The Global Fund lacks master data for health products, thereby driving inefficiency in data consolidation/analysis.

- Metrics and KPIs: Due to the limited real-time data for non-PPM spend, the Global Fund only tracks metrics at a centralized level for PPM. For PPM spend, the Global Fund only has predefined targets and KPIs for availability/affordability, and not the other MSS objectives. Therefore, the Global Fund has limited ability to systematically identify and intervene in opportunities to improve health product management; and reporting to Global Fund governance bodies only gives a partial view of MSS performance. The Global Fund does not currently report on market-shaping for TB products.
- Partnerships: Limitations in partnerships are described in the relevant sections on outcome objectives below.

We identified four key findings (including strengths and limitations) across the Global Fund's five outcome objectives for market shaping. See the Figure B below for a summary of these findings.

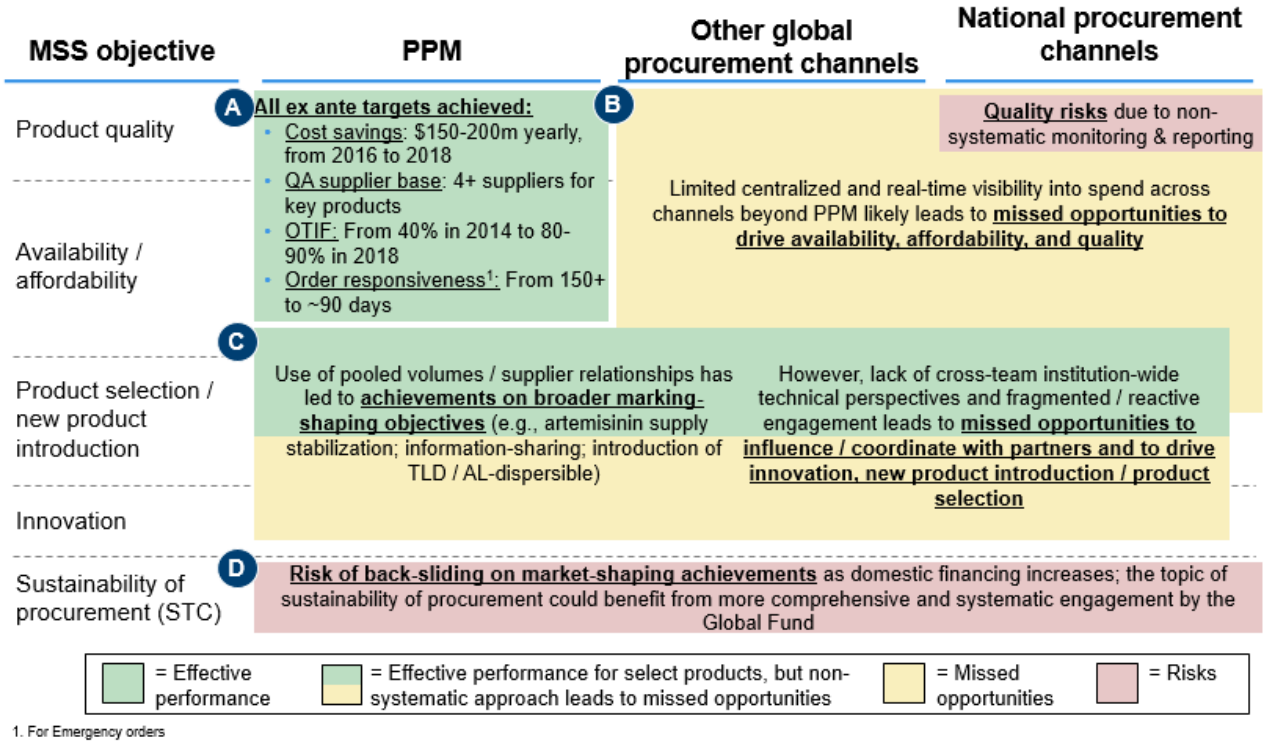



Figure B - Summary of Global Fund performance related to MSS outcome objectives

A. The Global Fund, with SSC leading, has used its tenders/implementation of performance-based long-term framework agreements and volume leverage through PPM ($1.1 billion in health product spend annually) to achieve cost savings, a broad quality-assured (QA) supplier base, improvements in on-time in-full delivery performance (OTIF), commensurate with best-in-class benchmark from the industry, and emergency order responsiveness for PPM spend.
   - Availability and affordability: The Global Fund has delivered value for PPM on availability (manufacturer OTIF increased from 40% to 80%-90% from 2014 to 2018; most products have four or more QA suppliers as of 2018) and affordability ($150 million to -$200 million in savings each year from 2016 to 2018, as defined by Board-approved methodology).
   - Quality: 82% of Global Fund-funded health product spend flows through PPM or other global procurement channels. The Global Fund faces low risks related to quality for procurement through these channels due to strict registration/quality control requirements.

B. Limited centralized and real-time visibility into spend across channels likely leads to missed opportunities to drive availability, affordability, and quality
   - Availability and affordability: Due to PQR data incompleteness and delays in reporting, there is limited real-time, centralized visibility into availability and affordability of products procured through non-PPM channels, although price review by Local Fund Agents limits the risk that Principal Recipients (PRs) pay prices substantively above Global Fund reference prices, as specified by Global Fund budgeting guidance.
   - Quality: The lack of standardized processes for reporting and closing quality incidents poses a risk for the Global Fund, especially for products procured through national procurement channels, which present higher risks of non-compliance with requirements. The lack of clarity on the mandate of the Global Fund QA Team vis-à-vis WHO-PQ and regulatory bodies for the assessment and resolution of incidents may lead to inefficient processes and suboptimal decisions.

C. Although the use of pooled volumes and supplier relationships has led to achievements on broader market-shaping objectives, the lack of institution-wide technical perspectives on market-shaping, limited visibility into TB markets, and fragmented and reactive engagement leads to missed opportunities to influence and coordinate with partners and to drive innovation, new product introduction, and product selection.
   - Performance across various objectives: The Global Fund, and in particular SSC, currently uses its leverage and relationships with partners and suppliers to drive broader market shaping for specific products. These successes include the stabilization of the artemisinin market, the introduction of a new contracting model for VL-EID, and the introduction of select new or more cost-effective products. The lack of a formally defined, institution-wide Global Fund strategy for market shaping related to TB product limits the organization's ability to engage on this topic, including with partners, in a coordinated way.
   - Innovation: SSC incentivizes innovation by suppliers by including it as an evaluation criterion in tenders, and suppliers noted that they appreciate this as a way to recognize R&D investments. However, because innovation is not a core Global Fund function, it relies on partnerships with organizations such as PDPs and Unitaid to drive R&D and evidence generation. Although Global Fund individuals and teams have perspectives on innovation needs, the Global Fund does not have an institution-wide, documented perspective on this topic that it can use to systematically influence partners.
   - New product introduction/product selection: The Global Fund is often expected to scale-up interventions/products piloted by Unitaid. However, for the "hand-off" of interventions and associated products from Unitaid to the Global Fund for scale-up, the Global Fund lacks clear criteria or decision points for whether and how to scale. Further, because the Global Fund operates on the principle of country ownership, it cannot unilaterally decide on behalf of PRs/countries to select certain products, and it therefore does not have full accountability over product scale-up. With regard to product selection, in instances where there is clear WHO guidance or another justification to use one product over another (e.g., TLD for first-line ARV treatment, AL-Dispersible over non-dispersible AL), the Global Fund proactively helps ensure that PRs/countries can procure these products. However, in instances where WHO does not specify a preferred product among several options or where limited cost-effectiveness data exists (e.g., historically for pyrethroid-PBO nets, among different ACTs), the Global Fund does not proactively fill these evidence/guidance gaps.

D. There is a risk of backsliding on market-shaping achievements as domestic financing increases; the topic of sustainability of procurement could benefit from more comprehensive and systematic engagement by the Global Fund
   - Sustainability of health product procurement: In particular, the Global Fund could strengthen its approach to addressing these topics by developing: a systematic assessment of risks/priorities across countries; stronger engagement across Global Fund teams for addressing sustainability of health product procurement, and an expansion of the Wambo pilot to domestically financed procurement by entities other than PRs, coupled with a rigorous evaluation and long-term strategy. Current restrictions on the Wambo pilot (e.g., which entities can procure on Wambo using domestic financing) limit its ability to comprehensively assess potential future scenarios for its use.

### What additional value could improvement to the current model bring?

Addressing these challenges could drive value in several ways. First, increasing visibility into all spend would allow the Global Fund to identify and address opportunities in availability, affordability, and quality across all procurement channels, potentially leading to cost savings and/or improvements in grant performance.

Second, driving agreement, accountability, and responsibility across Global Fund teams and with core partners on market-shaping priorities would help lead to more effective collective action. In particular, more systematically defining issues, priorities, and roles would help increase the likelihood of fully addressing these issues. This is especially true for objectives related to innovation and product introduction/selection, where multiple Global Fund teams beyond SSC, and core partners, have important roles to play. Examples of products where this approach could have driven value and could still drive value going forward include:

- RDTs: A systematic approach to driving RDT interchangeability would include accountability for including interchangeability criteria in the current tender (as SSC has already done), updating national guidelines for testing algorithms, country-level product registration, and (re-)training health workers.
- LLINs: Recent changes to WHO guidance on pyrethroid-PBO nets, plus the development of innovative new nets through a joint project with partners, has significantly increased the complexity of the bednets product category. As planned by SSC, the Global Fund should develop a "bridging strategy" for the next several years which defines the future outlook for this market and how the Global Fund will allocate product selection and volumes between LLINs, pyrethroid-PBO nets, and innovative new nets across geographies.
- TB products: Unlike for HIV and malaria, the Global Fund currently has no product-specific strategies for TB products. Having TB product strategies would help the Global Fund systematically identify ways that it can contribute to market shaping for TB products, including by expanding some of its existing market-shaping tools (e.g. reference pricing) to TB products. TB product strategies should build on an assessment of TB markets, which would ideally be developed jointly with USAID, Stop TB, Unitaid, and other partners, given the wide range of partners involved in these markets. This effort would also help align with partners on KPIs across market-shaping objectives. This effort will be important as TB medicines markets evolve, as well as to address affordability issues for TB diagnostics.

- ANTMs: Global health partners need to ensure supply security for ANTMs that have one or two QA suppliers (e.g., Injectable Artesunate, Amodiaquine+SP, SP, DHA-Piperaquine).

Lastly, more comprehensively and systematically addressing sustainability of procurement as domestic financing increases would help ensure that countries and the global health system maintain market-shaping successes achieved to date by the Global Fund and partners.

Unlocking this additional value means that the Global Fund needs to move fully from "smart procurement" activities focused on availability/affordability/quality of PPM spend to "proactive market-shaping" activities across all MSS outcome objectives, including using leverage from PPM spend and other market-shaping tools (including partnerships) to drive performance on these outcomes.

## Based on its performance, where should the Global Fund focus market shaping over the next two years?

To address this review's four key findings, and to move fully from "smart procurement" to "proactive market-shaping," the Global fund should undertake four key actions, with several sub-actions, over the next two years. See the Figure C below for a summary of these actions. These actions should be completed by the end of the MSS (2021). The Global Fund should provide adequate resourcing for all necessary activities and avoid diverting resources away from ongoing activities to undertake new activities in any way that could put ongoing activities at risk.

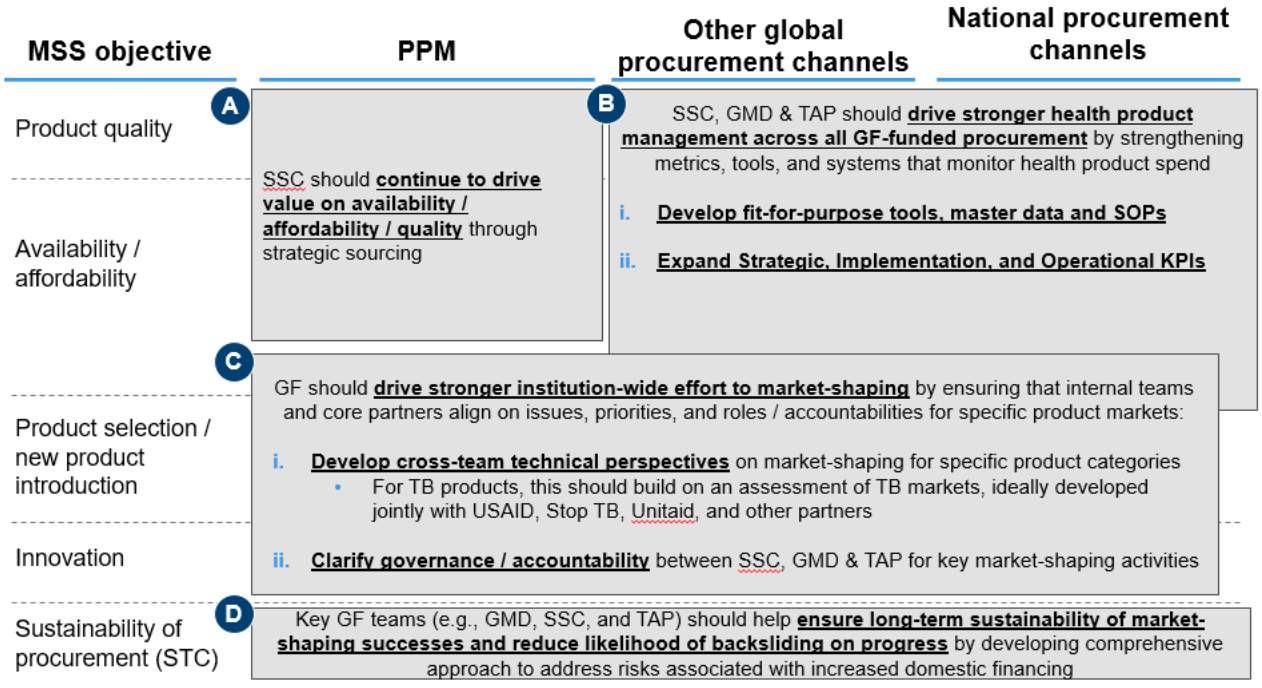



Figure C – Summary of recommended actions

A. SSC should continue to drive value on availability, affordability, and quality by using its strategic sourcing capabilities and leverage with suppliers. This involves continuing activities already underway by SSC, including ongoing supplier relationship management, and the implementation and execution of performance-based LTAs. This will require maintaining the current level of resourcing for SSC.

B. SSC, GMD, and TAP should drive stronger health product management across all Global Fund-funded procurement (not just PPM) by strengthening metrics, tools, and systems that monitor health product spend

i. The Global Fund should develop fit-for-purpose tools, master data, and standard operating procedures to track health product spend, including demand forecasting, transaction management, and reporting/resolution of quality incidents.

ii. The Global Fund should expand its Strategic, Implementation, and Operational KPIs to cover market-shaping objectives beyond availability and affordability, to cover spend channels beyond PPM, and to include TB products. In particular, SSC, GMD, and TAP should introduce metrics to monitor: 1) new product introduction (i.e., product scale-up/phase-out rates, volumes, number of countries), 2) availability and affordability of non-PPM spend (i.e., expansion of Board-approved KPIs to spend from other global procurement channels, national procurement channels, and TB products), and 3) operational KPIs on the severity level and closure rate for quality incidents.

C. The Global Fund should drive a stronger institution-wide effort to market-shaping by ensuring that internal teams and core partners align on issues, priorities, and roles/accountabilities for specific product markets

i. For specific product categories, the Global Fund should develop cross-team technical perspectives (with input from partners) that articulate how market shaping will contribute to the fight against the three diseases. Evolving from "smart procurement" to "proactive market shaping" implies that the Global Fund develops and formalizes a broader perspective on products and market. These product-specific perspectives should span the entire product lifecycle, ensure accountability for market shaping across all teams (not just SSC), and help drive alignment with partners. These technical perspectives on product markets can also contribute to broader Global Fund technical perspectives articulating the priorities in the fight against the three diseases. They would identify any market-shaping challenges impeding progress on these priorities.
   - While current product category strategies developed by SSC with inputs from TAP and GMD can serve as the basis for these perspectives on market-shaping, they will have to be expanded to ensure comprehensiveness across the entire product lifecycle and accountability by teams outside SSC, and to link with other technical matters outside market shaping.
   - The Phase 2 Roadmap developed by SSC in 2017 includes a proposal for a biannual joint stock take among SSC, GMD, TAP, and partners for new product introduction progress and bottlenecks. Global Fund teams could pilot this approach to drive alignment on any product that faces market-shaping challenges (not only new products).
   - As mentioned, examples of product categories where this could drive value include HRDTs, LLINs, TB products, and ANTMs. For TB products, this should build on an assessment of TB markets, ideally developed jointly with USAID, Stop TB, Unitaid, and other key partners.

ii. In parallel to developing these product-specific technical perspectives, the Global Fund should also clarify the governance/accountability between SSC, GMD, and TAP for activities which require input and decision-making on country-level, technical, and sourcing topics. If

this effort results in any new accountabilities for teams (e.g. for SSC, Country Teams, or TAP), these accountabilities should be formally documented and possibly included in teams' performance metrics.

- Influencing partners on innovation: Developing clear perspectives on innovation requirements will help the Global Fund influence partner R&D priorities, target product profiles, evidence generation, and other upstream activities in the product lifecycle.
- Coordinating with Unitaid on early adoption/scale-up: For Unitaid projects where the Global Fund may be expected to scale the intervention/associated products, the Global Fund and Unitaid should align on the definition of success and quantified conditions for scale up. The Global Fund should provide systematic input into the design of Unitaid's grant, including on grant KPIs if that is identified as a limitation to the strength of the proof of concept. If the Global Fund identifies meaningful barriers to scale-up based on the design or execution of the Unitaid pilot, it should clearly communicate these challenges, and if these disagreements cannot be resolved, the Global Fund should communicate that it may not be able to drive scale-up. The Global Fund (Country Teams, SSC, TAP) should work with PRs and Unitaid to set criteria and decisions for determining whether and how to scale-up new products piloted by Unitaid (both in countries where pilots have taken and in new countries). These decisions should acknowledge that the Global Fund operates on the principle of country ownership, and therefore cannot unilaterally decide on behalf of countries to scale products. In certain cases, failure to meet certain criteria at the end of the pilot could result in a proactive decision not to scale certain products/interventions. There may be additional root causes for scale-up shortcomings that Unitaid and the Global Fund will have to jointly identify and mitigate against. One should note that the recently developed Unitaid Mid-Term Strategy Review also highlights coordination with scale-up partners such as the Global Fund as a priority area.
- Providing guidance to PRs on product selection: When gaps exist from partners on guidance for product selection, especially for cost-effectiveness analysis, the Global Fund should fill these gaps either by developing internal guidance for grantees based on existing evidence, or by commissioning necessary research for specific product categories and/or for specific contexts. Examples of products that could potentially benefit from cost-effectiveness research include HIV facility-based versus self-test diagnosis strategies, pyrethroid-PBO nets (as part of an Insecticide-Treated Nets/New Nets strategy), and ANTMs (e.g. DHA-Piperaquine versus AL).

D. Key Global Fund teams (e.g., GMD, SSC, and TAP) should help ensure long-term sustainability of market-shaping successes and reduce the likelihood of backsliding on progress by developing a comprehensive approach to address risks associated with increased domestic financing. A proposal to address these risks would include:

- Benchmarking information (new or already existing) to assess risks/bottlenecks and prioritize solutions associated with countries' abilities to conduct key procurement and regulatory functions.
- A proposal for how to organize Global Fund functions to address these issues. This should address questions including whether the Global Fund should use only existing grant funds versus adding a new strategic initiative; whether to develop new expertise in RSSH team or leverage existing SSC team to provide TA; how best to incorporate activities into grant

objectives where Country Teams can influence but not control outcomes; and how to coordinate among SSC, GMD, and other teams to address these topics.

- A plan to expand the Wambo pilot granting access to LTAs for domestically financed procurement. This pilot should assess the value, operational barriers, and long-term potential risks to country systems, and it should inform a long-term Wambo strategy and governance model. A long-term strategy would consider topics like Wambo's potential impact on country-level procurement systems, its impact on global markets for health products, and its value proposition for countries and suppliers as compared with other global/pooled procurement channels. The Global Fund should lift certain restrictions on which entities can procure through Wambo (e.g. governments in Global Fund-supported countries where the government is not a current PR) for the pilot to ensure that purchases made through the pilot are similar to those which may be part of a longer-term Wambo strategy.

Delivering impact on channels and objectives outside of PPM will likely require process and resourcing adjustments (since current processes are tailored to availability/affordability and quality of PPM). Given the strategic importance of proposed actions B.ii., C.i., C.ii., and D., we recommend that these actions are considered in relation to the Global Fund's overall strategy and as part of Strategic Review (SR) 2020.

### Where could the Global Fund expand its market-shaping mandate in the long-term?

We believe that the priority for the Global Fund in the next couple of years is to address the limitations and proposed actions described above. At a later stage and possibly for the next MSS, the Global Fund could consider expanding its role into:

- New stages of the product lifecycle (e.g. innovation, new product introduction/product selection) for current product categories by taking additional ownership for outcomes in these stages
- New product categories within the three diseases (e.g. Indoor Residual Spray for malaria) or new diseases (e.g. sexual and reproductive health)
- New market-shaping objectives (e.g., economic development of countries through local manufacturing or quality testing)

## Acronyms

| | |
|---|---|
| 1L | First-line |
| 2L | Second-line |
| ABC | Abacavir |
| ACT | Artemisinin-based Combination Therapy |
| AELAC | Asia, Eastern Europe and Latin America |
| AI | Active Ingredient |
| AL | Artemether-Lumefantrine |
| ANTM | Antimalarial medicine |
| AQ+SP | Amodiaquine + Sulfadoxine-Pyrimethamine |
| API | Active Pharmaceutical Ingredient |
| ARV | Antiretroviral medicine |
| ART | Antiretroviral Therapy |
| AS | Artesunate |
| ASAQ | Artesunate-Amodiaquine |
| ATV/r | Atazanavir/ritonavir |
| BMGF | Bill & Melinda Gates Foundation |
| CHAI | Clinton Health Access Initiative |
| CD4 | Cluster of Differentiation 4 |
| COGS | Cost Of Goods Sold |
| CPM | Co-Payment Mechanism |
| CSO | Civil Society Organization |
| d4T | Stavudine |
| DA | Disease Advisor |
| DNDi | Drugs for Neglected Diseases initiative |
| DR-TB | Drug Resistant Tuberculosis |
| DS-TB | Drug Susceptible Tuberculosis |
| DST | Drug Susceptibility Testing |
| Dx | Diagnostics |
| EPRD | Expert Review Panel Diagnostics |
| ERP | Expert Review Panel |
| FDA | United States Food and Drug Administration |
| FPM | Fund Portfolio Manager |
| FPP | Finished Pharmaceutical Product |
| GDF | Global Drug Facility |
| GF | Global Fund |
| GMD | Grant Management Division |
| GOS | Grant Operating System |
| H2 | Second Half |
| HIC | High-Income Countries |
| HPM | Health Product Managers |
| HRDT | HIV Rapid Diagnostic Test |
| HSS | Health System Strengthening |

| | |
|---|---|
| IP | Intellectual Property |
| IRS | Indoor Residual Spraying |
| IVCC | Innovative Vector Control Consortium |
| KPI | Key Performance Indicator |
| LFA | Local Fund Agent |
| LLIN | Long-Lasting Insecticidal Net |
| LMIC | Low- and Middle-Income Countries |
| LNZ | Lamivudine/Nevirapine/Zidovudine |
| LOHP | List of Health Products |
| LPV/r | Lopinavir/ritonavir |
| LTA | Long-Term Agreements |
| LZ | Lamivudine/Zidovudine |
| MA | Marketing Authorization |
| MDR-TB | Multi Drug Resistant Tuberculosis |
| MRDT | Malaria Rapid Diagnostic Test |
| MSF | Médecins Sans Frontières |
| MSS | Market-Shaping Strategy |
| NCD | Non-Communicable Disease |
| NNRTI | Non-Nucleoside Reverse Transcriptase Inhibitor |
| NPA | National Procurement Agent |
| NRA | National Regulatory Authority |
| NRTI | Nucleoside Reverse Transcriptase Inhibitor |
| NSP | National Strategic Plan |
| NTD | Neglected Tropical Diseases |
| NVP | Nevirapine |
| OTIF | On-Time, In-Full |
| PAHO | Pan-American Health Organization |
| PBO | Piperonyl ButOxide |
| PDP | Product Development Partnership |
| PEPFAR | President's Emergency Plan for AIDS Relief |
| Pf | Plasmodium falciparum |
| PMI | President's Malaria Initiative |
| PnA Framework | Performance and Accountability Framework |
| PoC | Point of Care |
| PPM | Pooled Procurement Mechanism |
| PQR | Price & Quality Reporting |
| PR | Principal Recipient |
| PSA | Procurement Service Agent |
| PSM | Procurement and Supply Chain Management of Health Products |
| Pv | Plasmodium vivax |
| PV | PharmacoVigilance |
| QA | Quality Assurance / quality-assured |
| QC | Quality Control |
| RA | Regulatory Authority |

| | |
|---|---|
| RDT | Rapid Diagnostic Test |
| RFP | Request For Proposal |
| RSM | Rapid Supply Mechanism |
| RSSH | Resilient & Sustainable Systems for Health |
| Rx | Medicines |
| SIID | Strategy, Investment and Impact Division |
| SKU | Stock Keeping Unit |
| SMART | Specific, Measurable, Attainable, Relevant and Timely |
| SMC | Seasonal Malaria Chemoprevention |
| SO | Strategic Objective |
| SP | Sulfadoxine-Pyrimethamine |
| SR | Strategic Review |
| SRA | Stringent Regulatory Authority |
| SSC | Sourcing and Supply Chain Team |
| STC | Sustainability, Transition, and Co-Financing |
| TAP | Technical Advice and Partnerships |
| TB | Tuberculosis |
| TCO | Total Cost of Ownership |
| TEE | Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate |
| TERG | Technical Evaluation Reference Group |
| TLD | Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate |
| TLE | Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate |
| TPMAT | Tuberculosis Procurement and Market-Shaping Action Team |
| TRIPS | Agreement on Trade-Related Aspects of Intellectual Property Rights |
| UHC | Universal Health Coverage |
| UMIC | Upper-Middle Income Country |
| UNDP | United Nations Development Programme |
| UNFPA | United Nations Population Fund |
| UNICEF | United Nations Children's Fund |
| USAID | United States Agency for International Development |
| USD | United States Dollar |
| VL-EID | Viral Load and Early-Infant Diagnosis |
| VMI | Vendor-Managed Inventory |
| WHO | World Health Organization |
| WHOPES | WHO Pesticide Evaluation Scheme |
| WHO-PQ | WHO Prequalification |
| WLA | WHO-Listed regulatory Authority |

## 1. Introduction and objectives

**Key takeaways:**

- The 2016-2021 MSS focuses on foundational elements and five outcome objectives – availability / affordability, quality, innovation, new product introduction / product selection, and sustainability of health product procurement
- The MSS applies to eight product categories: ARVs, ANTMs, LLINs, MRDTs, HRDTs, VL-EID, TB medicines, and TB diagnostics
- This mid-term review has three objectives:
    1. Assess performance to date against the six MSS objectives
    2. Assess the Global Fund Secretariat's "Phase 2 Roadmap" (developed in Q4 2017) for implementing the MSS
    3. Identify other actions to drive value for market-shaping

The Global Fund to Fight AIDS, Tuberculosis and Malaria is a partnership organization that was founded in 2002 to accelerate the end of AIDS, tuberculosis, and malaria as epidemics. The Global Fund mobilizes and invests nearly $4 billion per year to support AIDS, tuberculosis, and malaria programs, of which $2 billion per year is spent on medicines, diagnostics, and prevention tools like insecticide-treated nets.

Adopted in November 2015, the Global Fund's 2016-2021 Market-Shaping Strategy (MSS) represents an important part of the Global Fund's contribution to fighting HIV, TB, and malaria. As stated in the MSS, "*the aim of this strategy is to provide principles, a framework and a set of tools that the Global Fund will use to guide its market shaping efforts focused on specific products or categories over the life of the strategy. It also identifies a number of cross-cutting initiatives that the Global Fund can implement to support its market shaping objectives. The strategy is not intended to detail specific market challenges or interventions on a product- or category-specific basis.*" [1]

In April 2019, at the request of the Strategy Committee, the Global Fund's Technical Evaluation Reference Group (TERG) initiated a mid-term review of the MSS. The goal of this review is threefold:

1. First, the review aims to assess and summarize the Global Fund's achievements to date with the implementation of the current MSS, in consideration of inherent trade-offs. This assessment will focus on the six objectives listed in the MSS for this assessment:
    - Ensure continued availability and affordability;
    - Promote consistent quality standards;
    - Support efforts to stimulate innovation;
    - Accelerate the adoption of new and/or cost-effective products (new product introduction/product selection);

- Prepare for country transition and long-term market viability (sustainability of health product procurement[h]); and
- Strengthen key foundational elements for market shaping.

**Additional information – Product categories covered by MSS**

The Global Fund's MSS focuses on eight product categories across the three diseases. The scope for this review includes all eight product categories.

- Antiretroviral medicines (ARVs);
- Antimalarial medicines (ANTMs);
- Long-Lasting Insecticidal Nets (LLINs);
- Malaria Rapid Diagnostic Tests (MRDTs);
- HIV Rapid Diagnostic Tests (HRDTs);
- Viral Load – Early Infant Diagnosis testing (VL-EID);
- TB medicines; and
- TB diagnostics.

Additionally, the MSS applies to other health products such as condoms or medicines for opportunistic infections and laboratory supplies

Box 1 - Product categories covered by the MSS

2. Second, the review will assess the Secretariat's plans for implementing "Phase 2" [2] of its current Market-Shaping Strategy, which included six strategic priority areas. The Secretariat developed this Phase 2 Roadmap in 2017, with internal and external consultations, as a means to provide concrete actions and plans for achieving market-shaping objectives. The review will assess the appropriateness of these plans, given the findings of the Global Fund's current performance on market shaping.

3. Third, this review will provide recommendations for additional focused efforts to consider in order to achieve transformative value (e.g., through existing or new mechanisms and/or tools).

This review includes the following sections:

- **What is the Global Fund's approach to market-shaping?** Before describing the findings or recommendations from the review, this document provides an overview of market-shaping, the Global Fund's positioning in the broader global health landscape with regards to market-shaping, and a description of the key market-shaping activities undertaken by the Global Fund, including those listed in the MSS.
- **Methodology and scope:** This section describes the methodology and approach for the review, including the evaluation framework and partner organizations that provided input into this review.

[h]Although the MSS refers to this objectives as "*country transition and long-term market viability*", this review refers to this objective as "*sustainability of health product procurement*" to reflect the fact that this objective applies to all countries, not just the formal cohort of projected transition countries, and to reflect the fact that solutions to addressing issues related to sustainability may sit at the global level (i.e., access to global public goods), in addition to the country level.

- What is the Global Fund's current performance on its market-shaping objectives? This section documents the review's findings regarding the Global Fund's performance on market-shaping activities and objectives (Review objective #1).
- Based on current performance, where should the Global Fund focus its market-shaping efforts? This section summarizes the Global Fund's achievements and gaps in market-shaping. It then details recommendations for achieving market-shaping objectives through the remaining period of the MSS (Review objective #3).
- How aligned are the mid-term review recommendations with the initiatives listed in the Phase 2 Roadmap? This section summarizes the alignment between the recommended actions coming out of this review and the priorities identified in the Phase 2 Roadmap (Review objective #2).
- Where could the Global Fund expand its market-shaping mandate in the long-term? This section describes preliminary ideas for where the Global Fund could consider expanding its mandate for market-shaping after the term of the existing MSS. Full consideration of the Global Fund's future ambition for market-shaping is beyond the scope of this review.

This review builds on previous reviews commissioned by the TERG and OIG, including:

- TERG Thematic Review on Sustainability, Transition and Co-financing (STC) [3]
- TERG Thematic Review on Resilient and Sustainable Systems for Health (RSSH) [4]
- OIG Follow-Up Audit on Procurement Processes [5]

## 2. What is the Global Fund's approach to market-shaping?

Key takeaways:

- Market-shaping includes a broad range of activities across the product lifecycle and strengthening of procurement and regulatory systems.
- The Global Fund has a unique position in global health markets due to its significant market share for many product categories, deep expertise in topics such as sourcing and translating WHO guidelines into technical guidance for countries, and deep relationships with partners and countries.
- The Global Fund's approach to market shaping leverages this unique position to directly and indirectly influence suppliers and markets.
- The Global Fund takes a limited role in driving innovation and influencing IP issues.
- The Global Fund's approach to market-shaping, as described in the MSS, is similar to the approach taken by other global health organizations, although some other organizations may take a more systematic institution-wide approach to diagnosing issues and selecting market-shaping interventions for specific products.

### 2.1 What is market-shaping?

Market-shaping aims to ensure the availability of affordable, quality-assured products that meet country needs. Market-shaping activities include but are not limited to strategic sourcing, and operate across the entire product lifecycle. An illustrative list of activities across the product lifecycle (not specific to the Global Fund) is included below. For a summary of these activities, see Figure 1.

- Product innovation: New product development (including product development partnerships) and evidence generation (including clinical or epidemiological trials)
- New product introduction: Pilots to test and stimulate early adoption; preparation of supplier base to ensure affordable, available, quality supply; preparation of countries and regulators to ensure product uptake; pooled procurement
- Established products: Pooled procurement; strategic sourcing (including tendering, implementation of long-term framework agreements, and supplier relationship management)
- Declining products: Coordination to minimize waste and ensure smooth transition to new products
- Activities across entire product lifecycle: Market-shaping for product-specific issues among suppliers, regulators, procurers, or countries; market information sharing; guidance on product selection; advocacy; issues related to IP/trade; normative guidance; QA systems
- Sustainability of health product procurement: Health system strengthening (HSS), capacity-building, and procurement and supply chain management policies; access to pooled procurement using domestic financing

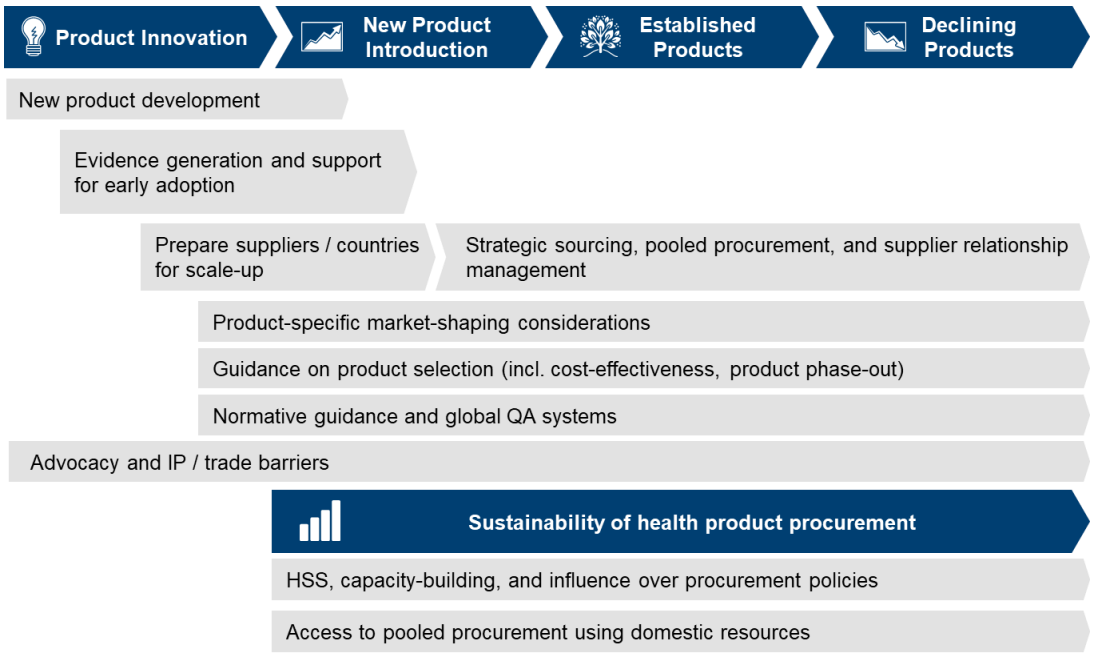
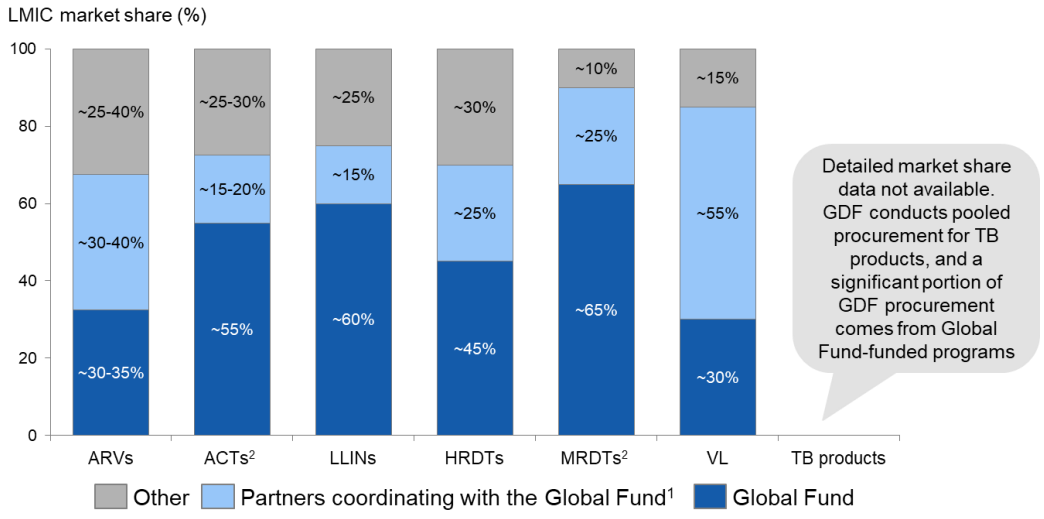



Figure 1 - Illustrative list of market-shaping activities along the product lifecycle

## 2.2 What is the Global Fund's position in key health product markets?

As one of several large procurers, the Global Fund has unique positioning in global health markets. The Global Fund and one or two other players (e.g., PEPFAR, PMI, UNICEF, and/or the South African Government, depending on health products) account for over 50% of the health product spend for ARVs, ANTMs, LLINs, RDTs, and VL-EID spend [6-16] in low- and middle-income countries (LMICs). For TB products, the Global Fund accounts for a significant portion of procurement through GDF, which leads global pooled procurement for TB products [17]. For a summary of market share for the Global Fund and key partners across health commodities, see Figure 2.




Note: For GF, market share is 3-year average 2016-2017-2018; for ARVs, lower bound is 3y average, higher bound is 2017 budget data; for VL 2017 PPM data, non-PPM estimated to be equivalent
1. For ARVs: PEPFAR & South African Government; For ACTs, LLINs & MRDTs: PMI; For MRDTS/HRDTs: PMI/PEPFAR & UNICEF; For VL: PEPFAR 2. Including private sector

Figure 2 - LMIC market share for the Global Fund and key partners across health commodities

The Global Fund also has deep expertise in sourcing, translating WHO guidelines into technical guidance for countries, health product management, and health systems strengthening. It has close working relationships with the supplier base for its HIV and malaria products, with other global health organizations, and with countries/Principal Recipients (PRs).

## 2.3 What activities does the Global Fund carry out to shape markets?

The Global Fund Board has requested that the Global Fund take an active role in market-shaping, consistent with its positioning in global health. The current MSS lasts from 2016-2021 and focuses on foundational elements plus five outcome objectives which aim to drive healthy markets for health products:

- Availability/affordability
- Quality
- Innovation
- New product introduction/product selection
- Sustainability of health product procurement

The MSS focuses on leveraging the Global Fund's health spend, expertise, tools, and partnerships to shape markets for new, established, and declining products. The Global Fund may shape markets using direct influence over suppliers, and indirect influence via countries and partner organizations. For a summary of the role of the Global Fund on key market-shaping activities, plus an illustrative representation of the role that partners play in market-shaping, see Figure 3.

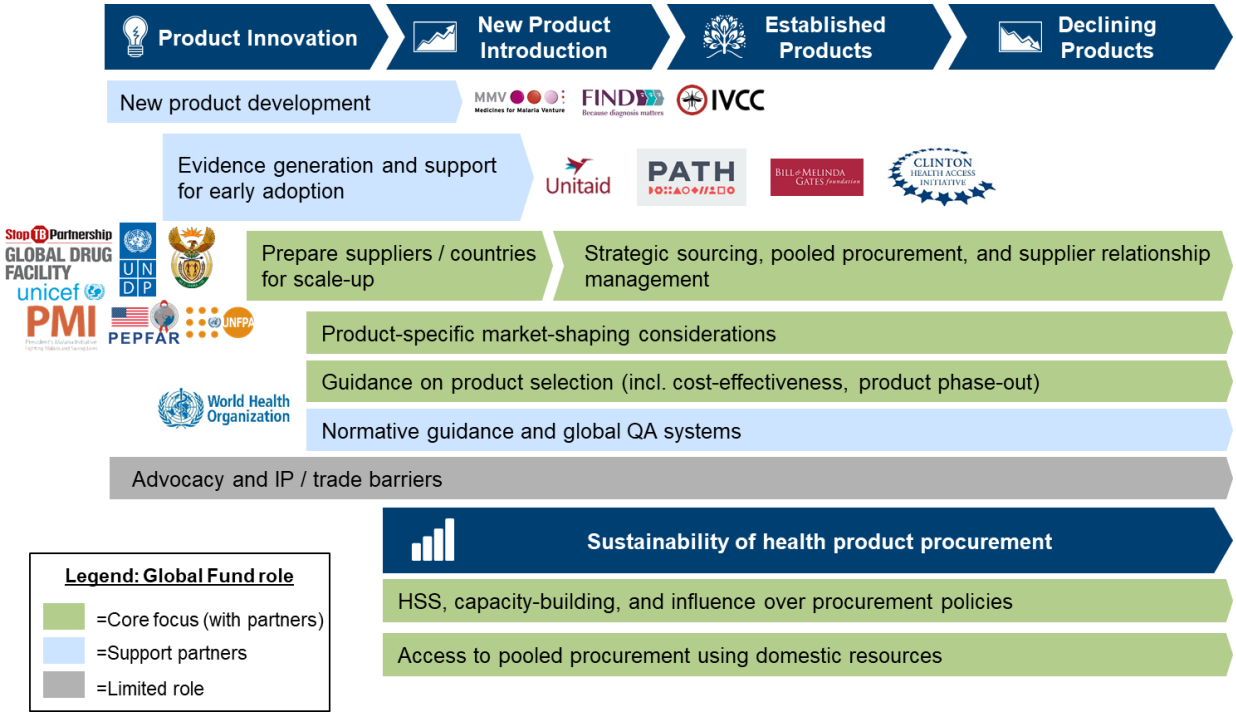



Figure 3 - Summary of the role of the Global Fund on key market-shaping activities.
Note that the logos for other partners are illustrative/indicative only. This not represent the full list of activities executed by a given partner, or the full list of partners executing a given activity.

### 2.3.1 How does the Global Fund directly influence markets?

In terms of its direct influence over suppliers, the Global Fund funds ~$2 billion in health product spend annually [15], which flows through multiple channels:

- Pooled Procurement Mechanism (PPM): $1.1 billion spent in 2018, with the majority of the spend flowing through Wambo[i]
- Global Drug Facility (GDF) for TB medicines and diagnostics: ~$150 million budgeted annually
- Other UN agencies, who serve as PRs for certain countries: ~$230 million budgeted annually
- National procurement channels: ~$350m budgeted annually

See Box 2 for a summary of requirements of health product procurement by PRs.

**Additional information - Summary of requirements for the procurement of health product spend**

Technically, the Global Fund does not procure any health product. PRs/countries use Global Fund grants to procure products through Procurement Service Agents (e.g., PFSCM, IDA for PPM spend) and National Procurement Agents (for procurement through domestic channels). For the sake of readability and clarity throughout the report, we will often use the phase "the Global Fund procures." This and similar statements reflect when the Global Fund funds procurement, or Global Fund-supported programs procure products.

PRs may use their health product budgets to buy either core products to prevent, diagnose, or treat any of the three diseases (HIV, TB, malaria) – 97% of spend – or 'non-core' products such as antibiotics or antifungals to treat adjacent diseases – 3% of spend.

Since the Global Fund operates on the principle of country ownership, the Global Fund cannot unilaterally decide on behalf of countries to procure new products and discontinue procurement of declining products.

For PRs to procure core products using Global Fund grants, products need to meet two key conditions:

- The product needs to be recommended for use by WHO; and
- There needs to be at least one quality-assured product available (quality-assured meaning approved by a Stringent Regulatory Authority, listed by WHO-Prequalification, or having received a time-limited approval by the Expert Review Panel).

If either of these conditions is not met, there will be no procurement with Global Fund grants. (Past examples include rectal artesunate suppositories, which WHO recommended for use as pre-referral treatment for severe malaria in 2003 but for which there was no WHO-Prequalified supplier until 2018. Conversely, the antimalarial Pyronaridine-Artesunate is WHO-Prequalified but not yet recommended by WHO. The Global Fund has therefore not procured Pyronaridine-Artesunate yet.)

The Global Fund also delists declining products that are no longer recommended for use because they are harmful or no longer efficacious (e.g., LNZ, Stavudine). To continue to procure them, PRs/countries need to go through a specific approval process.

Box 2 – Summary of requirements for the procurement of health product spend [18, 19]

[i] Emergency orders via the Rapid Supply Mechanism (RSM) do not flow through Wambo

The Global Fund's high volume of spend and performance-based long-term agreements (LTAs) with suppliers through PPM gives SSC significant leverage over suppliers. The SSC Team conducts strategic sourcing activities – e.g., pooling demand, developing and implementing product category strategies, supplier relationship management, and demand management – that help shape markets and drive value for the Global Fund. See Section 4.1.3 for more detail on the Global Fund's performance-based approach to managing supplier relationships.

The SSC Team also uses leverage over and relationships with suppliers to conduct broader market-shaping to address challenges faced by specific product markets, including preparing the supplier base for the introduction of new products.

The SSC Team also enforces international quality standards for manufacturers. The Quality Assurance Team sets policies related to quality, receives reports on quality non-compliance, and issues guidance on how to resolve issues. The Expert Review Panel (ERP) also helps ensure access to quality-assured products. See Box 3 for a description of the ERP.

**Additional information - ERP**

The Expert Review Panel (ERP) is an independent advisory body of technical experts coordinated by WHO and for which the Global Fund provides administrative support. The ERP assesses the quality risks of pharmaceutical products that do not have yet an SRA approval or a WHO-PQ listing. An ERP approval allows time-limited procurement by the Global Fund, usually for one year. It may be renewed. An equivalent mechanism exists for diagnostics: the Expert Review Panel on Diagnostics (ERPD).

Box 3 - Expert Review Panel mechanism

Outside of the SSC Team, other Global Fund teams also play a key role in market-shaping through direct influence on health product spend:

- The Grant Management Division's (GMD) Health Product Managers (HPMs) influence markets by serving as focal points to PRs/countries for Global Fund-funded health product spend, maintaining lists of health products (LOHPs), and supporting PR/country demand forecasting
- The Technical Advice and Partnership (TAP) Team's Disease Advisors (DAs) provide technical guidance on appropriate interventions including health product selection

### 2.3.2 How does the Global Fund indirectly influence markets?

In addition to directly influencing markets via health product spend, the Global Fund has several means to indirectly influence markets via other institutions. The Global Fund coordinates with a number of global health partners on a wide range of market-shaping activities. These partners include:

- Other major procurers of health products and pooled procurement channels, such as USAID/PEPFAR, USAID/PMI, the South African Government (for ARVs), the Stop TB Global Drug Facility (GDF), UNICEF, UNDP, UNFPA
- Other donors such as Unitaid, and the Bill & Melinda Gates Foundation
- Technical partners and NGOs such as CHAI, MSF, the Treatment Action Group (TAG)
- Product Development Partnerships such as Medicines for Malaria Ventures (MMV), FIND
- WHO

The SSC Team collaborates on pooled procurement and tendering with other major global health procurers. The Global Fund has a partnership with Unitaid primarily focused on innovation and new product introduction. The Global Fund and Unitaid recently signed a strategic framework for collaboration. Although this strategic framework lays out principles to govern engagement between the two organizations and areas for collaboration (which already exists in many ways), it does not lay out detailed responsibilities for individual Global Fund or Unitaid teams. The two organizations plan to develop a matrix to guide collaboration based on this strategic framework.

The Global Fund can also indirectly shape markets by strengthening domestic procurement capacity and systems in countries, especially as it relates to risks associated with increased domestic funding and procurement of health products.

Finally, to influence global pricing for health products, the Global Fund increases transparency by sharing market information with partners and suppliers, including reference prices[j] accessible to all through the SSC website in the public domain, and accessible to registered PRs through the Wambo.org platform. The PQR tool also provides market transparency by including transaction data at the country level (e.g., specification of the product procured, supplier, volumes procured, unit price, total cost, purchase order date, and scheduled and actual delivery dates).

The MSS specifies that the Global Fund will take only a limited role in certain market-shaping activities:

- Innovation: Given the Global Fund's limited core focus on innovation, and core focus by other organizations such as PDPs and Unitaid on this topic, the Global Fund primarily contributes to innovation by supporting other partners' efforts
- Intellectual property: The MSS states that "*while supportive of using the TRIPS agreement to protect public health, the Global Fund does not prescribe how countries implement their obligations and flexibilities under TRIPS, as those decisions remain the responsibility of each country*".

## 2.4 How does the Global Fund market-shaping approach compare with that of other organizations?

One can compare the Global Fund's market-shaping activities with those of other organizations on two different dimensions:

- The way organizations identify and select market-shaping interventions; and
- The market-shaping interventions taken by these organizations.

[j] Reference prices are conservative prices that PRs will use for budgeting purposes for the next two to three years as opposed to actual prices that will be charged to their grants (at or below reference prices). The Global Fund commits to average actual prices for products procured at or below the reference price for the grant period. Reference prices account for the fact that price may vary from one manufacturer to another. At a given time, for a given manufacturer, the Global Fund will receive one single price.

### 2.4.1 How does the Global Fund identify and select market-shaping interventions compared with other organizations?

The MSS states the need to "*assess the risks of implementing product- or category-specific strategies and* [the need to] *develop indicators to monitor risks of unintended consequences in the market.*" It also explains that product-specific strategies developed by the Global Fund *"will include assessment of the market size and growth, demand forecast and fragmentation, structure (number of quality-assured suppliers per product, market share), key regulatory institutions, and identification of market shortcomings. In particular, these analyses will be used to identify high-risk or high-opportunity markets which may especially benefit from intervention, along with other market challenges*."

As described in the MSS, this approach is similar to the approach for identifying market-shaping interventions recommended by USAID, and the approach taken by Gavi, the Vaccine Alliance. Although the Global Fund Secretariat does develop product-specific strategies, it does not always comprehensively assess market dynamics across all relevant MSS outcome objectives, and does not always include accountabilities for undertaking market-shaping interventions outside SSC. For more information on the Global Fund's product category strategies, see Section 4.1.1, and the sections on product-specific performance. For information on the approach to identify market-shaping interventions recommended by USAID, see Box 4. For a description of how Gavi identifies market-shaping interventions and develops workplans to execute these interventions, see Box 5.

**Case Study – USAID Framework for Healthy Markets**

USAID developed a systematic pathway toward Market-Shaping to assess whether and how interventions may be appropriate for a specific underperforming market. This pathway is articulated around five consecutive steps.

- Step 1 – Observe Market Shortcomings: The first step consists of assessing the current health of the market and identifying market shortcomings that limit health impact. The key healthy markets dimensions are used to structure the analysis: affordability, availability, quality assurance, appropriate design, and awareness.
- Step 2 – Diagnose Root Causes: The second step consists of carrying out detailed analysis to identify root causes of the shortcomings. These may include cost of goods sold analysis. For instance, high prices could be explained by expensive costs for active pharmaceutical ingredients, high supplier margins, low volumes, or a combination of factors.
- Step 3 – Assess Market-Shaping Options: The third step consists of assessing market-shaping intervention options for addressing each of the identified root causes. The expected benefits for these interventions should outweigh the drawbacks. The interventions may include reducing transaction costs, increasing market information or balancing risks between supply and demand actors.
- Step 4 – Implement Customized Intervention: The fourth step consists of carefully planning and executing the intervention(s). This includes determining who should be engaged and how, what trade-offs will be required, how to minimize unintended consequences, and how to ensure sustainable results.
- Step 5 – Measure Results: The fifth step consists of measuring and evaluating the intervention's impact on both market and global health outcomes. Frequent evaluation during the implementation of an intervention may also be useful to make adjustments, if necessary.

Box 4 - USAID Framework for Healthy Markets [20]

Case study - Gavi approach to managing market-shaping activities

Gavi uses two key tools to drive its market-shaping activities.

First, in collaboration with partners such as UNICEF and the Bill & Melinda Gates Foundation (BMGF), Gavi uses a *Healthy Market Framework* to analyze the state of the market for a specific product. Gavi, UNICEF, and BMGF jointly developed this framework. It includes analysis along four levels with nine dimensions (see figure below):

- Is there inadequate supply?
- Does supply meet demand?
- Does the product meet country preferences?
- Does the product have a healthy market along other market dimensions?
    - Buffer capacity
    - Individual supplier risk
    - National Regulatory Authority (NRA) risk
    - Total system effectiveness
    - Long-term competition
    - Product innovation

Gavi and partners use this framework to assess both the current state and the desired future state for each product market. The assessment applies a green/yellow/red scale (met/partially met/unmet need) to each dimension in order to summarize the current state of the product market and associated risks.

Building on this assessment, Gavi and partners define key objectives and associated outcomes in a *Market-Shaping Action Plan* (See figure below). This plan defines:

- Target Outcomes: Goals for the market-shaping strategy for the specific product
- Interventions: Detailed, measurable, and time-limited activities
- Stakeholder liaisons: Teams accountable, responsible, and supporting the initiative
- Start Date/End Date/Status: Clearly defined dates and approach to measure progress against activities

To conduct this assessment and select market-shaping objectives, Gavi and partners use activities such as strategic forecasting, scenario building, and trade-off analyses. These trade-off analyses are normally a critical part of the strategy development, where they prioritize certain objectives and outcomes over others. Gavi and partners use this action plan for each product to steer market-shaping activities and report/monitor progress against overall market-shaping objectives in a consistent way across all products.

Using these two frameworks, Gavi ensures collaboration and progress on its market-shaping objectives. This approach has key strengths including its:

- Clear view on market strengths and weaknesses at the product level
- Clear linkage between the product-specific market-shaping strategy and the strategy used by UNICEF to conduct the tender for the product
- Clearly structured prioritization of the strategic objectives for a given product
- Detailed action plan provided for Gavi teams and partners, completely aligned with market-shaping strategic objectives
- Detailed action plan which is specific enough and traceable to monitor progress and redirect as needed
- Clear accountability, both internally within Gavi and among external partners

The Global Fund already has its own framework for healthy markets and set of objectives defined in its MSS, and these sometimes serve as the basis for product-specific strategies. The Global Fund could take a more clearly articulated project management approach across G teams similar to the one used in the Market-Shaping Action Plan to ensure clearer accountability from all internal teams and better alignment with external partners regarding key objectives to achieve at specific product level.

## Box 5 - Case study: Gavi approach to managing market-shaping activities

Case study - Gavi approach to managing market-shaping activities (continued)

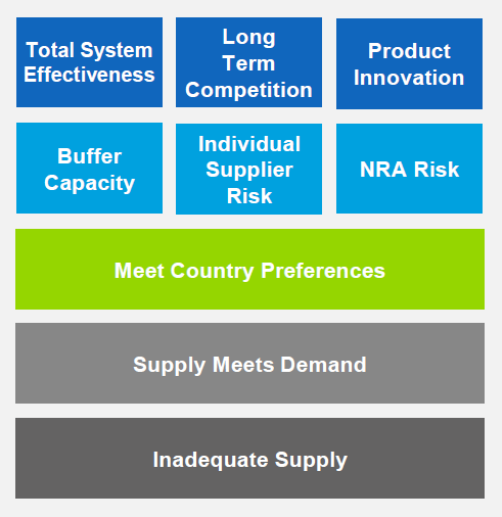



Figure - Gavi Healthy Market Framework

**1. Market shaping action plan**

| Obj | Target Outcomes | Priority level (High, Medium, Low) | Interventions | Stakeholder Liaison | | | Start date/ End date / Status |
|---|---|---|---|---|---|---|---|
| | | | | Accountable (The person ultimately responsible for the intervention) | Responsible (The main actor and coordinator of related activities) | Supporting (Stakeholders who are or may be acting in support of A/R) | |
| Supply objective | TO 1: | | | | | | |
| | TO 2: | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | TO 3: | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Innovation and TSE objective | TO 4: | | | | | | |
| Cost objective | TO 5: | | | | | | |
| | | | | | | | |
| Procurement | | | | | | | |

Figure - Gavi Market-Shaping Action Plan

### 2.4.2 How do the Global Fund's market-shaping interventions compare with those of other organizations?

As described, the Global Fund has a unique position in the global health landscape, and its role in market-shaping differs from that of other organizations which have different positions in the market-shaping landscape, such as:

- Product development partnerships, which focus on driving innovation to address unmet global health needs

- Unitaid, which has strategic objectives on innovation, access to products, and scalability. The Global Fund collaborates with Unitaid on new product introduction – For more information on this partnership, see Sections 4.9 and 4.10.

The Global Fund has relatively similar position for market-shaping to other major procurers of health products such as PEPFAR for HIV products, and PMI for malaria products. Of course, the governance of these organizations differs considerably from that of Global Fund. Nonetheless, the Global Fund collaborates with PEPFAR and PMI by sharing information (without providing confidential or commercially sensitive information), providing demand forecasts, aligning on key supplier performance metrics, and coordinating sourcing approaches and messaging, among other activites. All three organizations use their leverage as major buyers to influence the availability, affordability, and quality of health products for specific commodities.

By contrast, the Global Fund's approach to new product introduction and product selection differs from that of PEPFAR and PMI. Because of the Global Fund's core principle of country ownership, PRs/countries ultimately drive demand for products purchased using Global Fund grants. Therefore, while the Global Fund may influence PRs/countries on product selection, it rarely takes a prescriptive approach to dictating product selection. By contrast, PEPFAR is more directive in product selection, as indicated by their active promotion of TLD which started as early as 2017 [21]. PMI is the most directive in terms of product selection: PMI will decide which health products to procure and then supply those products to countries. It is also worth noting that PMI has a different approach towards quality standards for ITNs than the Global Fund. We describe these product-specific differences to market-shaping in further detail in the sections and appendices with findings on these products.

The GDF model for market-shaping, strategic sourcing, and procurement varies from that of the Global Fund. For additional information on GDF, please see Section 4.7.

CHAI has played an active role in market-shaping, including for ARVs and contraceptive implants. CHAI's activities in market-shaping include the following [20, 22]:

- Increase of market information by conducting and sharing demand forecasts
- Negotiation of volume-based discounts
- Inclusion of "non-price" criteria in their public tenders, such as "number of in-country registrations" and "historical supplier performance"

These activities aim to increase on-time deliveries (through the evaluation of historical supplier performance), reduce the duration of delays as well as lower prices. The Global Fund engages on similar activities for its product categories. Additionally, the Global Fund and CHAI have opportunities to share lessons learned on market-shaping through the various forums in which they both participate (e.g., ARV Procurement Working Group, Project Advisory Committee on ARVs).

# 3. Methodology and scope

**Key takeaways:**

- This review covers all MSS objectives and procurement channels.
- This review is based on over 60 interviews with partners, suppliers, and Global Fund staff, quantitative analyses, extensive literature review, and case studies, including five country deep-dives.
- Out-of-scope areas for this review include:
  - Assessment of market-shaping performance by partner organizations
  - In-country supply chain, distribution, and logistics
  - Assessment of Wambo as a technology platform

## 3.1 Evaluation approach

As already mentioned, this review will assess the Global Fund's performance on market-shaping along the six objectives listed in the MSS.

1. Foundational elements
2. Availability/affordability
3. Quality
4. Innovation
5. New product introduction/product selection
6. Sustainability for health product procurement

The review begins with an assessment of foundational elements for conducting market-shaping activities. In other words, the review treats the Foundational Elements objective as an input that can support performance on the other five objectives, which are considered outcome objectives. See Figure 4 for the evaluation framework for this review.

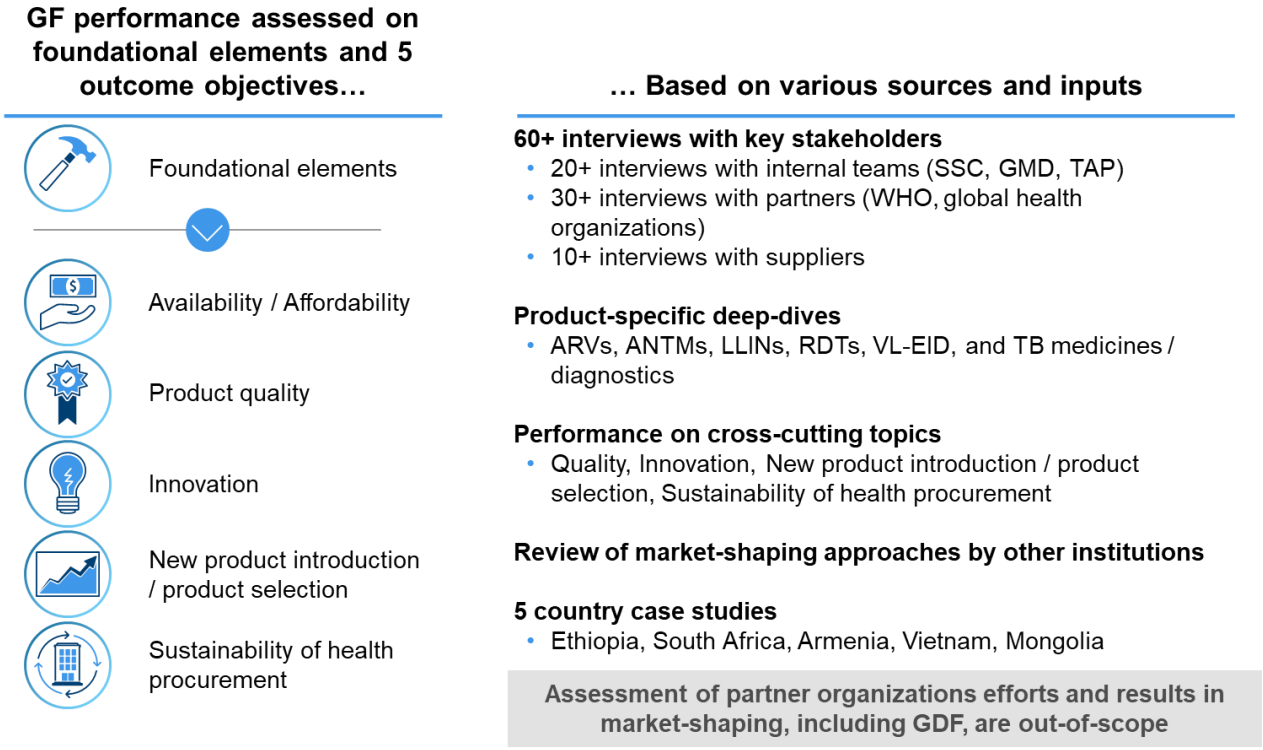



Figure 4 - Evaluation framework and inputs

We assess product-specific performance for four of the five outcome objectives: availability/affordability, quality (with a focus on specific considerations for that product category), innovation, and new product introduction/product selection, for the following product categories:

- Antiretroviral medicines
- Antimalarial medicines
- Long-Lasting Insecticidal Nets
- Malaria Rapid Diagnostic Tests
- HIV Rapid Diagnostic Tests
- Viral Load – Early Infant Diagnosis testing

This assessment covers all procurement channels: PPM, other global procurement channels, and domestic procurement channels. However, due to data incompleteness and delays in reporting for non-PPM spend, analyses for availability/affordability objectives mostly focus on PPM spend (which has complete data available from PSA transaction files). On the contrary, findings on quality, innovation, and new product introduction/product selection apply to the overall markets for each product; therefore, the findings are not limited to health products procured through PPM. When relevant, we have included illustrative "counterfactuals" to determine what would have happened from a market-shaping perspective in the absence of action by the Global Fund. The counterfactuals can give an indicative sense of how the Global Fund's actions, in coordination with partners, have impacted the market. These counterfactuals are noted in "boxes" throughout the report.

Given that the Global Fund does not conduct pooled procurement for TB products, but GDF does, and GDF serves as the global leading organization for market-shaping for TB products, we take a different approach for assessing the Global Fund's performance on market-shaping for TB products, as described in Section 4.7.

We then assess performance on four of the five outcome objectives that have cross-cutting components: quality, innovation, new product introduction/product selection, and sustainability of health product procurement.

## 3.2 Key informant interviews, quantitative analyses, and sources

This review uses both qualitative and quantitative information to conduct its assessment.

We conducted over 60 semi-structured key informant interviews with a broad range of stakeholders. See Figure 5 for a list of stakeholders interviewed for this review.

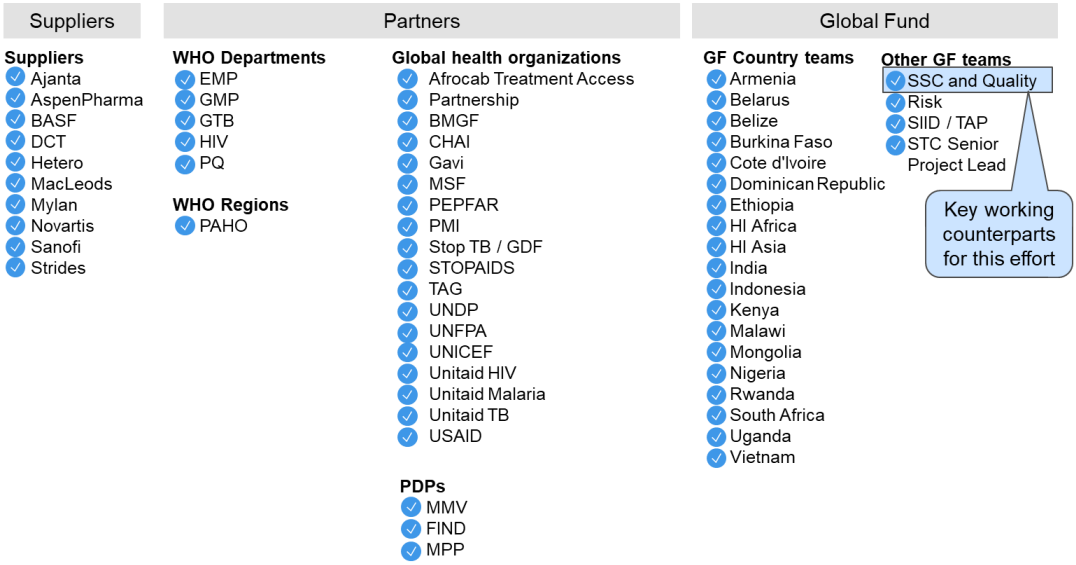



Figure 5 - List of stakeholders interviewed for this review

See Figure 6 for a non-exhaustive list of key quantitative indicators included in this review. When KPIs and ex-ante targets exist for specific MSS objectives (e.g. OTIF, number of quality-assured suppliers), we assess the Global Fund's performance against these KPIs. When they do not exist, we assess the Global Fund's performance against additional KPIs that we defined (e.g., price comparison with other procurers, diversity of supplier base) in consultation with TERG Focal Points, Global Fund colleagues, and topic experts.

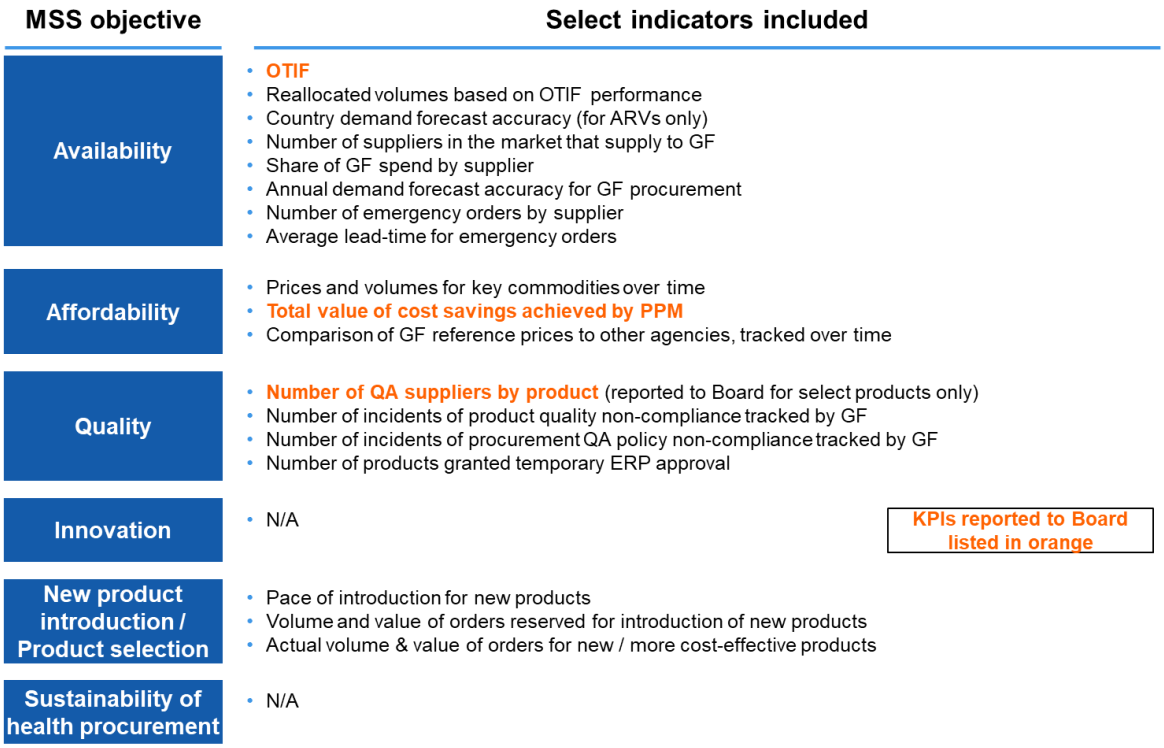



Figure 6 - Non-exhaustive list of key quantitative indicators included in this review

One key analysis conducted for select product categories is the "sustainable price analysis", which combines multiple indicators/metrics to assess whether the Global Fund has achieved prices that allow for the sustainability of a broad supplier base while also allowing for affordability by PRs. See Box 6 for a description of the methodology for this analysis.

**Sustainable price analysis - Methodology**

When assessing affordability, we also looked at whether the Global Fund is achieving sustainable prices, that is to say prices that allow for the sustainability of a broad supplier base while also allowing for affordability by PRs. To conduct this analysis, we looked at four metrics:

- High-level estimates of margins: This is an indication of whether manufacturers are generating reasonable margins for their health products, or whether the Global Fund has an opportunity to further reduce prices. Unfortunately, it is very difficult to get reliable data on this metric due to issues of confidentiality. Therefore, whenever possible, we used estimates of manufacturing/production costs or margins based on third-party benchmarks and publicly available research. Discussions with manufacturers and global experts also informed those estimates.
- Number of suppliers actively supplying to the Global Fund: This is an indication of whether prices are sustainable to maintain a broad supplier base and for the market to be viable for new entrants to generate increased competition.
- Diversity of supplier base: This is an indication of whether there is a healthy level of competition in the Global Fund's supplier base, which can help drive prices down. A highly fragmented supplier base may reduce opportunities for price reductions due to the absence of economies of scale, but a supplier base with limited diversity might create too much dependence on one supplier, and prevent prices from going down.
- Evolution of prices over time, including benchmark to other procurers: Long-standing health commodities should see their prices go down, due to manufacturing efficiencies, new products arriving, increased competition, etc. The evolution of prices paid by the Global Fund indicates whether the Global Fund benefits from these trends over time. We compare this evolution with that of prices paid by other large procurers.

Our search methodology for publicly available information on production/manufacturing costs and margins included publications from 2000-2019 from the following sources:

- PubMed, Google scholar, WHO, UNICEF, Specific company reports, country reports, Journals (Springer, Science Direct, Research Gate, Wiley), Unitaid reports
- Thomson One (research database)
- Industry reports
    - ICRA Rating
    - WARBURG RESEARCH GMBH
    - Oxford Business group

Our search included the following search terms: "profit margin", "COGS", "cost of goods sold", "pricing", "manufacturing cost", and "production cost", along with all product categories and individual product names.

The sustainable price analysis is included for the following product categories: ARVs, ANTMs, and LLINs. It has been excluded for the other categories for the following reasons:

- RDTs: Given that the Global Fund is actively conducting a tender for RDTs, the assessment of sustainable prices for RDTs is a time-sensitive topic and we will not address it in this report.
- VL: Prices may differ and include many different components based on the selected contracting option, which makes it difficult to conduct a sustainable price analysis.
- TB medicines: The price per treatment depends on the treatment regimen selected, which varies based on individual patient requirements and country guidelines. TB medicines pricing for Global Fund-funded products is secured through GDF tenders, an assessment of which are out-of-scope for this analysis.
- TB diagnostics: Concessional price per cartridge ($9.98) was negotiated by USAID, the Bill & Melinda Gates Foundation, and Unitaid in 2012. Anecdotal evidence suggests that price represents affordability challenge for Global Fund grants.

Box 6 - Methodology for sustainable price analysis

We also conducted an extensive literature review. All relevant materials reviewed are included in the references of this document.

### 3.3 Out-of-scope areas

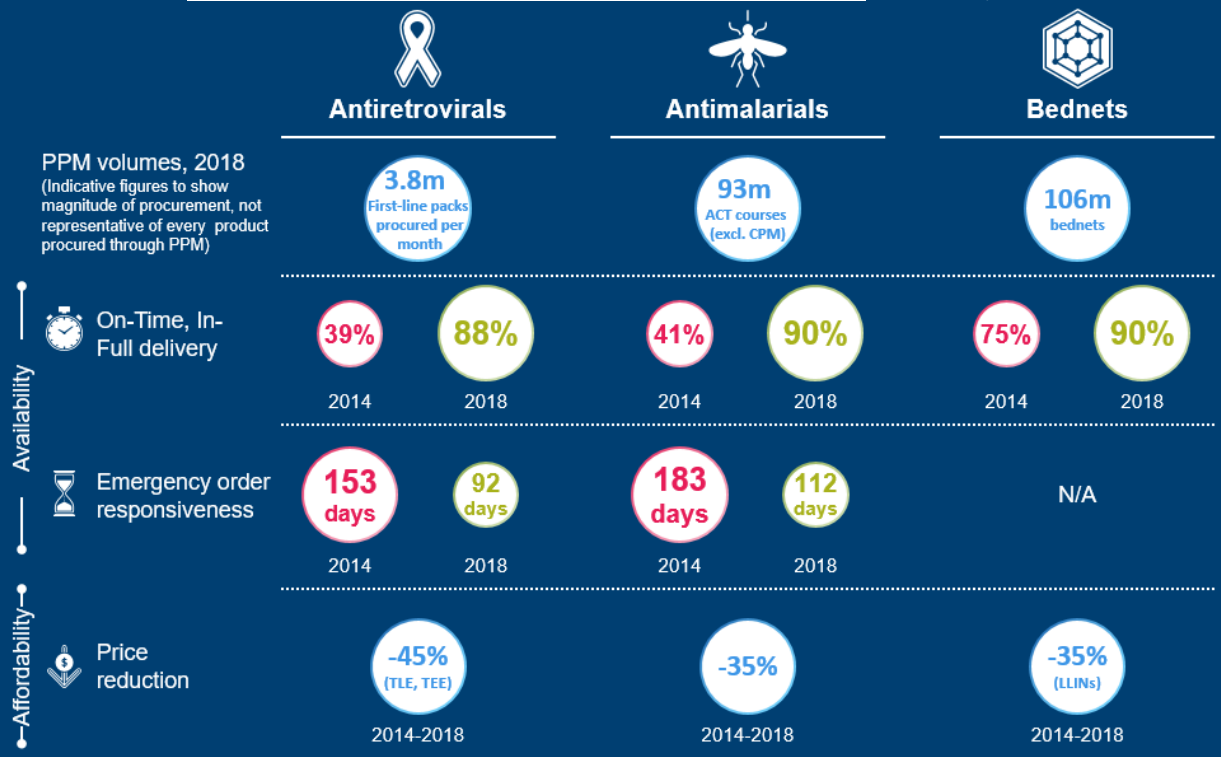
Three key topics fall outside the scope of this review:

- Assessment of market-shaping performance by partner organizations (the assessment of the Global Fund's engagement with these partners on market-shaping is in scope; any assessment of "other global procurement channels" refers to the Global Fund's engagement with these channels, not performance by other market-shaping institutions)
- In-country supply chain, distribution, and logistics
- Assessment of Wambo as a technology platform (the assessment of pooled procurement and transactions flowing through Wambo are in scope)

## 4. What is the Global Fund's current performance on its market-shaping objectives?

Key takeaways:

- The Global Fund has effective foundational elements, including strategic sourcing capabilities, to drive availability, affordability, and quality of products procured through PPM, which we refer to as "smart procurement".
- For performance on the five MSS outcome objectives:
  - A. The Global Fund, with SSC in lead, has achieved cost savings through price reductions, a broad QA supplier base, improvements in OTIF (now commensurate with best-in-class benchmark from the industry), and order responsiveness for PPM spend




  - B. Limited centralized and real-time visibility into spend across channels beyond PPM likely leads to missed opportunities to drive availability, affordability, and quality
  - C. Although the use of pooled volumes / supplier relationships has led to achievements on broader marking-shaping objectives, the lack of cross-team institution-wide technical perspectives and fragmented / reactive engagement leads to missed opportunities to influence / coordinate with partners and to drive innovation / new product introduction / product selection
  - D. The lack of a systematic approach by the Global Fund to address sustainability of procurement creates a risk of back-sliding on market-shaping achievements as domestic financing increases
- See Figure 7 for a summary of these findings.

This section summarizes the Global Fund's performance on foundational elements, and the five outcome objectives. For a summary of the Global Fund's performance against the five MSS outcome objectives, see Figure 7.

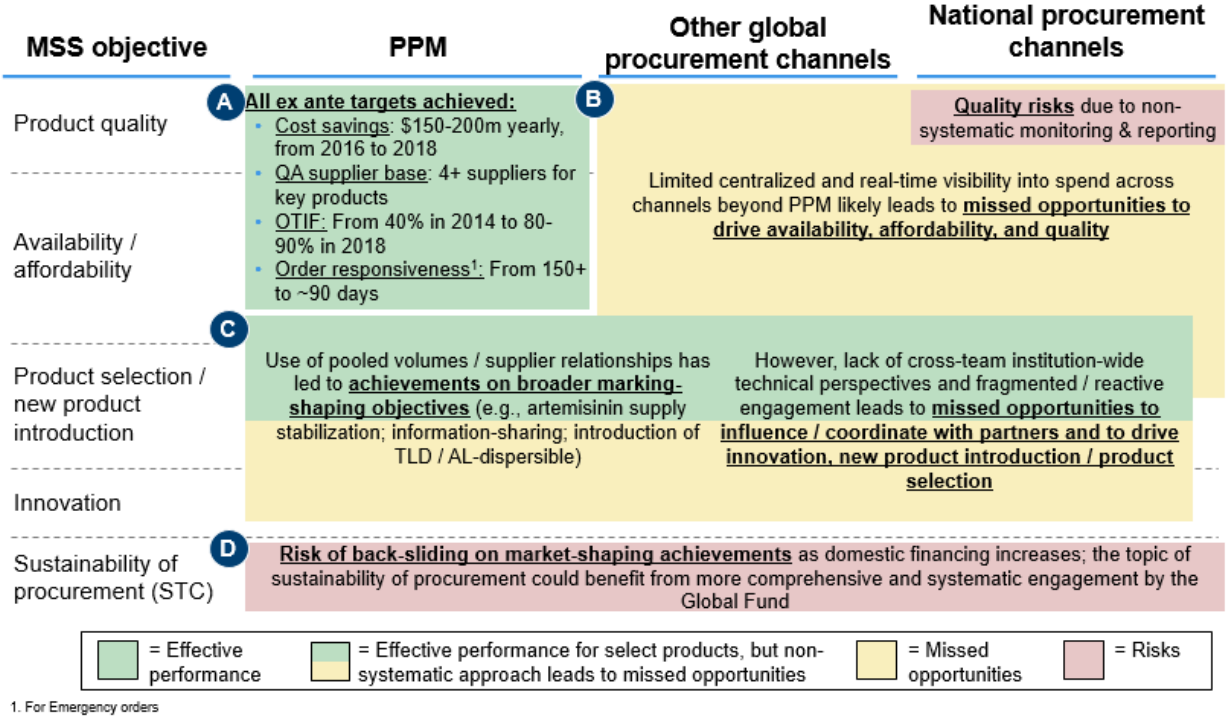



Figure 7 - Summary of Global Fund performance against five MSS outcome objectives

## 4.1 Foundational elements

Before evaluating the Global Fund's performance on any specific outcome objective, it is instructive to assess the Global Fund's performance on foundational elements, as they have direct impact on the five outcome objectives of the MSS.

Foundational elements encompass several dimensions, including:

- Strategies (overall, and product-specific) and implementation of these strategies
- Roles and engagement of teams across the Global Fund
- Strategic sourcing capabilities
- Metrics and KPIs
- Tools and systems
- Partnerships

Overall, the effectiveness of the Global Fund's foundational elements for market-shaping is as follows (a summary of the effectiveness of the Global Fund's foundational elements for driving performance on its other market-shaping objectives can be found in Figure 8):

A. The Global Fund has effective foundational elements, including strategic sourcing capabilities, to drive availability, affordability, and quality of PPM spend, which we refer to as "smart procurement"
B. PQR data incompleteness and delays in reporting means PQR is not fit-for-purpose to manage health product performance and enforce quality requirements. The Global Fund

does not have any ex ante targets/KPIs for monitoring MSS performance outside of PPM availability and affordability

C. The Global Fund lacks **cross-team institution-wide technical perspectives or accountabilities** for addressing product-specific market-shaping objectives. The Global Fund has **limited visibility into TB markets**. The Global Fund also has **fragmented and reactive engagement** to support partners on innovation, drive early adoption/scale-up of products, and commission cost-effectiveness research, and engage with partners on market-shaping for TB

D. There are many siloed efforts to address sustainability of procurement, but there is an **opportunity for more systematic and comprehensive engagement** approach to assess or mitigate risks across countries

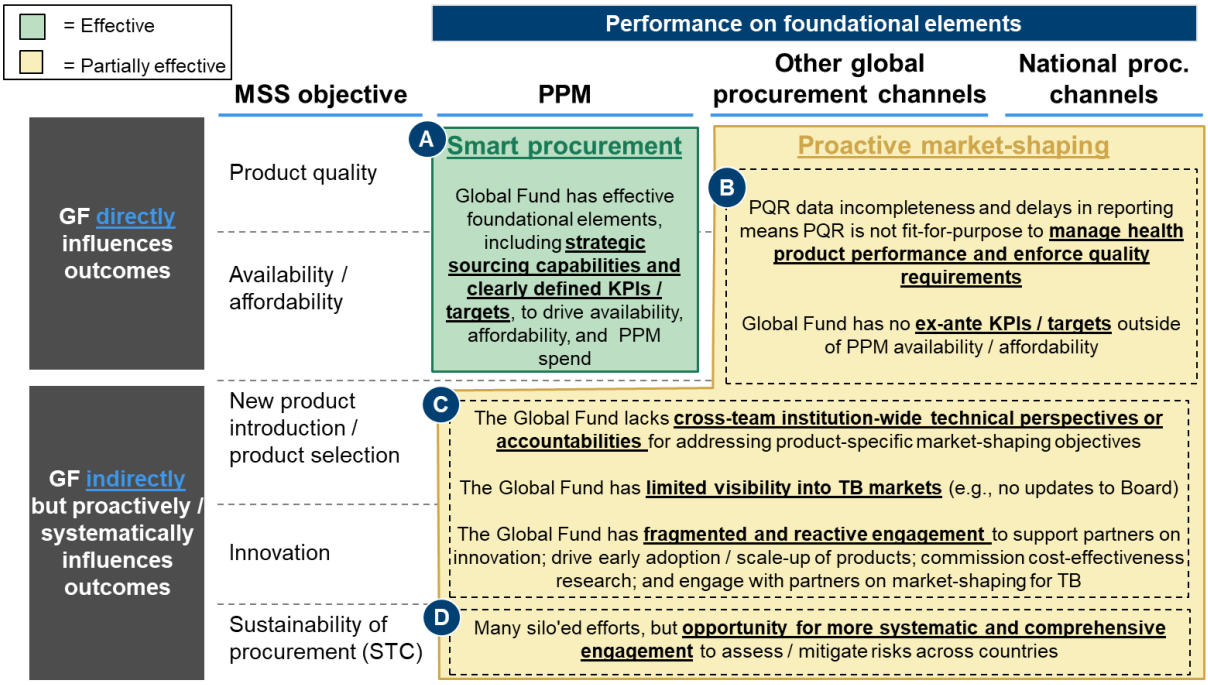



Figure 8 - Summary of the effectiveness of the Global Fund's foundational elements for driving other market-shaping objectives

### 4.1.1 Strategies

The Global Fund has an overall MSS detailing the key areas where it needs to weigh in to ensure healthy markets. However, the MSS does not include any targets or metrics, and it only includes a summary assessment of market dynamics and challenges for specific product categories; it does not provide detailed market-shaping objectives or activities for specific product categories.

The Global Fund also has individual product category strategies for six of its eight main product categories (all products except TB medicines and TB diagnostics), developed by SSC. While these product-specific strategies provide a clear input for the design of the tender and performance-based LTAs and often touch on other market-shaping objectives, they face several key limitations. These limitations are described below, and more information on them can be found in other relevant sections as noted:

- Alignment with partners on objectives and activities: Product-specific strategies drive some alignment with partners, but there is an opportunity to strengthen this alignment. The level of formalized coordination between Global Fund and partners varies greatly among products. (For further details, see Section 4.1.6.)
- Accountabilities for executing strategies across Global Fund teams: Although the SSC team develops these strategies in consultation with a broad set of partners and other Global Fund teams, the strategies do not include a mechanism for driving accountability for execution outside of SSC. (For further details, see Section 4.1.2.) In particular, the accountability is unclear for executing activities which requires input and decisions on country-level, technical, and sourcing topics, since this expertise is divided across three different Global Fund teams (GMD, TAP, and SSC, respectively). The strategies often focus on availability, affordability, and quality of product categories, and take a less systematic approach to other MSS objectives (e.g., new product introduction/product selection, innovation).

The Global Fund's overall 2017-2022 Strategy [23], "Investing to End Epidemics," is generally consistent with the MSS, but the ways in which the MSS will contribute to the Global Fund's four overarching strategic objectives is not always clear. It is important to note that the MSS did not include any KPIs, metrics, or quantitative targets when it was published in 2015. The overall strategy introduced some Board-level KPIs, including two KPIs linked to market-shaping. See Section 4.1.3 for more information on these KPIs. The alignment of the MSS with the Global Fund's overall strategy by strategic objective is as follows:

- Strategic Objective 1 (Maximize Impact Against HIV, TB, and Malaria) does not have a clear link to the MSS. Of course, achieving MSS outcome objectives will have an indirect influence on the fight against the three diseases. For instance, SO 1 focuses on scaling up evidence-based interventions and evolving the allocation model to have the greatest impact. However, the fact that the strategy does not clearly link how MSS activities can maximize impact against the three diseases limits clarity on the role that market-shaping plays in the Global Fund's broader objectives.
- Strategic Objective 2 (Build Resilient and Sustainable Systems for Health) has one operational objective that directly ties to the MSS:
    - "*Strengthen global and in-country procurement and supply chain systems"*
        - This section refers to the role of the Global Fund in encouraging PRs/ countries to invest in strengthening their procurement/supply chain systems to address challenges such as *"issues related to forecasting and quantification, storage and inventory management, distribution, quality assurance, and information management and reporting"*
        - This operational objective aligns with the MSS objective focused on sustainability of health product procurement
        - KPI 6a) and 6b) measure the share of the portfolio that meets expected standards for procurement and supply chain systems, but these KPIs are not currently tracked or reported
- Strategic Objective 3 (Promote and Protect Human Rights and Gender Equality) does not have a direct relationship to market-shaping, although of course both are critical in the fight against the three diseases

- Strategic Objective 4 (Mobilize Increased Resources) has two operational objectives that directly tie to the MSS:
    - "*Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines and technologies*"
        - This section refers to the Global Fund's ability to negotiate procurement terms on behalf of PRs/countries and ensure market transparency to promote competition
        - This operational objective aligns with the MSS objectives related to availability/affordability and quality
        - KPIs 12a) and 12b) are linked to availability (number of quality-assured suppliers) and affordability (annual savings achieved by PPM), respectively
    - "*Support efforts to stimulate innovation and facilitate the rapid introduction and scale-up of cost-effective health technologies and implementation models*"
        - This section refers to the Global Fund's role in partnering with organizations like Unitaid to support innovation and facilitate the scale-up of new products, including by developing strategic "roadmaps" for the scale-up of key products
        - This operational objective aligns with the innovation and new production introduction/product selection MSS outcome objectives

The implementation timeframes for the overarching Global Fund strategy (2017-2022) and for the Global Fund's Market-Shaping Strategy (2016-2021) do not match perfectly. To ensure consistency in terms of temporality and content, the Global Fund should consider developing its next overarching strategy and next MSS simultaneously during the next cycle or directly incorporating market-shaping into the overall strategy. Extending the MSS for one year to cover year 2022 might be a way to align timeframes. This may also provide the opportunity to assess whether merging the two strategies or keeping them distinct is the best way forward.

### 4.1.2 Roles, responsibility, and accountabilities across teams

As defined in the MSS and other Global Fund documents, the roles across Global Fund teams for market-shaping include the following:

- SSC
    - Lead market-shaping activities as the owner of many of the tools that the Global Fund uses for these activities
    - Coordinate across the Secretariat for market-shaping
    - Perform tenders for health product procurement and implement long-term performance-based framework agreements with suppliers including relationship management with suppliers
    - Set targets and monitor KPIs for availability/affordability, including savings and OTIF
- Grant Management Division (GMD)/HPMs
    - Interface with Principal Recipients (PRs) on PSM topics throughout the grant-making and grant implementation process
    - Advise recipients on product selection
    - Monitor grant compliance with PSM policies

- Technical Advice and Partnerships (TAP)
    - Inform product selection (by PRs)
    - Support in-country capacity-building

While there is strong ownership of the MSS by the SSC Team, engagement and accountability by other teams on the MSS is variable, despite clear roles being laid out in the MSS for the different teams. Many colleagues outside of SSC indicated that they did not participate in market-shaping activities, although when they described their roles at the Global Fund, they often named functions related to market-shaping.

In order to assess the current levels of accountability for key market-shaping activities, we use a three-level approach:

- Low
    - Relevant Global Fund team(s) are not fully aware of/engaged on accountability for this activity, and performance metrics and priorities for the team either do not include this activity or include this activity in a very limited manner, OR
    - Teams accountable for this activity are unclear
- Medium
    - Relevant Global Fund team(s) are aware of and undertaking this activity
    - However, their role is not fully defined, requisite capabilities are not fully built out, or the interface across multiple teams for accountability is unclear
- High
    - Relevant Global Fund teams are fully aware of/engaged on accountability for this activity
    - Performance metrics and other priorities for relevant team(s) fully incorporate this activity

We identified three areas where there is currently low accountability for executing market-shaping activities at the Global Fund. For these areas, the low accountability is partly driven by the fact that making certain decisions require country-level, technical, and sourcing inputs. Because this expertise is divided across three teams (GMD, TAP, and SSC, respectively) the Global Fund faces challenges executing these activities in a systematic way.

- Supporting partners on innovation: Product development partnerships (PDPs) and Unitaid are the key relevant partner organizations for innovation in market-shaping. Although Global Fund individuals and teams have perspectives on innovation needs, the Global Fund does not have an institution-wide, documented perspective on this topic that it can use to influence partners, so the Global Fund does not execute this activity in a systematic way today. For more information, see Section 4.9.
- Supporting partners on evidence generation and early adoption: Similar to the point above, while the Global Fund engages with Unitaid and other partners on these topics, Global Fund colleagues indicated that they do not have an internally coordinated approach for systematically and proactively providing input into Unitaid or managing the hand-off from Unitaid to the Global Fund for intervention scale-up. For more information, see Section 4.10.1.

- Guidance for PRs on product selection (including cost-effectiveness, product phase-out): When there is limited guidance from WHO on preferred products, and/or limited cost-effectiveness data exists, it is unclear which team(s) – i.e., SSC, GMD, and/or TAP – would be accountable for helping to fill these gaps. For more information, see Section 4.10.2.

See Figure 9 for a summary of the current levels of accountability for key Global Fund market-shaping activities. Note that these activities tie to the activities listed in Figure 3.

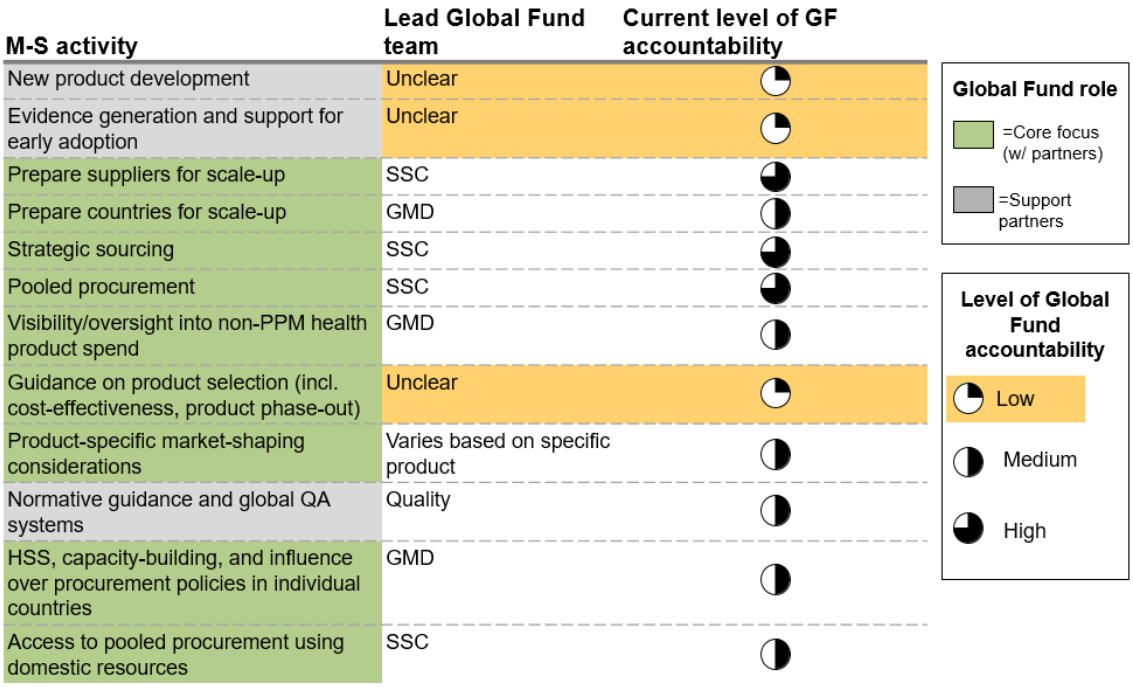



Figure 9 - Summary of levels of accountability for key Global Fund market-shaping activities

### 4.1.3 Strategic sourcing capabilities

Compared with traditional spot tenders and short-term contracting, the Global Fund strategic sourcing approach aims to maximize the value creation for the full duration of the multi-year Long-Term Agreements.

The Global Fund takes a performance-based approach to managing supplier relationships/category strategies in order to incentivize performance on key metrics (e.g., price, on-time, in-full [OTIF] delivery performance, among others). The SSC Team begins by conducting market analyses and developing a product-specific market-shaping strategy in consultation with other relevant Global Fund teams and external partners. For certain products, this may include conducting a cost of goods (COGS) analysis to set target prices. The SSC Team then translates this strategy into a tender, which includes technical criteria (e.g., OTIF performance, number of countries in which select products are registered, special projects linked to each product category [for instance interchangeability for RDTs]) and commercial criteria (e.g., price) for assessing suppliers' response to the tender. The balance between technical and commercial weighting is tailored to the issues to be driven for a specific product category.

After selecting a panel of suppliers based on their response to the tender, the SSC Team translates global demand into volume allocations for these suppliers, and, for certain products – ARVs and ANTMs – into committed volumes (usually a percentage of volume allocations) that come with a financial compensation in the event that those commitments do not materialize. SSC then revisits these volume allocations yearly based on criteria from the tender and supplier performance. For example, missing the OTIF target means a portion of the volumes that would have been allocated to the under-performing supplier will go to a reallocation pool and will be reallocated among all suppliers based on updated commercial and technical scores (all technical and commercial tender criteria are reapplied annually to determine volume allocations). Although the reallocation of volumes happens once a year, the Global Fund holds quarterly performance review meetings with suppliers to align on key issues and on how to improve performance. This performance-based approach allows the Global Fund to use tenders and long-term framework agreements with suppliers as a market-shaping tool, because they incentivize suppliers to meet certain criteria and perform in certain ways in order to gain volumes with the Global Fund.

As part of its supplier relationship management and execution of performance-based LTAs, SSC may also encourage efficiency improvements among suppliers by alternative sourcing of raw materials, process improvements, and innovative technology.

As already mentioned, SSC also publishes reference prices to drive market transparency, influence global pricing trends, and serve as guidance for the budgeting process for grants.

In general, this approach has been effective for driving the availability of affordable quality products and represents the core strategic sourcing activity undertaken by SSC. Product-specific performance is documented in the product-specific sections 4.2 through 4.6.

SSC is organized into various teams involved in the activities described above: Strategic Sourcing (12 FTEs); PR services (7 FTEs); Data, Analytics, Processes, and Tools (9 FTEs); Quality Assurance (3 FTEs); and Supply Chain and Indirect Sourcing (which are out-of-scope for this review).[k] Previous analyses conducted by the Global Fund Secretariat indicate that SSC is a relatively lean team given the total volume of spend managed. Given that this relatively lean team has delivered on its core targets of driving availability, affordability, and quality for PPM spend, plus a wide range of broader market-shaping activities, continuation of this team's work will require, at minimum, maintaining the team's current size, and adding new or expanded roles for this team would likely require incremental resourcing.

### 4.1.4 Tools and systems

Tools and systems should support oversight for health product management. Currently, the Global Fund has extensive transaction data for PPM spend, provided by Procurement Service Agents (e.g., PFSCM, IDA). The SSC Team is currently able to use this data to conduct relevant analyses (e.g., performance delivery, product uptake, weighted average prices). However, there

[k] Note that this count of FTEs does not include consultants but does include unfilled positions.

are noteworthy gaps, which drive inefficiency in consolidating and analyzing data. These gaps include:

- No master data (i.e., static reference data used across tools), meaning the same product may be labeled differently in different tools
- No comprehensive data source for non-PPM spend as PQR data is incomplete and often faces delays between the execution of transactions and the time when they are actually input into PQR
- Separate tools to manage demand forecasting, transactions, spend reporting, and quality incident reporting
- No automated links between the different datasets, meaning time-intensive manual actions are required to integrate data and conduct analyses

SSC is considering ways to reduce dependency on third-party data (e.g., transaction data) in the future.

Similarly, there is no standardized process or centralized tool for diverse actors to report quality incidents on health products procured with Global Fund grants.

The original intent of PQR was to drive price transparency across markets. While it has achieved some success in that regard, there is now a need for a more comprehensive health product management tool that would allow for better demand forecasting, management of transaction data, and linkages with management quality incidents, among other things. With these new business needs and given the shortcomings of PQR (e.g., incomplete data, delays in reporting), PQR may no longer be considered as a fit-for-purpose tool. For a summary of select pain points related to data for health products, see Figure 10.

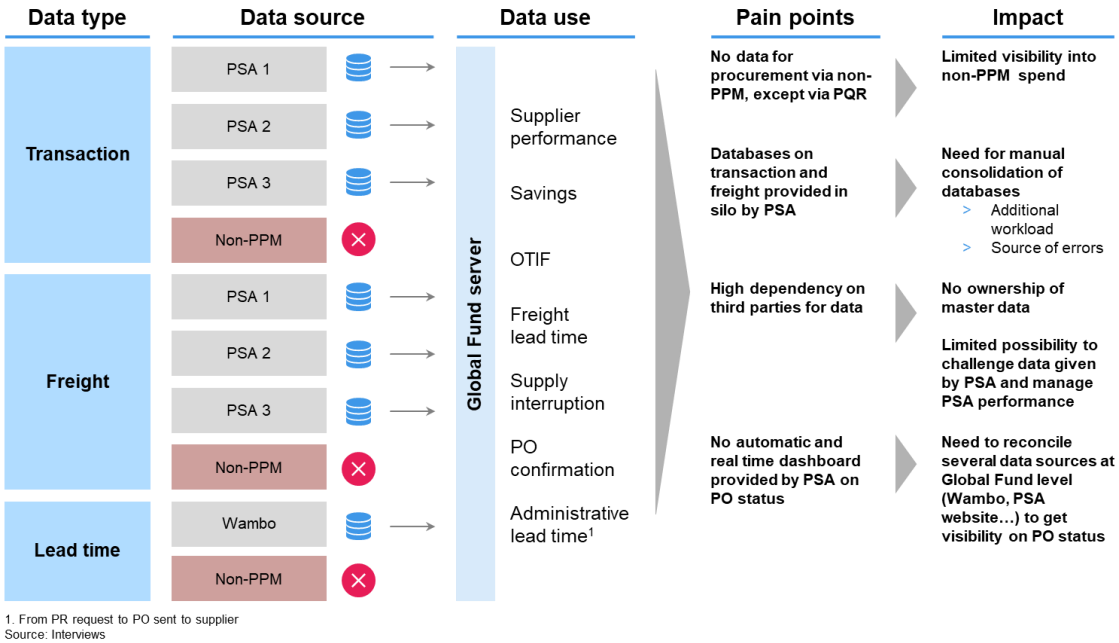



Figure 10 - Summary of select pain points related to data capture for health products

### 4.1.5 Metrics and KPIs

For PPM spend, there is regular measurement of KPIs for availability and affordability. These KPIs include OTIF delivery performance, annual cost savings, and the number of quality-assured suppliers available for select products. However, the Global Fund lacks metrics and KPIs for other MSS objectives, and it does not track or report on market-shaping related to TB products. This lack of comprehensive metrics across all MSS objectives limits oversight for performance on the MSS. For a summary of Global Fund KPIs mapped to MSS outcome objectives, see Figure 11. For a summary and assessment of the Global Fund's methodology for calculating cost savings from pooled procurement of health products, see Box 7.

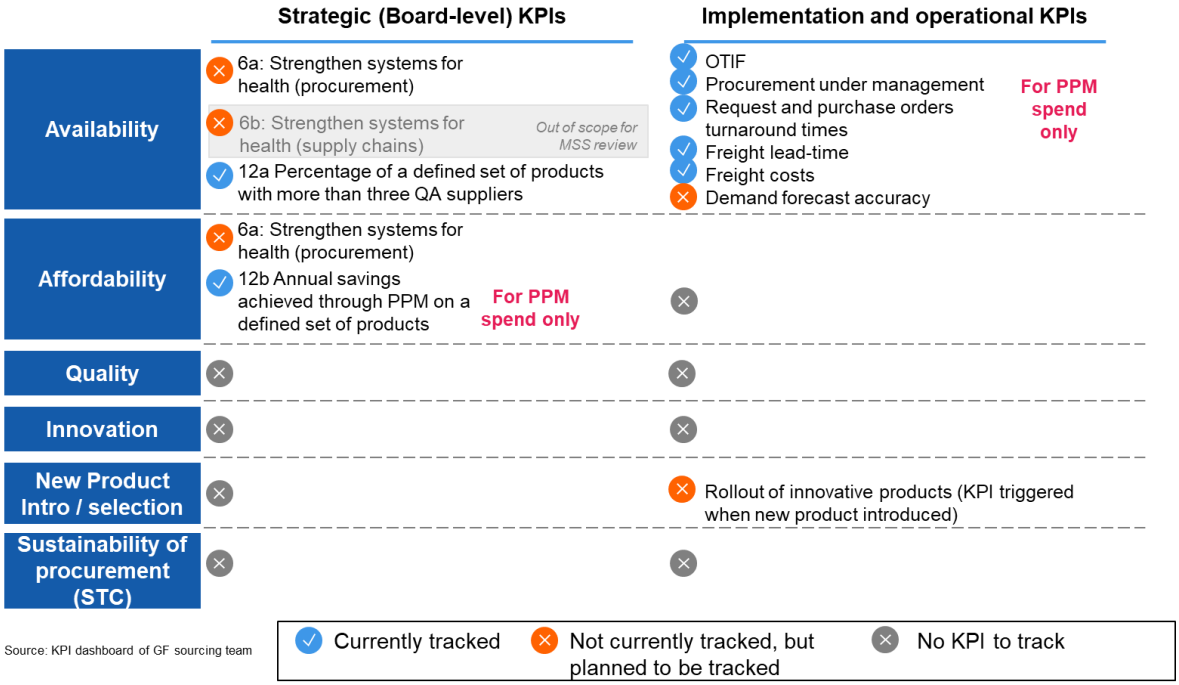



Figure 11 - Key Performance Indicators mapped to MSS outcome objectives

KPI definitions

- KPI 6a: Share of the portfolio that meets expected standards for procurement systems to improve outcomes for procurement conducted through countries' national systems in terms of price, OTIF delivery, and administrative lead-time.
- KPI 6b: Share of the portfolio that meets expected standards for supply chain systems, based on the percentage of health facilities with tracer medicines available on the day of the visit, and the percentage of health facilities providing diagnostic services with tracer items on the day of the visit.
- KPI 12a: Percentage of a defined set of products with four or more suppliers that meet Quality Assurance requirements (Stringent Regulatory Authority approval, WHO-Prequalification listing or Expert Review Panel approval).
- KPI 12b: Annual savings achieved through PPM on a defined set of key products (mature and new), compared with the prior year. See Box 7 for an assessment of the calculation methodology for this KPI.

- OTIF: A purchase order is considered on-time and in-full if the order is picked up at the supplier within seven days of the promised pick-up date (Manufacturer OTIF).
- Procurement under management: Percentage of health product expenditure through procurement under management (ARVs, LLINs, ANTMs, RDTs).
- Freight lead-time:
    - For 75% of all shipments, the freight actual lead-time should be within +/-5% of the PSA's initial quoted lead-time (gross). This includes issues that are within and outside of the PSAs' control.
    - For all shipments, the freight actual lead-time must be within +/-10% of the PSA's initial quoted lead-time (gross). This includes issues that are within and outside of the PSAs' control.
    - For 75% of all shipments, the freight actual lead-time should be within +/-5% of the PSA's initial quoted lead-time (net). This includes issues that are within the PSA's control, based on Global Fund and PSAs' agreed upon reason codes.
    - For all shipments, the freight actual lead-time must be within +/-10% of the PSA's initial quoted lead-time (net). This includes issues that are within the PSA's control, based on Global Fund and PSA's agreed upon reason codes.
- Freight costs:
    - For 80% of all shipments, the freight actual cost should be within +/-5% of the PSA's initial quoted cost.
    - For all shipments, the freight actual must be within +/-10% of the PSA's initial quoted cost.
- Demand forecasting accuracy: Percentage of demand forecasts for key products (ARVs, ACTs, LLINs) with acceptable variance to actual demand.
- Rollout of innovative products: Portfolio penetration of the innovation health product against expected benchmark.

**Additional information - Cost-savings calculation methodology**

For KPI 12b, the Global Fund Board agreed to the following specific definition of cost savings: "*Annual savings achieved through PPM on the total cost of product delivery (including product cost, procurement agency fees, freight and logistics cost) on a defined set of key products (mature and new).*"

As stated in the Board-level KPIs approved by the Board in 2017, this metric *"intends to measure the Secretariat's procurement efforts to reduce the cost of health products for the programmes we support. These efforts can be through tenders and negotiating long-term agreements with favourable prices, capturing price developments in the market, or mitigating price increases in an environment of rising prices."*

The cost-savings calculation methodology used by the Global Fund to determine savings is

[ (Baseline Price) – (Actual Price) ]* Actual Volume

This calculation methodology uses the difference in historic price and actual price received to quantify the total savings achieved by product category. This cost-savings calculation methodology is aligned and consistent with the definition set by the Board. The calculation methodology does not control for general market trends which would have occurred even without intervention by the Global Fund Secretariat, but the intention of the KPI is to include the Secretariat's capturing of price developments in the market in the calculation methodology. One should note that it would be technically very difficult to isolate the Global Fund's contribution to these trends due to methodological and data confidentiality issues.

One should note that the Global Fund ensures transparency on the savings calculation methodology. The methodology is publically available in the "2017-2022 Strategic KPI Framework: Proposed Performance Targets" report.

Finally, the Global Fund's approach to calculating baseline price and cost savings from pooled procurement activities is similar to that of USAID (PMI), UNICEF, and GDF.

Box 7 - Global Fund methodology for calculating cost savings from pooled procurement [24-26]

Due to PQR data incompleteness (PQR being the Global Fund's only centralized, cross-country source of data for actual — as opposed to budgeted — spend by PRs procuring health products through non-PPM channels), there is limited real-time visibility into non-PPM spend. This means that even if KPIs existed for this non-PPM spend, tracking them using PQR data would only give a very partial picture[l].

### 4.1.6 Partnerships

Because the Global Fund occupies a unique position in the market-shaping landscape, coordinating with partners who occupy other positions, or who also have large market share for select product categories, will help maximize the Global Fund's market-shaping impact.

[l] Fully assessing PQR data completeness for all spend (including non-PPM spend) would require a grant-by-grant review of all health product purchases, which is beyond the scope of this review. However, the Global Fund has a second centralized source of transaction data for PPM spend (PSA transaction files), thereby allowing for an assessment of total PPM spend reported in PQR without grant-by-grant review. For this analysis, we compared annual spend reported in PSA transaction files for 2015-2017 with data on PPM spend reported in PQR (as of April 2019) for the same years. We found that for 2015 and 2016, the total value of spend in PSA transaction files and PQR for PPM spend was relatively similar (less than 10% variation between the two sources), but for 2017, the total value of transactions reported in PQR only accounted for approximately 67% of the total value of transactions reported in PSA transaction files.

The Global Fund coordinates with a number of global health partners on a wide range of activities. These partners include:

- Other major procurers of health products and pooled procurement channels such as USAID/PEPFAR, USAID/PMI, the South African Government (for ARVs), the Stop TB Global Drug Facility (GDF), UNICEF, UNDP, UNFPA
- Other donors such as Unitaid, the Bill & Melinda Gates Foundation
- Technical partners and NGOs such as CHAI, MSF, the Treatment Action Group (TAG)
- Product Development Partnerships such as Medicines for Malaria Ventures (MMV), FIND
- WHO

#### 4.1.6.1 Collaboration on specific products

The level of coordination between the Global Fund and partners varies greatly between product categories, and this variation is at least partially driven by the existence (or lack) of formal forums for collaborating with partners on product-specific topics. For a summary of forums for collaboration on market-shaping for specific products, see Figure 12.

Among the Global Fund's product categories, ARVs have the most formal collaboration. Large procurers will share consolidated ARV demand forecasts with suppliers, identify roadblocks hindering the introduction and scale-up of new products, and discuss any potential capacity issue during yearly Large Buyers & Sellers Forums. The Project Advisory Committee (PAC) ensures alignment between the Global Fund, WHO, Unitaid, USAID, and CHAI on evidence gaps, impact of future WHO guidance, supplier base readiness, and regulatory status to support uptake. For instance, partners will make sure they are not funding the same studies to bridge evidence gaps that would slow down the introduction of innovative products. Initially created for pediatric ARVs, the ARV Procurement Working Group has since expanded into low-volume and new products, and coordinates demand/ supply planning and industry engagement to support uptake.

Although an ACT Supply Task Force existed in the past, there is currently no standing forum in the ANTM space for coordinating procurement. Most of the coordination happens in an ad-hoc way. This may have led to shortcomings in recent years, for example when the scale up of Amodiaquine + Sulfadoxine-Pyrimethamine (AQ+SP) for Seasonal Malaria Chemoprevention (SMC) in 2017 was marked by capacity issues as USAID/PMI, Unitaid, and the Global Fund were in effect competing for procurement of a single-source product. We discuss this example further in the ANTM section 4.3.5.

HRDTs also lack a formal coordination forum for procurement. In those cases, coordination happens on an ad-hoc basis and essentially relies on personal relationships. Even for product categories for which forums do exist, much coordination happens outside of these formal meetings. This is consistent with the findings from the Thematic Review of Partnerships commissioned by the TERG in 2018: *"In situations where there are not clear agreements in place, cooperation between organisations is dependent on personal relationships, political will, commitment and perceived value."* [3]

When/if these product categories face market-shaping challenges that may require cross-partner coordination, it could be useful to create a formal forum to address these issues. In the case of HRDTs, where the market will face changes due to the proposed introduction of product interchangeability, formal coordination across partners is likely important in the near-term. For ANTMs, there may be a need for a formal forum to coordinate on a joint response to address supply security challenges (e.g., ACTs in the Greater Mekong Sub-region) and to prepare the introduction of new antimalarials (e.g., Tafenoquine for *Plasmodium vivax* malaria).

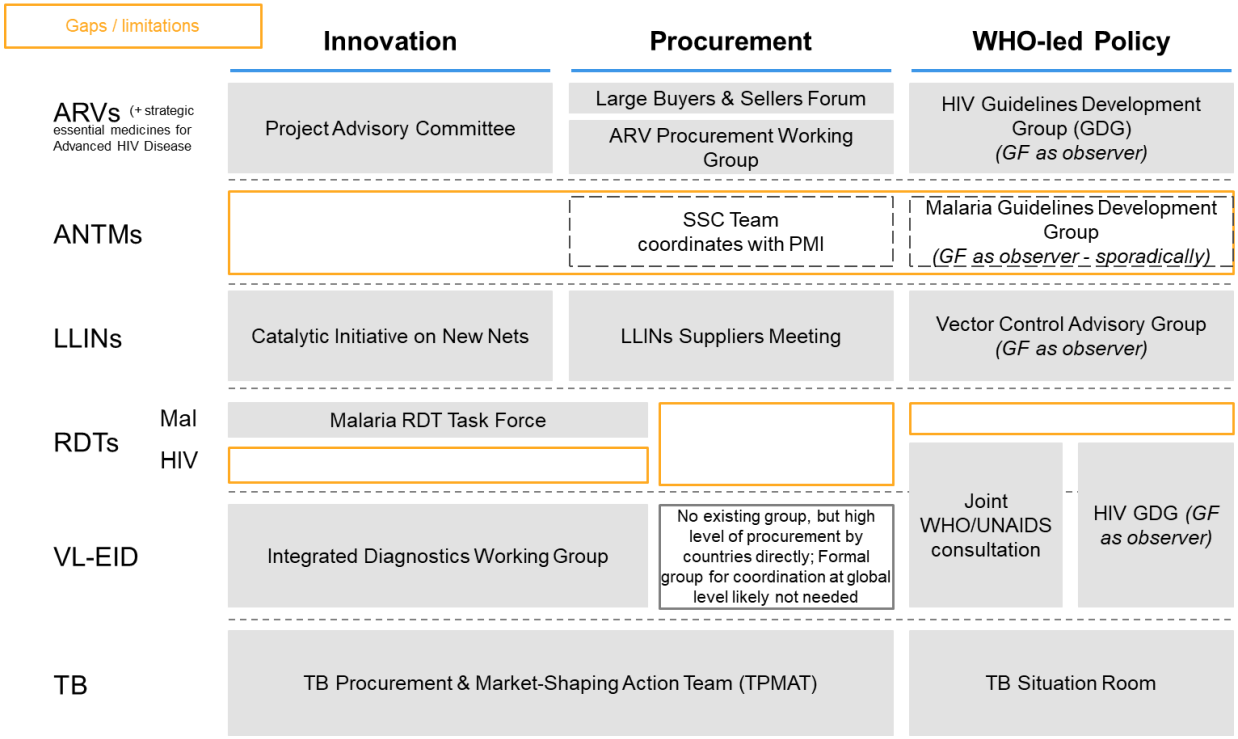



Figure 12 - Mapping of forums for collaboration on market-shaping for specific products

#### 4.1.6.2 Partnership with Unitaid

The partnership between the Global Fund and Unitaid is focused on innovation and new product introduction. Therefore, we review this partnership in the assessment of the Global Fund's performance on innovation and new product introduction/product selection in Sections 4.9 and 4.10, respectively.

#### 4.1.6.3 Partnership with GDF

The partnership between the Global Fund and GDF is specific to tuberculosis products. Therefore, we review this partnership in the assessment of the Global Fund's performance on TB medicines and TB diagnostics in Section 4.7.

### 4.2 Product-specific performance: Antiretroviral medicines (ARVs)

This section summarizes product-specific performance for ARVs.

### 4.2.1 Context

In the absence of an HIV cure, people living with HIV must continue to take medicines for life. In recent years, the standard antiretroviral regimens have evolved toward single tablet regimens, reducing the number of pills to one per day. Taking one single pill – usually combining three antiretrovirals – every day, instead of taking two or more, makes the treatment plan easier to follow.

HIV impacts high-income countries (HICs) as well as low- and middle-income countries (LMICs), with 10% of the 37 million people living with HIV residing in HICs [6]. Innovation in the HIV space is mostly driven by the HIC market. Direct licensing transfers from originators to generics-makers allow for new ARVs to become available to LMICs at much lower prices (several hundred times lower sometimes [6]). Consequently, even though LMICs account for 90% of ARV volumes, they only account for 10% of the global ARV market in value because of the lower prices[m] [27].

The annual LMIC ARV market is estimated at $1.8 billion [6, 28, 29], with ~82% of that value going to first-line adult and adolescent treatments, 12% to second-line adult and adolescent treatments and 6% to pediatric treatment [6, 30]. Market analysis shows that the Global Fund accounts for ~35% of the LMIC ARV market (value), and coordinates closely with PEPFAR and the South African Government, which account for another 30-40%, giving the Global Fund significant leverage over the LMIC market [7, 8].

Following a 2018 WHO recommendation, the adult first-line treatment market is transitioning to Dolutegravir/Lamivudine/Tenofovir Disoproxil Fumarate (TLD), the third major transition in ten years after the transition to Lamivudine/Nevirapine/Zidovudine (LNZ) in 2010 and the transition to Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate (TLE) in 2013 [31-33].

The Global Fund is using its commercial leverage to effectively shape the ARV market. Major sourcing activities like the 2018 procurement strategy for ARVs (and other strategic medicines used in HIV programmes), the associated ARV tender, the supplier relationship management strategy, and the execution of long-term performance-based framework agreements (LTAs) are all aligned with the MSS outcome objectives with a specific focus on driving availability, affordability, and quality. After the first ARV sourcing strategy and tender in 2015, the Global Fund developed and implemented a new strategy and tender in 2018. The Global Fund evaluated bids against technical and commercial criteria which included price and OTIF performance in addition to responsiveness and supply security and visibility, among others.

### 4.2.2 Availability

Looking at supply security, analysis of PPM transactions shows that, although more suppliers have signed long-term framework agreements, the supplier base has consolidated since 2014 with the top four suppliers capturing 90% of the spend, and the top supplier capturing 60% of the spend.

[m] Of the 21.7 million people globally accessing ARVs at the end of 2017, 19.3 million were in LMICs (mostly generic accessible markets) and about 2 million were in HICs that predominantly purchase from pharmaceutical companies that innovate ARVs rather than produce generics.

However, the supplier base has diversified geographically with new suppliers in China and South Korea, in addition to suppliers in India.

In terms of delivery performance, we analyzed PPM transactions from 2014 to 2018. Manufacturer OTIF performance has increased since 2014 to 75-80% (near the 80% target OTIF), with further increase to 85-90% in 2018. The annual volume reallocation mechanism rewarding suppliers meeting the OTIF target helped drive the improvement. In January 2018, the target OTIF increased to 90%, which is comparable to best-in-class benchmark from the industry.

Combined, late orders (orders placed four to five months ahead of the requested delivery date) and emergency orders (orders placed less than three months ahead of the requested delivery date) have increased from 31% of ARV PPM spend in 2014 to 47% in 2018. Late orders have increased from 18% in 2016 to 44% in 2018, despite accurate annual demand forecasting at Global Fund level. This increase is likely due to countries backfilling late supplies from other channels, weak disincentives to follow order lead-time guidelines, and poor quarterly country demand forecasting accuracy. On the contrary, emergency orders have declined from 18% of value in 2014 to 3% in 2018, and the introduction of the Rapid Supply Mechanism (RSM)/Vendor-Managed Inventory (VMI) for some emergency orders has cut lead-times so suppliers now meet the emergency order target delivery (average lead-time of 92 days in 2018, close to 90-day target versus 153 days in 2014). Note that RSM/VMI comes at no cost or risk to the Global Fund as it is leveraged through the long-term framework agreements the Global Fund has with the suppliers. Indeed, the responsibility for making the products available and managing the shelf life of the products lies with the manufacturer, as opposed to the traditional stockpiling approach where the buyer assumes the risks.

### 4.2.3 Affordability

Market research shows that the Global Fund's ARV reference prices are lower than or in line with the catalogue prices of other large buyers (USAID/PEPFAR and the South African Government), and PPM transaction analysis shows that actual prices for monthly ARV packs declined by 15%-45% between 2014 and 2018 [6-8, 34-37]. For a summary of the evolution of the annual per-person treatment cost for preferred first-line ARVs, see Figure 13.

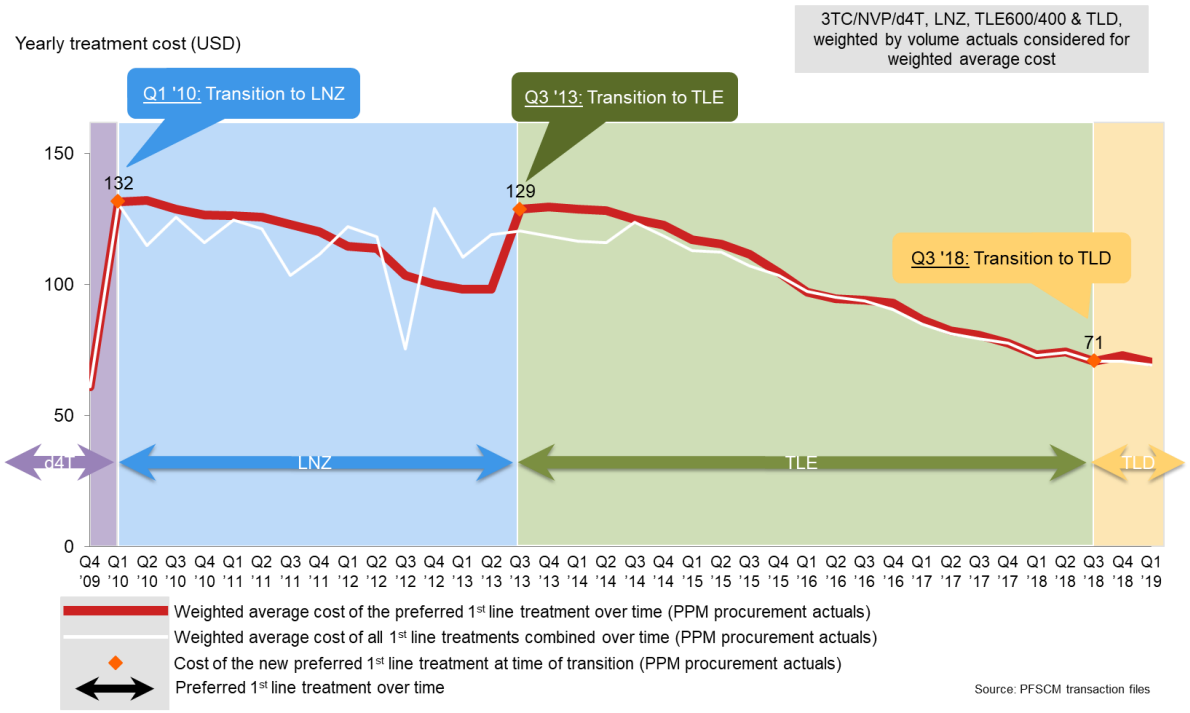
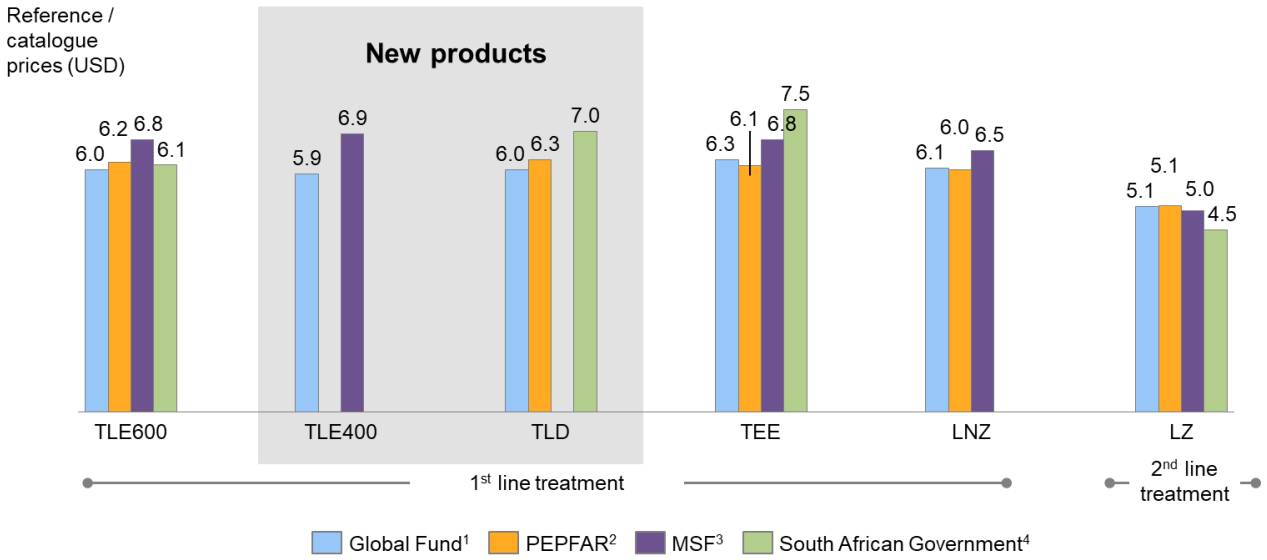



Figure 13 - Evolution of the annual per-person treatment cost for first-line ARVs

Initiatives such as the target-price-setting mechanism (where SSC asks suppliers to provide roadmaps toward meeting a price target based on a Cost of Goods Sold analysis) have helped the Global Fund achieve lower prices. Consequently, the transition from TLE to TLD will be the first transition of preferred first-line treatment that will not incur a price increase: countries/PRs may procure TLD at roughly the same price as TLE. Additionally, TLD will be available at scale, thanks to the supplier base preparation work conducted by the Global Fund and partners (the Global Fund has LTAs with six quality-assured suppliers for TLD). Secular market trends, such as increased competition between generics makers, new product introductions, and manufacturing process efficiencies, have also driven price reductions. See Figure 14 for a benchmark of 2018 unit ARV reference/catalogue prices for select procurers.




1. Global Fund PPM Reference Price, July 2018 2. GHSC-PSM E-Catalog, July 2018 3. MSF Price, July 2017 4. RSA reference price, September 2018
Source: CHAI Benchmark, Department of Health, Republic of South Africa

Figure 14 - Benchmark of unit ARV reference/catalogue prices for select procurers

**Counterfactual:** If the Global Fund, in coordination with the global health community, had not negotiated the price of TLD, the switch to TLD as the preferred first-line treatment would probably have resulted in a price increase, similarly to what happened with the transition from d4T to LNZ (+113%) and from LNZ to TLE (+30%). The Global Fund led this effort, in coordination with partners, in particular with the use of its target price-setting mechanism using COGS analyses to determine a sustainable price for TLD.

Box 8 - Counterfactual (TLD pricing)

**Sustainable price analysis**

For a yearly adult treatment based on TLE, Active Pharmaceutical Ingredient (API) costs were estimated at $75 in 2014. API costs typically represent ~80% of costs for generic Finished Pharmaceutical Products. Given that the Global Fund's yearly treatment price for TLE in 2014 was $125, we can infer that manufacturers achieved ~30% profit margin for TLE in 2014, when TLE became the preferred first-line treatment. This profit margin is consistent with typical generic-maker margins at 15-30%. It is unlikely that the profit margin for TLE increased significantly as TLE volumes ramped up given that variable costs (including API costs) account for at least 80% of total costs. Further, there is a high level of competition in the market with five manufacturers actively supplying to the Global Fund. There is, however, some limitation to the diversity of the supplier base as the top player captures ~60% of Global Fund PPM spend. Finally, the price of TLE has been almost halved since 2013 and other procurers are paying similar prices. Combined, these elements show that the Global Fund prices are likely in the range of sustainable prices, despite the limited diversity of the supplier base.

Box 9 - Sustainable price analysis for ARVs [38, 39]

### 4.2.4 Quality

The analysis of the FDA-approved, WHO-PQ-listed, and ERP-approved ARVs shows that all major ARVs meet the Global Fund target of having four or more quality-assured suppliers, with the exception of $TLE_{400}$ – a first-line ARV with a lower dose of Efavirenz compared with $TLE_{600}$ –

introduced in 2013, for which only two quality-assured suppliers exist, partly due to recent guideline uncertainty and the resulting uncertainty in need. The global health community now expects $TLE_{400}$ to have an extended lifetime because of TLD safety concerns. $TLE_{400}$ suppliers are expected to resubmit their regulatory approval applications after withdrawing them because of the push to transition to TLD. There has been no procurement of ERP-approved ARVs through PPM (see Section 4.8.2 for more detail).

### 4.2.5 Innovation and New Product Introduction/Product Selection

The Global Fund is supporting innovation by coordinating with partners through forums like the ARV Procurement Working Group to mitigate transition challenges from innovation to scale-up (Unitaid has been funding this Working Group for more than seven years and uses it as part of its project implementation to support product uptake). These challenges may include switching from a time-limited procurement channel linked to a pilot to the general Global Fund procurement mechanism, but also managing the switch at country level from product donation by Unitaid to the use of a Global Fund grant to procure products. Case studies (e.g., Unitaid/Global Fund collaboration to support the launch of Flucytosine for advanced HIV disease) show how the Global Fund can prepare suppliers for new product introduction. The opportunity exists to formalize this approach.

The Global Fund has successfully facilitated the introduction of TLD and $TLE_{400}$ in recent years, and is actively supporting country transition to TLD per 2018 WHO guidelines update. The Global Fund delivered the first TLD shipment ordered through PPM six months after the WHO recommendation change. TLD is expected to reach a 20% LMIC coverage in 15 months, a faster introduction pace than for other health commodities [40]. As already mentioned, the fact that there was no price increase compared with TLE may also explain the successful introduction of TLD.

The scale-up of capacity for pediatric pellets/granules of Lopinavir/ritonavir (LPV/r) is another example of how the Global Fund and partners successfully used their commercial leverage to increase global capacity for products for which there is no long-term need. In light of the limitations of nevirapine-based regimens (decreased efficacy), countries needed to shift away from them for both adults and children. While TLD became available for adults, there was a need for pediatric ARVs, pending the introduction of pediatric formulations of Dolutegravir. More complex pellets/granules of LPV/r for children had the advantage of addressing some of the key issues of the existing pediatric syrup with high alcohol content (bad taste, difficulty to administer, need for refrigeration). However, the global capacity for these pellets/granules was only 30-50% of the demand. The Global Fund discussed these issues with partners (USAID/PEPFAR in particular) in the ARV Procurement Working Group and coordinated the response. Through its long-term framework agreements, the Global Fund was able to provide the volume visibility to manufacturers so that they could support the investment in capacity. As a result, two manufacturers are scaling up their production by a factor of four, which means that by early 2020, for the first time since the approval of these LPV/r formulations in 2015, there will likely be enough supply to meet the demand.

## 4.3 Product-specific performance: Antimalarial medicines (ANTMs)

This section summarizes product-specific performance for ANTMs.

### 4.3.1 Context

The Global Fund procures antimalarial medicines aimed at preventing or treating the two most prevalent forms of malaria, *Plasmodium falciparum* (Pf) malaria, which accounts for 99% of prevalence in Africa (Africa has 80% of the world malaria burden), and *Plasmodium vivax* (Pv) , which accounts for 75% of the cases in South America. Artemisinin-based Combination Therapies (ACTs) constitute the backbone of malaria treatment. Market research shows that the annual ACT market represents 350 million three-day treatment courses, worth $250 million [9].

**Additional information - ACTs**

WHO currently recommends five ACTs:

- Arthemeter-Lumefantrine (AL)
- Artesunate-Amodiaquine (ASAQ)
- Artesunate-Mefloquine (ASMQ)
- Artesunate-Sulfadoxine-Pyrimethamine (AS-SP)
- Dihydroartemisinin-Piperaquine (DHA-PPQ)

Box 10 - WHO-recommended ACTs

There has been limited innovation in the Pf treatment space since the introduction of ACTs 20 years ago [18, 41], with the exception of innovative formulations such as dispersible pediatric formulations. Some innovation has happened in chemoprevention with the use of Amodiaquine + Sulfadoxine-Pyrimethamine in Seasonal Malaria Chemoprevention, among others [42]. A new drug, Tafenoquine, was approved by the US FDA as a single-dose radical cure for Pv in 2018 [43]. WHO does not yet recommend Tafenoquine; therefore, the Global Fund cannot procure this new antimalarial.

The Global Fund accounts for ~55% of the ACT market in LMICs (volume) and coordinates with USAID/PMI, which accounts for another ~15-20% [10, 11, 44]. (ACTs account for 75% of the Global Fund's spend in ANTMs.) This gives the Global Fund significant leverage over the LMIC market.

The Global Fund market share includes the Co-Payment Mechanism (CPM), by which co-payments are made to suppliers on behalf of participating private sector importers with the aim of making quality-assured ACTs more available and affordable through private sector channels [45]. CPM met and sometimes even exceeded expectations in improving access to quality-assured ACTs in the private sector (ACT availability increased by at least 20 percentage points in six of the eight pilot countries) and making ACTs more affordable (ACT full treatment course prices in the private sector dropped by $1.28-$4.82 in six of the eight pilots) [46, 47]. Nevertheless, CPM grant funding has gone down in recent years as a result of competing priorities in countries, with countries giving a higher priority to meeting public sector needs, including the increased importance of ensuring access to diagnostic testing for malaria.

The Global Fund is using its commercial leverage to effectively shape the ANTM market. Major sourcing activities like the 2017 sourcing strategy and associated ANTM tender, the supplier relationship management strategy, and the execution of LTA are all aligned with the Market Shaping Strategy outcome objectives with a specific focus on driving availability, affordability, and

quality. The Global Fund evaluated bids for the 2017 tender against technical and commercial criteria, with the focus placed on price, among other things such as stabilizing the supply of artemisinin and introducing environmental health and safety requirements for sourcing artemisinin.

### 4.3.2 Availability

Looking at supply security, analysis of PPM transactions shows that the supplier base has remained broad with the top seven suppliers capturing ~80% of Global Fund spend.

The key challenge in recent years has been to stabilize the artemisinin supply [48]. The Global Fund led two initiatives in this regard in 2017:

- The Global Fund has pushed the development of semi-synthetic artemisinin. Semi-synthetic artemisinin is produced six times faster than natural artemisinin
- The Global Fund assembled a panel of quality-assured artemisinin suppliers for Finished Pharmaceutical Product suppliers to source from and sign Long Term Agreements with

These initiatives have borne fruit in terms of achieving supply and price stability as lead-times have decreased and actual ACT prices have been lower than reference prices.

In terms of delivery performance, we analyzed PPM transactions from 2014 to 2018. Manufacturer OTIF performance has oscillated around the 80% OTIF target (between 60 and 95%), with performance below the target due to supplier-related issues (as opposed to late ordering, poor demand forecasting, etc.). The annual volume reallocation mechanism rewarding suppliers meeting the OTIF target should help drive improvement moving forward. Since January 2018, the target OTIF has increased to 90%, which is comparable to best-in-class benchmark for the industry.

Combined, late and emergency orders – orders placed less than five months before the requested delivery date – have decreased from 65% of ANTM PPM spend in 2016 to 35% in 2018, in line with improved demand forecast accuracy. The introduction of the Rapid Supply Mechanism (RSM)/Vendor-Managed Inventory (VMI) for some emergency orders has cut lead-times so suppliers are now closer to meeting the emergency order target delivery (average lead-time of 112 days in 2018, close to 90-day target versus 183 days in 2014). One should note that RSM/VMI comes at no cost or risk to the Global Fund as it is leveraged through the long-term framework agreements the Global Fund has with suppliers. Indeed, the responsibility for making the products available and managing the shelf life of the products lies with the manufacturer, as opposed to the traditional stockpiling approach where the buyer takes on the risks.

### 4.3.3 Affordability

On average, ANTM PPM prices have decreased by ~35% while the number of courses procured has doubled between 2014 and 2016. However, price decreases for specific products vary depending on volume:

- High-volume product prices have dropped because of higher competition and the introduction of more sources of dispersible Artemether-Lumefantrine;

- Lower volume product prices have stagnated because of their small quality-assured supplier base (e.g., Injectable Artesunate, Amodiaquine + Sulfadoxine-Pyrimethamine, Sulfadoxine-Pyrimethamine).

Global Fund PPM weighted average prices have historically matched market trends. Prices have gone down globally due to the introduction of new/more cost-effective products (e.g., AL-Dispersible), but also due to higher competition between generics makers and manufacturing process efficiencies. For key products, Global Fund 2018 PPM weighted average prices are lower than or in line with prices of other large procurers [44, 49].

Price equalization between dispersible and non-dispersible pediatric Artemether-Lumefantrine is set to materialize after an ambitious target to fully replace non-dispersible Artemether-Lumefantrine by September 2019 was set by the Global Fund. Dispersible pediatric Artemether-Lumefantrine (AL) accounted for 85-95% of pediatric AL treatments procured in 2018. For a summary of PPM weighted average price and volume evolution for AL non-dispersible and dispersible, see Figure 15 and Figure 16, respectively.

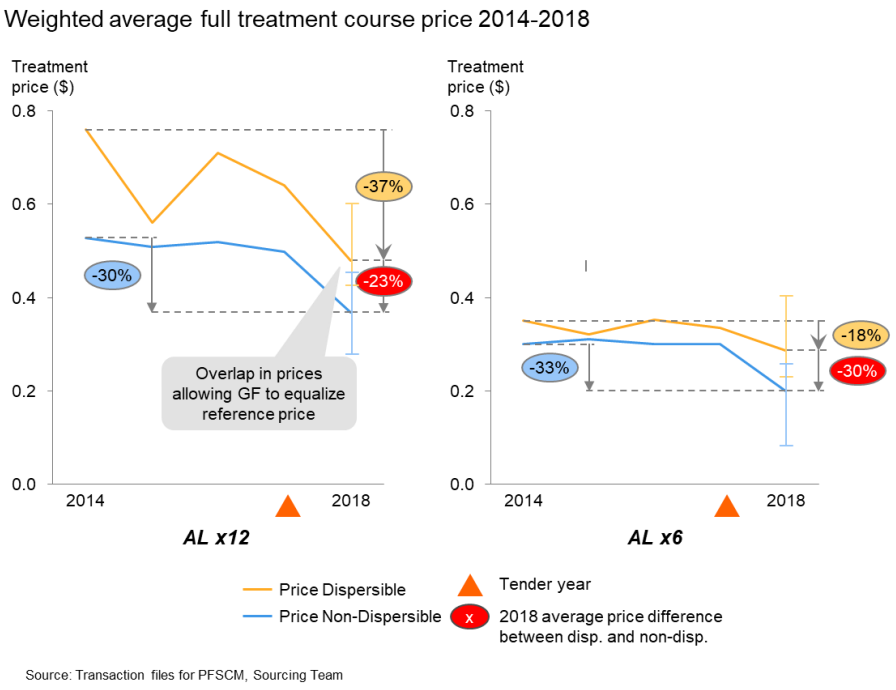



Figure 15 – Weighted average PPM price evolution for pediatric dispersible and non-dispersible AL

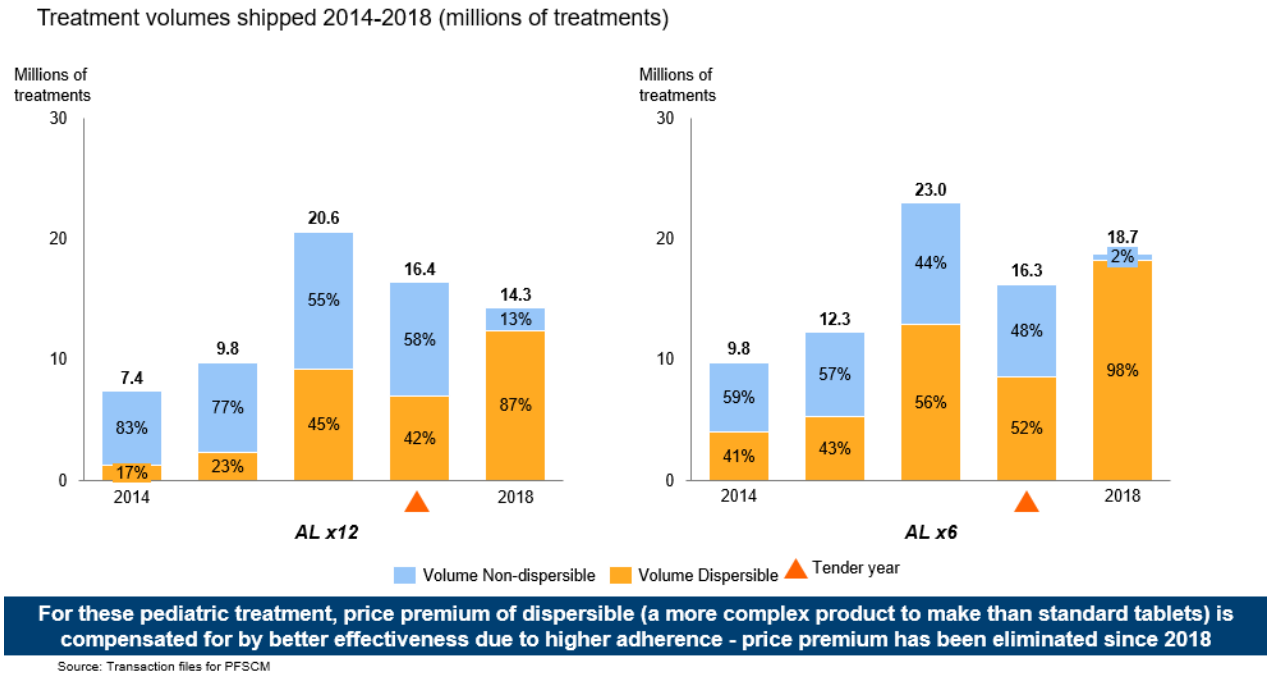



Figure 16 – PPM volumes for dispersible and non-dispersible pediatric AL [50]

The SSC Team used Cost of Goods Sold analyses for some products to determine what a target sustainable price could be for select ANTMs. The SSC Team used this method to drive price discussions on Injectable Artesunate at a time when there was only one supplier. The SSC Team also used this approach to demonstrate to suppliers that they could equalize the prices of dispersible and non-dispersible AL (which was achieved).

**Counterfactual:** Had the Global Fund not launched its initiatives to stabilize the artemisinin supply in 2017, including the prequalification of artemisinin suppliers from which FPP suppliers have to source and the promotion of the use of semi-synthetic artemisinin, ACT prices likely would have continued to fluctuate between -10% and +2% yearly (weighted average). Instead, ACT prices went down by 25% despite volumes dropping by ~6% in 2018, during the first full year of implementation. See figure below for the evolution of the PPM weighted average price for all ACTs.

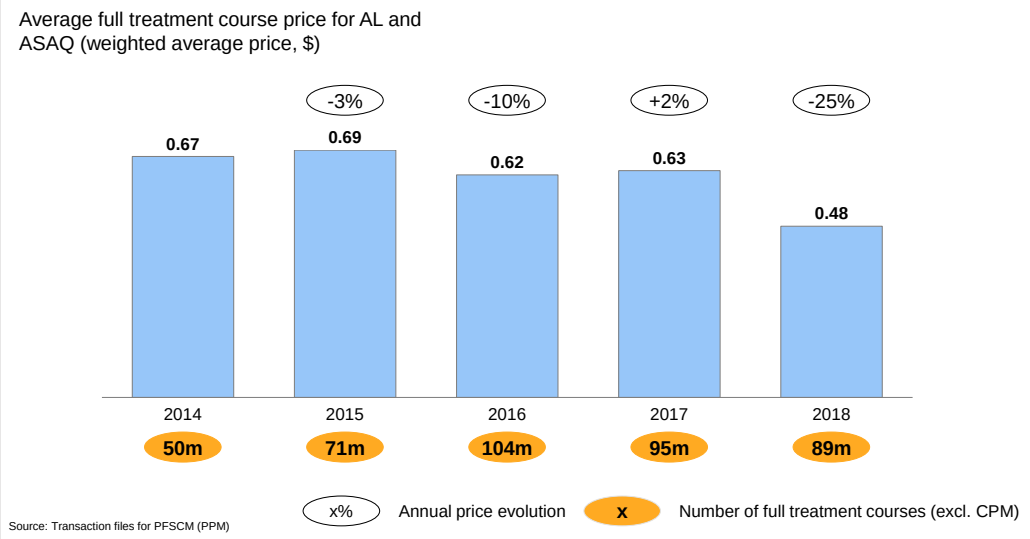



Figure – PPM price evolution of AL and ASAQ

Box 11 - Counterfactual (ACT prices)

**Sustainable price analysis**

Our literature review did not yield any results on average manufacturing costs for ACTs. There is likely limited research into this topic because ACTs have been established products on the markets for many years. As for ARVs, generic ACT costs are probably mostly driven by API costs (artemisinin-based APIs), which means variable costs would account for the bulk of ACT costs, limiting the impact of volumes on margins. Additionally, there is a high level of competition in the market with ten manufacturers actively supplying to the Global Fund. Moreover, the ACT generic market has a healthy degree of diversity in the supplier base, with the top Global Fund supplier accounting for 17% of PPM spend and the top seven suppliers only accounting for 80% of PPM spend in 2018 (these number have remained stable since 2014). Further, the price per treatment course of ACTs has gone down over time from $2.40 in 2003 (one supplier) to $0.48 in 2018 (ten suppliers), and other procurers are paying similar prices. Combined, the elements show that the Global Fund prices are likely in the range of sustainable prices.

Box 12 - Sustainable price analysis (ACTs) [51] [16]

### 4.3.4 Quality

The analysis of the SRA-approved, WHO-PQ-listed and ERP-approved ACTs shows that all major ACTs (AL, ASAQ) meet the Global Fund target of having four or more quality-assured suppliers. The two ACTs that countries in the Greater Mekong Subregion are transitioning to due to the emergence of artemisinin resistance, Artesunate-Mefloquine and DHA-Piperaquine, have only one and two quality-assured suppliers respectively, which is creating issues in terms of supply security. Current demand for Artesunate-Mefloquine is very limited so far (about one third of a

batch per year), which means there is no room for a second supplier. Countries in the Greater Mekong Subregion wanting to transition to this ACT (e.g., Cambodia) might be reluctant to do so because they are anticipating supply issues due to the limited supplier base.

Smaller volume products for chemoprevention or the treatment of severe malaria fail to meet the Global Fund target for QA suppliers. Injectable Artesunate, Amodiaquine + Sulfadoxine-Pyrimethamine (AQ+SP) and Sulfadoxine-Pyrimethamine (SP) only have two quality-assured suppliers. The number of quality-assured suppliers for these ANTMs has, however, doubled in recent years. An Expert Review Panel approval helped to ensure the availability of SP when the only quality-assured supplier was temporarily delisted in 2016. As a result, 25% of SP orders in value during the 2014-2017 period came through the ERP-approved supplier. The Global Fund procured $5 million of ERP-approved AS+SP for Seasonal Malaria Chemoprevention in 2017-2018. This allowed AQ+SP to start being rolled out one year before a first supplier was prequalified. Therefore the Global Fund successfully used the ERP mechanism to accelerate the introduction of a new product.

### 4.3.5 Innovation and New Product Introduction/Product Selection

The introduction of Amodiaquine + Sulfadoxine-Pyrimethamine (AQ+SP) for Seasonal Malaria Chemoprevention (SMC) faced capacity issues in 2017. The Global Fund was effectively competing for procurement with other procurers such as PMI and partners such as Unitaid, which was donating products. The fact that there was only one quality-assured AQ+SP supplier at the time (ERP-approved) and that demand was concentrated in the transmission season reinforced these capacity issues. The lack of formal coordination forums between partners, and the lack of coordination within the Global Fund between the TAP and SSC Teams, contributed to this issue.

The Global Fund and PMI eventually found solutions, as the Unitaid project wound down, to successfully facilitate the introduction of AQ+SP. Partners aligned on when to place orders and swapped orders to avoid missed deliveries and long lead-times. As a result, transaction files show that volumes for AQ+SP doubled in 2018 compared with its 2017 introduction year. Moving forward, these types of working relationships, both with partners and internally, need to be formalized, especially for the product scale-up phase.

## 4.4 Product-specific performance: Long-Lasting Insecticidal Nets (LLINs)

This section summarizes product-specific performance for LLINs.

### 4.4.1 Context

Designed to physically block mosquitoes, Insecticide-Treated Nets (ITNs) are bednets that have been treated with residual insecticide – usually of the pyrethroid class – for the purpose of killing and repelling mosquitoes that carry malaria parasites. In addition to providing personal protection, ITNs provide community-level protection by killing mosquitoes and are therefore a key intervention to reduce malaria prevalence. A Long-Lasting Insecticidal Net (LLIN) is an ITN designed to remain effective for at least three years [52]. LLINs are considered to be the largest

contributor in malaria case reduction since 2000, with an estimated 68% of averted cases due to LLINs [53].

Recent years have seen the appearance of pyrethroid resistance, potentially limiting the effectiveness of pyrethroid-only LLINs. Pyrethroid-Piperonyl ButOxide (PBO) Insecticide-Treated Nets (PBO is a synergist making pyrethroid more potent) and new dual Active Ingredient (AI) ITNs ("New Nets") have emerged to address this issue.

Market research shows that the Global Fund accounts for ~60% of the LLIN market (volume) – 250 million nets per year, $500 million – and coordinates with PMI, which accounts for another ~15%, giving the Global Fund significant leverage over the LMIC market [9-11, 44].

The Global Fund is using its commercial leverage to effectively shape the LLIN market. Major sourcing activities like the 2015 LLIN procurement strategy and tender, the supplier relationship management strategy, and the execution of performance-based LTAs are all aligned with the Market Shaping Strategy outcome objectives with a specific focus on driving availability, affordability, and quality. The Global Fund evaluated bids for the 2015 tender against technical and commercial criteria, with the focus placed on price.

### 4.4.2 Availability

Looking at supply security, analysis of PPM transactions shows that the supplier base has remained broad with the top six suppliers capturing ~80% of PPM spend.

In terms of delivery performance, we analyzed PPM transactions from 2014 to 2018. Manufacturer and in-country OTIF have significantly increased since 2014 and are now above the 95% and 75% targets, respectively. The annual volume reallocation mechanism rewarding suppliers meeting the OTIF target helped drive the improvement. The new 95% target for Manufacturer OTIF is consistent with best-in-class benchmark from the industry.

Late orders – orders placed less than six months (versus five months for other product categories) before the requested delivery date – have decreased from 33% of LLIN PPM spend in 2014 to 19% in 2018, in line with the improved accuracy of demand forecasting. The concept of emergency order does not exist for LLINs, as LLIN procurement is driven mostly by planned mass campaigns. There is no Vendor-Managed Inventory mechanism for LLINs, although some suppliers keep stock available in case of emergencies.

### 4.4.3 Affordability

On average, LLIN PPM prices have decreased by ~35% while the volume of nets doubled between 2014 and 2018. This price reduction is distributed evenly across nets (dimensions, shape, colors). In the meantime, the Global Fund has procured higher denier nets. (Denier, "d", gives a measure of how easy the net material will tear: higher denier means the net will be less likely to tear – WHO recommends nets that are at least 100d.) 150d nets now account for 61% of LLINs procured in 2018 vs. 4% in 2014. Note that denier is not a criterion for product selection by PRs and that the increased proportion of 150d nets reflects the fact that the industry is moving

toward producing higher denier nets. Secular market trends, such as increased competition between LLIN/ITN manufacturers, new product introduction, and manufacturing process efficiencies, have also driven price reductions for all procurers. For a summary of the evolution of average PPM price/volumes for the top six LLINs by 2014-2018 PPM spend (excluding pyrethroid-PBO nets), see Figure 17.

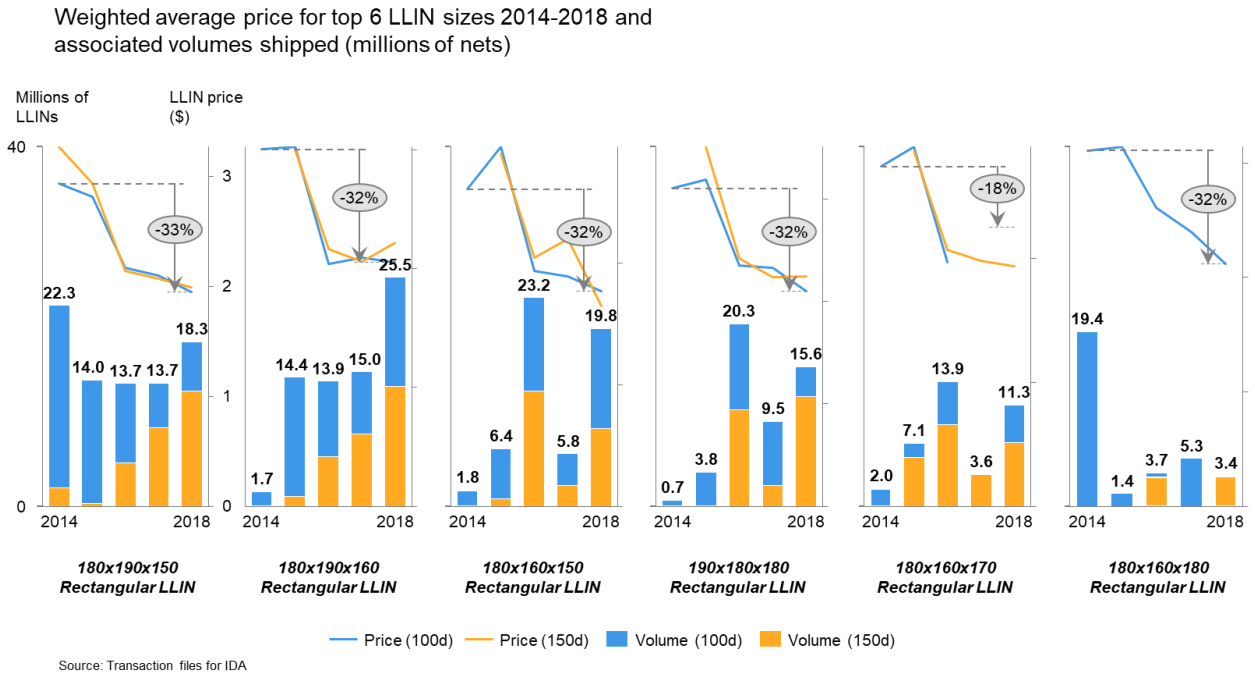



Figure 17 - Evolution of PPM average price/volumes for top six LLINs (excluding pyrethroid-PBO nets)

Market research show that Global Fund PPM weighted average prices are slightly higher than those of other procurers, mostly due to differences in specifications (Global Fund PPM prices include a standard set of accessories [hooks and strings] that cost $0.8-$1.0) [10, 11, 44, 54, 55]. The Global Fund led the process among procurers of standardizing net specifications, by capping the height of the nets procured to 180cm, among other things. As a result, the Global Fund ITN catalogue has shrunk from 200+ to ~20 items. Other procurers then aligned with the Global Fund initiative, and have since moved forward with further limitations on color, accessories, and sizes to reach lower prices. The Global Fund could similarly push standardization even further. Tradeoffs need to be assessed, as some standardized characteristics might hinder product uptake (e.g., culturally, white – which is the most standard net colour – has a negative image in some African countries as it is associated with death [56]).

**Counterfactual:** Because taller nets are more expensive, had the Global Fund not capped the height of nets to 180cm in 2016, $4m more would have been required in 2018 to procure the same number of bednets. Another way to look at this is to consider that with the same grant money, coverage would have decreased by 2 million bednets. Had the Global Fund capped the height of nets to 170cm like PMI did, the Global Fund would have saved $5.4m or procured 2.7m additional nets, given the $0.27 average price difference between 180cm-tall bednets and 170cm or less-tall bednets. The Global Fund has chosen not to cap bednets at 170cm because some countries still choose to procure 180cm bednets.

Box 13 - Counterfactual (Spend on LLINs)

**Sustainable price analysis:** The analysis of available cost data shows that LLIN manufacturing costs were estimated at $3.35 per net in 2013, higher than the $3.24 per net the Global Fund paid on average in 2013, which points to likely low margins by suppliers supplying to the Global Fund. There is a high level of competition in the market with ten manufacturers actively supplying to the Global Fund as well as a healthy level of diversity in the supplier base, with the top Global Fund supplier capturing 18% of PPM spend in 2018 and the top six suppliers accounting for 80% of PPM spend in 2018 (these numbers have remained stable since 2014). Further, the price per net has gone down over time to $2.00 in 2018. Other procurers are paying slightly lower prices, but this is due to the fact that the Global Fund prices include a standard set of accessories (e.g., hooks and strings). Combined, these elements show that the Global Fund prices are likely in the range of sustainable prices.

Box 14 - Sustainable price analysis (LLINs) [57] [16]

### 4.4.4 Quality

The analysis of the WHO-PQ-listed ITNs shows that both pyrethroid-only LLINs and pyrethroid-PBO ITNs meet the Global Fund target of having four or more quality-assured suppliers. Only one of the five WHO-prequalified pyrethroid-PBO nets has demonstrated epidemiological efficacy (impact on disease prevalence as opposed to entomological efficacy that measures how many mosquitoes are killed or knocked down). Consequently, procurement of the other four pyrethroid-PBO nets – which are structurally different – has remained low (25% of procured pyrethroid-PBO nets according to transaction data). Two new nets (dual AI) are WHO-Prequalified as pyrethroid-only nets but do not yet have associated WHO policy recommendations. The Global Fund can therefore procure them for pilot purposes only.

### 4.4.5 Innovation and New Product Introduction/Product Selection

The global health community recognizes the scale-up of pyrethroid-PBO nets may have been a missed opportunity due to a lag in the demonstration of their value-add. Pyrethroid-PBO nets had WHOPES recommendations (the precursor of WHO-Prequalification for vector control tools) ten years ago but, in the absence of a WHO policy recommendation indicating an added benefit for the additional cost, were not procured by the Global Fund until 2017 when a conditional WHO recommendation was issued [58]. Despite significant investment, pyrethroid-PBO nets' market share remains low at 6% of procured nets in 2018, while 68 countries face pyrethroid resistance. This is largely due to insufficient budgets for the higher priced nets rather than a lack of country demand. Key shortcomings included the 50% price premium vs. pyrethroid-only nets, guideline

uncertainty, and unclear cost effectiveness. Now that demand for pyrethroid-PBO nets is picking up, suppliers may face a challenge scaling up production to meet demand.

A multi-partner 'New Nets' project (2018-2021) was established to support the market entry of new nets combining pyrethroid and non-pyrethroid active ingredients. This project targets some of the barriers that prevented rapid scale-up of pyrethroid-PBO nets to aim for a more successful market entry. Trials to generate epidemiological data will allow WHO to consider a policy recommendation. In addition, pilots will generate operational cost-effectiveness information to support country decision-making. Conducted in parallel to trials, the Global Fund will make this cost-effectiveness information available to PRs/countries as soon as a WHO policy recommendation is in place, thus speeding scale-up. A co-payment mechanism ensures that countries piloting new nets do not have to cover the additional cost of new nets while partners are still working on building evidence. Volumes supported through the pilots, and concurrent work by partners on a volume guarantee, will mean net prices are lower by the time a WHO policy is in place (target is Q1 2020), then again speeding scale-up. The fact that the price negotiation is done by a third party might represent a missed opportunity to use the Global Fund's commercial leverage, but can also be useful for negotiating with suppliers on behalf of the various partners involved in the project.

The emergence of pyrethroid-PBO nets and new nets in the ITN landscape has significantly increased the complexity of this product category. As planned by SSC, the Global Fund should develop a "bridging strategy" for the next several years which defines the future outlook for this market and how the Global Fund will drive product selection and allocate volumes among LLINs, pyrethroid-PBO nets, and innovative new nets across geographies.

## 4.5 Product-specific performance: Rapid Diagnostic Tests (RDTs)

### 4.5.1 Context

Rapid Diagnostic Tests are low-cost, simple to use and read sensitive diagnostic assays designed for use in Point-of-Care (PoC) settings. In a matter of minutes, they can give a reliable indication of whether a patient is infected by the targeted disease. This is particularly interesting for malaria, as several diseases share malaria symptoms such as fever. The Global Fund procures many types of RDTs, but malaria RDTs (MRDTs) and HIV RDTs (HRDTs) account for 99% of RDTs procured by the Global Fund [16].

The lack of interchangeability between RDTs has characterized the RDT market, and consequently countries have been tied to their historical suppliers. Changing suppliers would require updating national guidelines (for HRDTs), redefining testing algorithms (for HRDTs – which RDT to use for screening vs. confirmatory vs. tie-breaker RDTs) and re-training health workers (for HRDTs and MRDTs). Recent years have also been marked by a new WHO recommendation promoting HIV self-testing to bridge the HIV diagnostic gap, by reaching populations that would not get tested to avoid stigma. Other than that, limited policy or technical innovations have occurred in the HIV/malaria RDT space.

Market research shows that the Global Fund has significant leverage over the HRDT and MRDT markets through its market share and coordination with partners

- The Global Fund accounts for ~45% of the HRDT market – volume – (~180 million HRDTs annually, ~$200 million) and coordinates with PEPFAR and UNICEF, which account for another ~25% [12-14, 49]
- The Global Fund accounts for ~65% of the MRDT market – volume – (~310 million MRDTs annually, ~$100 million) and coordinates with PMI and UNICEF, which account for another ~25% [9-11, 13, 14, 44, 59]

RDTs are the latest product category for which the Global Fund has decided to develop a sourcing strategy, including a global tender and implementation of long-term performance-based framework agreements with suppliers (in lieu of tenders by PSAs). This new sourcing strategy will allow the Global Fund to use its commercial leverage to effectively shape the RDT market.

### 4.5.2 Availability

Looking at supply security, analysis of PPM transactions shows that, due to the (perceived) lack of interchangeability between RDTs, neither the HRDT or the MRDT supplier bases have diversified with one or two suppliers capturing the majority of PPM spend. Although an additional player is emerging in the HRDT market, the top supplier still captures ~65% of PPM spend. The MRDT market has the top two suppliers capturing 95% of PPM spend. For a summary of the evolution of the diversity of the supplier bases for HRDTs and MRDTs, see Figure 18.

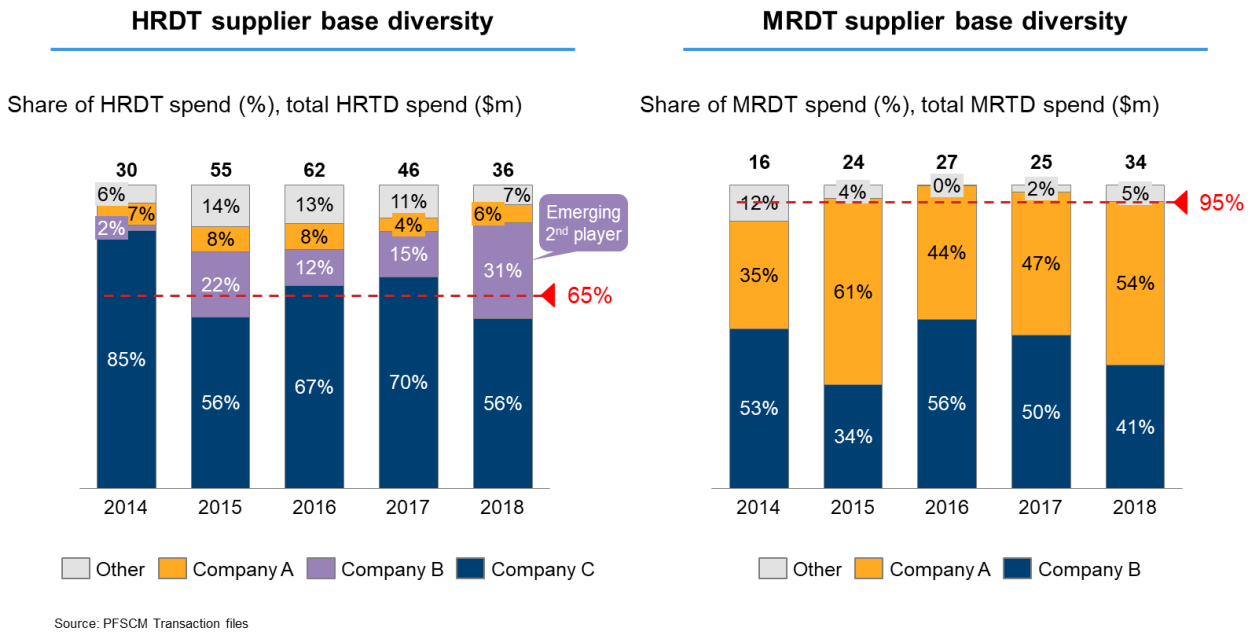



Figure 18 - Diversity of the supplier base for HRDTs and MRDTs

The lack of interchangeability is a key driver putting supply security at risk. Historical reasons for the current situation include WHO recommending field validation of tests before use (for HRDTs), perceived lack of interchangeability driven by supplier marketing (for MRDTs), early development

of manufacturer-specific training material by partners (for MRDTs), and countries not willing to retrain health workers (for HRDTs and MRDTs).

The global health community is generally aligned on the notion that the (perceived) lack of interchangeability is an issue in terms of supply security. However, driving a successful interchangeability strategy across the Global Fund and partners will require coordination and a comprehensive approach to market-shaping. One aspect of the Global Fund's response to the interchangeability challenge is asking manufacturers that are bidding on the RDT tender to develop detailed plans to provide technical support to increase in-country capacity to manage product interchangeability.

At the end of 2019, WHO is set to release updated guidelines for HIV testing strategies. In line with normative guidance, testing algorithms need to be validated at national and regional levels, as test kit performance may vary across populations and settings. The Global Fund will identify countries to conduct validation of testing algorithms. As part of this validation exercise, the Global Fund will recommend countries include a minimum of two tests for First Line Assay, Second Line Assay, and Third Line Assays. This will be phase 1 of the interchangeability approach for HIV RDTs.

While malaria RDTs have similar technical features, product selection has often been linked to historical training, resulting in "single source" procurement requests. However, interchangeability of MRDTs has gained acceptance as procurement data and recent surveys indicate that many countries have in practice been using multiple brands with different test protocols concurrently [13]. In alignment with PMI and other donors, the Global Fund will limit country requests for specific malaria RDTs unless justified epidemiologically. The Global Fund will publish guidance in 2019 to support countries through the transition to generic training in support of product interchangeability.

In terms of delivery performance, we analyzed PPM transactions from 2014 to 2018. Manufacturer OTIF has remained near 80%. In the absence of Global Fund LTAs with suppliers (the tendering process is ongoing), PSAs allocate RDT volumes to suppliers. Therefore, SSC has not set OTIF targets for suppliers and does not track performance or incentivize suppliers to improve OTIF performance. The evolution of OTIF is therefore purely indicative. Going forward, a 90% OTIF target was included in the RFP for the RDT tender.

For HRDTs, late orders – orders placed between four and five months before the requested delivery date – have increased from 16% of RDT PPM spend in 2014 to 35% in 2018, while emergency orders – orders placed less than three months before the requested delivery date – have decreased from 43% to 8%. For MRDTs, late orders increased from 28% in 2014 to 35% in 2018 while emergency orders have decreased from 29% to 5% in the same period.

### 4.5.3 Affordability

The volume-weighted average HRDT PPM price increased by ~5%, while volumes of HRDTs remained roughly constant between 2014 and 2018. This slight volume-weighted price increase is partially due to a product mix change, with a more expensive HRDT increasing its market share

from 2% to 25%. The lack of interchangeability means that the impact of competition is limited, preventing prices from decreasing.

The volume-weighted average MRDT PPM price decreased by ~25% while volumes of MRDTs increased threefold between 2014 and 2018. This price reduction is due to the Pf HRP2 test – a mono test detecting the HRP2 antigen linked to Pf malaria – price reduction and the increased weight of this cheaper MRDT in the product mix. MRDT suppliers say they receive too much price pressure from procurers [60]. The Global Fund will receive detailed cost breakdowns as part of the 2019 tender and will be able to carry out a COGS analysis to assess that claim.

Market research shows that Global Fund weighted average PPM prices have historically matched those of other procurers, and Global Fund 2018 weighted average actual PPM prices are in line with or lower than those of other large procurers [12, 13, 59]. In the MRDT space, the increase in volume has brought prices down, despite the fact that the MRDT supplier base has not diversified. In the HRDT space, the fact that the majority of Global Fund-funded spend belongs to one supplier has prevented price reductions.

We did not perform a counterfactual analysis for RDTs as, in the absence of a global tender, the Global Fund's market-shaping power has been limited.

Given that the RDT tendering process is underway, the assessment of sustainable prices for RDTs is a sensitive topic for the Global Fund, and we do not include it in the review.

### 4.5.4 Quality

WHO has standardized the quality assurance process for MRDTs and HRDTs with MRDTs transitioning from round-based approvals by the WHO-Global Malaria Programme to prequalification by WHO-PQ, which has been the standard for HRDTs.

Analysis of the WHO-PQ list shows that the main HRDTs and MRDTs meet the Global Fund target of having four or more quality-assured suppliers. New HIV Self-Tests have two WHO-PQ-listed suppliers and an additional two suppliers with ERPD-approved products.

### 4.5.5 Innovation and New Product Introduction/Product Selection

The Task Force on Malaria RDTs allows the Global Fund and partners to coordinate on demand/supply and new product introductions. No such dedicated forum exists for HRDTs. There is however a joint WHO/UNAIDS consultation with diagnostic manufacturers, partner organizations, and other stakeholders which meets annually. They look at diagnostic demand for HRDT, VL-EID, and CD4 diagnostics but not procurement per se.

The pace of introduction of HIV self-testing following the new recommendation that WHO issued in 2016 remains unclear due to the lack of coordination among partners. HIV self-tests have been procured in the current grant cycle as part of early adoption work by Unitaid. According to Global Fund colleagues, partners have yet to make their projects on HIV self-testing transparent. The global health community also needs to clarify when to recommend usage of facility-based

diagnostic testing versus self-tests (i.e., for which population segments, delivery contexts, etc.), especially since self-tests are about three times more expensive than HRDTs and require additional resources for program implementation beyond the cost of the health product itself. If PRs choose to procure self-tests, they would have to reprogram grants to procure the products and possibly cover the associated additional programmatic costs. The 2019 tender and subsequent implementation of long-term framework agreements should however facilitate the scale-up of HIV self-tests by potentially broadening the supplier base.

## 4.6 Product-specific performance: Viral Load – Early Infant Diagnosis (VL-EID)

This section summarizes product-specific performance for VL-EID.

### 4.6.1 Context

The 2013 WHO HIV guidelines introduced virological testing as the preferred monitoring approach to diagnose and confirm ARV treatment failure (Viral Load) as well as testing infants (under two years old) for HIV (Early Infant Diagnosis). These technologies exist both as lab-based and as point-of-care (PoC) technologies [30, 32, 61, 62]. This represents a major shift from the previous recommendation, which was to monitor CD4 count [31]. CD4 count monitoring remains, however, the preferred monitoring method for patients with advanced HIV disease [63]. VL testing technology will be a key tool for monitoring the global 90-90-90 targets: "*By 2020, 90% of all people living with HIV will know their HIV status; By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy; By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression*." [30]

Market research shows that the VL and EID LMIC market represents ~15 million tests annually (90% of which are VL) and ~$250 million and is expected to double by 2022 [6, 64]. Global Fund PPM spend accounts for ~15% of the total LMIC market, and it is estimated that non-PPM spend adds another ~15% in value. The Global Fund has less direct leverage over suppliers for this product category than it does for other products, since only a small amount of the total market share flows through PPM.

In 2014, the emerging VL-EID space faced several issues. Transaction data shows that there was high variability in prices both geographically – between and within countries – and over time. Limited transparency characterized prices, with "hidden" costs linked to VL equipment (e.g., servicing, warranty, consumables). This led to underutilization of VL equipment. Additionally, just two main suppliers dominated the market.

The Global Fund developed a novel approach to address these market dynamics. The Global Fund's strategy had the goal of bringing transparency and stability to the VL-EID market, which they did by issuing a tender in 2015 to create a panel of suppliers. Bidders provided detailed machine specifications, breakdown of costs, and price-breaking points. The Global Fund listed eight suppliers – including the two historical players – based on a range of criteria.

A new contracting option has become viable in LMICs: "reagent rental," an all-inclusive pay-by-the-test price, which includes machine rental, maintenance, service, warranty and consumables.

Reagent rental is attractive to countries because it creates predictable, all-inclusive costs with no additional hidden costs or the need to pay for separate annual maintenance contracts. Machine uptime is also higher as suppliers are incentivized to keep their machines up and running. Reagent rental is also attractive to suppliers as they get volume commitments from countries (the fixed price per test depends on an annual volume commitment). Finally, reagent rental is attractive to the Global Fund as it will require countries to be clearer on their needs as they will be commiting to certain volumes.

A successful collaboration between the Global Fund and partners led to this success. Partners aligned on the diagnosis of issues and the way forward within the Integrated Diagnostics Working Group. USAID/PEPFAR was instrumental in helping implement VL programs at the local level in 50+ countries through their country teams. Consequently, PEPFAR is expected to replicate the Global Fund's tender approach in their 2019 tender. This will potentially give the Global Fund leverage to renegotiate the terms of its own tenders.

Moving forward, the Global Fund will have to determine whether it wants to push for certain VL technologies and offers over others or continue to consider all the available offers as equivalent. The Global Fund also needs to investigate whether the advertised prices are actually the ones paid by PRs, especially for non-PPM spend. Awareness of the Global Fund-negotiated prices might need to be increased. Further, the Global Fund will have to keep a close watch on distributor mark-up, as this might offset the gains of the negotiated prices.

Contrary to ARVs and ANTMs, the Global Fund makes no volume commitments at the global level: countries make volume commitments directly. This means that countries have to be clearer on their needs, which can help ensure countries strengthen their demand forecasting capacity.

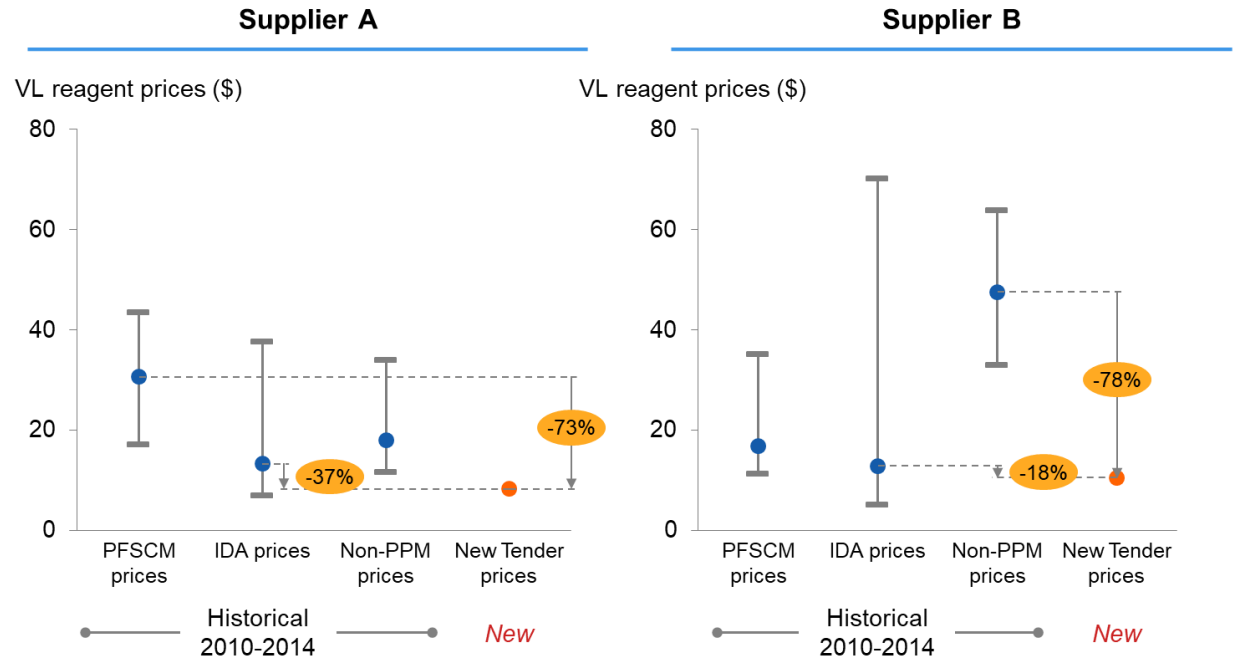
### 4.6.2 Availability / New product introduction

The VL-EID strategy and tender outcomes facilitated the scale-up of VL-EID interventions. As a result, the number of countries procuring VL/EID has increased from 32 in 2015 to 50 in 2018, as shown by PSA transaction files and PQR data.

### 4.6.3 Affordability

This new approach resulted in lower variability and reductions in prices. Any public sector organization within a list of eligible countries will receive a single price for a given test with a given supplier.

Not only has price variability decreased, but the average test prices have also dropped by 20-80% from pre-tender to post-tender. For a comparison of VL prices before and after the Global Fund tender, see Figure 19.




Source: Viral Load and Early Infant Diagnosis (EID) RFP: TGF 14-063, based on PFSCM, IDA, and (incomplete) PQR records

Figure 19 - Comparison of VL prices before (by PSA – PFSCM or IDA for PPM spend and non-PPM spend) and after Global Fund tender

**Counterfactual:** Had the Global Fund not brought transparency to the VL-EID market by detailing technical specifications of VL machines and listing all the components of reagent rental prices, prices would likely have continued to vary country by country, with some countries paying ten times the price paid by others. Countries would also likely still be struggling to understand what the total cost to use these machines is and the scale-up of VL-EID would probably have been slower, due to the perceived risks by countries of additional hidden costs linked to using these machines.

Box 15 - Counterfactual (VL)

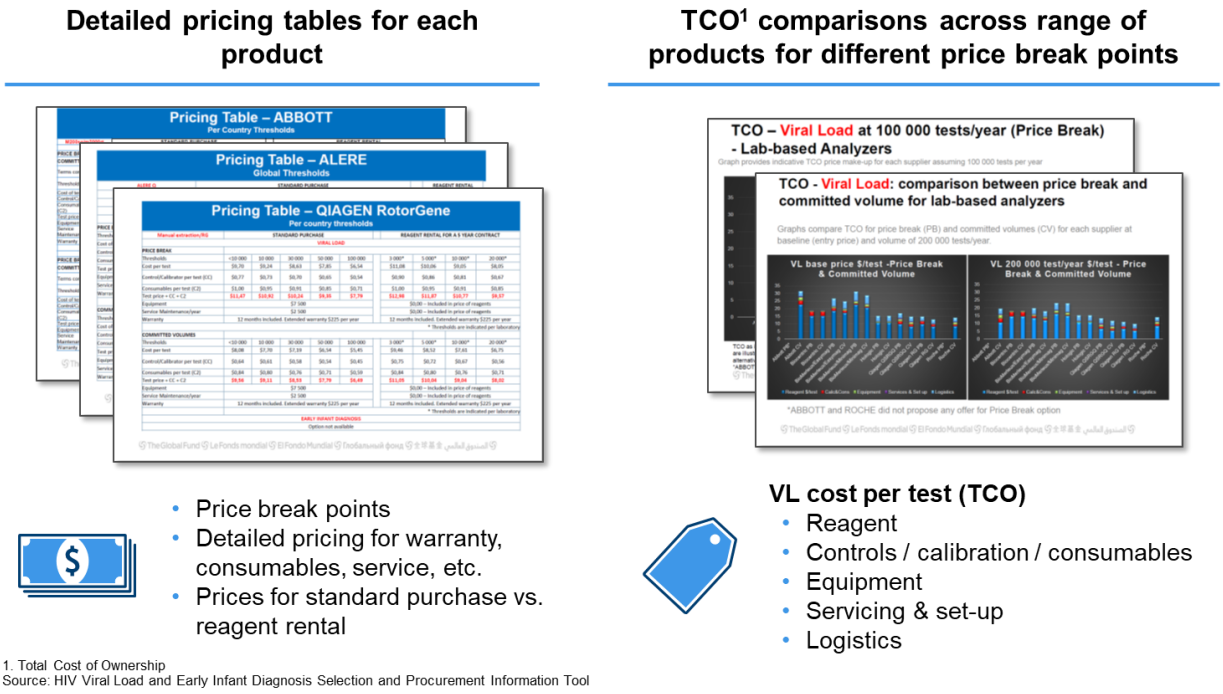
### 4.6.4 Quality

Analysis of WHO-PQ-listed VL tests and tests having the CE Mark delivered by the Global Harmonization Task Force (considered a valid quality-assurance body for VL) shows that lab-based viral load meets the Global Fund target of having four or more quality-assured suppliers. However, lab-based EID and Point of Care tests fall short of meeting the target. Three suppliers offer combined VL+EID lab-based products. Only two suppliers offer Point of Care tests, for EID and/or VL.

### 4.6.5 Country systems strengthening

As an outcome of the VL-EID procurement strategy, the Global Fund developed a tool to help countries make informed decisions, which allows them to obtain the negotiated Global Fund price from suppliers. The tool lists important criteria countries need to take into account to choose between suppliers and contracting options. It also gives detailed price points for different

volumes across the panel and uses a total cost of ownership approach to make offers comparable. For a summary of the contents of the Global Fund's VL-EID decision tool, see Figure 20.




1. Total Cost of Ownership
Source: HIV Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool

Figure 20 - Contents of the Global Fund's VL-EID decision tool

## 4.7 Product-specific performance: Tuberculosis medicines and diagnostics

The Stop TB Global Drug Facility (GDF) serves as the global lead for both market-shaping and global pooled procurement of TB medicines and diagnostics. Global Fund funding is used to procure TB products through multiple channels, including through GDF, PPM (including GeneXpert products), and domestic procurement channels. The Global Fund's Guide to Procurement and Supply Chain Management Policies specifies, "*all procurement of medicines to treat multidrug-resistant TB shall be performed through a designated procurement facility of GDF.*" [19]

Assessment of GDF activities beyond Global Fund-funded procurement is out-of-scope for this review. GDF has its own governance: GDF reports to the Stop TB Coordinating Board, with USAID being its major donor, and to donors who support its time-based projects. Given the separate governance of the two organizations, GDF has not been involved in the formal approval of the Global Fund's MSS, which is approved by the Board of the Global Fund. The Global Fund MSS Strategy was created without consultation with GDF colleagues. Specifically, although the draft MSS was presented to the Core Group of the Stop TB Partnership in July 2015, and the Stop TB Partnership provided written comments on the draft MSS in September 2015 [65, 66].

For consistency, and in order to provide the reader with a view of market-shaping and pooled procurement as it relates to TB, it is important to note the activities of GDF. These activities are largely funded by USAID, and they have a direct impact on global TB markets, including for products which are funded by the Global Fund. It would be impossible to assess pooled

procurement solely for Global Fund-funded products through GDF, since many GDF procurement activities, such as tendering, apply to all GDF-procured products.

Therefore, due to the unique nature of the market-shaping arrangements for TB products between the Global Fund and GDF, the approach taken to document market-shaping activities for these products is different than for other products. As agreed with GDF colleagues, the approach taken in this review is the following:

- Provide a high-level summary of the context for TB medicines and diagnostics.
- Provide an overview of GDF activities.
- Assess the Global Fund's performance on market-shaping, with a particular focus in terms of the Global Fund's coordination with GDF and potential areas for improvement in terms of partnership with GDF. This report does not include an assessment of GDF activities. Information on GDF is either based on publicly available sources or on a description of GDF activities and results provided by GDF to the independent review team.

### 4.7.1 Context for TB medicines and diagnostics

Markets for TB medicines and diagnostics face some unique challenges not faced by products for HIV and malaria. In particular, the total volume of products for TB markets is much smaller than for HIV or malaria markets. In 2017, there were approximately 10 million cases of TB (of which 558,000 were drug-resistant TB [DR-TB]), compared with approximately 40 million people living with HIV and 220 million cases of malaria. Of these TB cases in 2017, only 6.4 million were reported (of which 161,000 were DR-TB). Fewer than 1,000 cases of DR-TB in children have ever been reported in published literature, although it is likely that approximately 1,000 children are treated for multidrug-resistant TB (MDR-TB) every year [67].

As an illustrative indicator of how differences in disease burden translate into differences in market size, GDF procured $165 million worth of TB medicines in 2016, compared with a generic ARV market in low- and middle-income countries of $1.8 billion (of which $350 million flowed through Global Fund's PPM in 2016), and a global ARV market of approximately $20 billion.

The global burden of disease for TB also has a higher concentration in middle-income countries with increasing levels of domestic financing and domestic procurement for health products [68]. The shift from donor-funded procurement for TB products to domestic financing for TB products means that global health partners such as the Global Fund and GDF have less leverage to mitigate against market and procurement risks from individual countries.

The TB medicines market faces high fragmentation for several reasons. Procurement for TB medicines to treat both drug-susceptible and drug-resistant TB faces fragmentation across different procurement channels (i.e., through domestic procurement by governments and international mechanisms including GDF). Procurement is fragmented between local and international suppliers of medicines, and suppliers with varying levels of quality standards. The high number of medicines and treatment regimens recommended by WHO for DR-TB further compounds fragmentation for this market. A treatment regimen for MDR-TB often requires four-to-five different medicines, and more than 50 treatment regimens are currently possible under WHO's 2018 MDR-TB treatment guidelines. Individualized therapies (i.e., WHO recommendations

to modify treatment regimens for individual patients based on their response to treatment) can lead to further fragmentation of medicines markets. As countries increase their domestic financing for health products (including in response to Global Fund co-financing requirements), fragmentation of procurement channels and medicines markets will continue to increase.

Recently, introduction of new products (specifically bedaquiline and delamanid) and new WHO guidelines for all-oral regimens for DR-TB have disrupted markets, resulting in wastage of previously recommended products for suppliers and countries. Changes to WHO treatment guidelines have also required changes to country treatment guidelines and programs. As innovation continues and the research pipeline yields new treatments and regimens, similar disruptions to markets, suppliers, and countries are likely to continue to occur. Addressing these disruptions will require coordinated market stewardship at the global, regional, country, and local levels.

TB diagnostics are required for both diagnosis of TB and determination of drug-susceptibility. TB diagnostic products face challenges such as low accuracy of certain diagnostic approaches (e.g., smear microscopy), and difficulty using certain diagnostic products due to the requirement of a good sputum specimen, which can often be difficult for a patient to produce. Drug-susceptibility testing (DST) is required at diagnosis for DR-TB in order to determine the appropriate drug regimen for the patient, and a monthly culture for DR-TB monitoring is also required. The GeneXpert test, a molecular test which diagnoses TB and tests for rifampicin susceptibility, was recommended by WHO as the initial test for TB, and the vast majority of the Global Fund budget for TB diagnostics is currently spent on GeneXpert. In 2012, PEPFAR/USAID, Unitaid, and the Bill & Melinda Gates Foundation negotiated a concessional price for GeneXpert cartridges procured using public sector or donors funds for certain countries. The negotiated concessional price of $9.98 represented a 40% price reduction compared with the price in 2010 [69]. In 2017, GDF accounted for 41% of the GeneXpert public sector cartridge market under concessional pricing [26]. GeneXpert currently has a monopoly on molecular testing for TB, and anecdotal evidence indicates that the price of cartridges currently presents an issue with regard to affordability of TB diagnostics. Service and maintenance of Xpert machines is expensive and inconsistently provided to National TB Programs. Beyond the rifampicin susceptibility tested by GeneXpert, DST for additional drugs entails the use of a molecular line probe assay and automated phenotypic liquid culture; both of these products are provided by sole-source manufacturers.

### 4.7.2 Overview of GDF activities

As previously mentioned, the purpose of this section is to describe GDF and document its activities with regards to market-shaping and pooled procurement for TB medicines and diagnostics. Information on GDF activities is either based on publicly available sources or from a description of GDF activities and results provided to the independent review team by GDF. The independent review team did not conduct an assessment of these activities or results.

GDF was founded in 2001 to establish an affordable, quality-assured medicines market for first-line TB medicines [70]. Since then, it has expanded its product base to become a one-stop shop for TB products, supplying all TB medicines and more than 500 diagnostic products and laboratory supplies. GDF is a unit within the Stop TB Partnership, which is hosted by UNOPS, and is therefore

part of the UN system. GDF is a donor-funded entity, which receives the majority of its budget for Secretariat operations from USAID, as well as funds from other donors (e.g., the Japanese government) for time-limited projects. The Global Fund does not provide any direct funding to support any GDF activities, but it does pay handling fees to GDF for the procurement of certain products.

GDF has 39 staff members, of whom 29 are based in Geneva, and ten are based in regional offices to support with technical assistance and capacity-building at the regional and country levels. GDF is organized into four teams (Market Strategies Team; Country Supply Team; Demand & Technical Assistance Team—which includes the ten regional staff members as well as a roster of 30 GDF consultants; and Strategic Procurement & Business Intelligence Team). Within the 2016-2020 Stop TB Operational Strategy, GDF has four strategic objectives:

- Manage and coordinate market activities across all stakeholders for the full portfolio of TB medicines, regimens, and diagnostics
- Develop state of the art business intelligence and data-driven approaches through early adoption of cutting-edge technology
- Undertake strategic procurement and executive innovative logistics solutions for TB medicines and diagnostics
- Accelerate the uptake of new medicines, regimens, and diagnostics using the GDF "launch pad" in close collaboration with TB REACH and Stop TB Partnerships Working Groups on new TB medicines

GDF conducts pooled procurement for TB medicines and diagnostics. GDF is an ISO 9001-certified organization, meaning that it meets a globally recognized set of standards for quality management systems. In 2005, GDF established an online, web-based tool to support procurement of TB medicines and diagnostics. As mentioned, the GDF client base is continuously expanding. Any country can procure TB products through GDF as long as using GDF is consistent with their national laws and regulations. In 2018, the UN Political Declaration on TB encouraged all nations to use GDF [71].

Evidence from 2012 indicates that GDF accounted for a significant market share of TB medicines procured through public sector channels [17]. Although data for TB markets is limited, GDF's spend on medicines has increased by 37%, and GDF's spend on diagnostics has more than tripled, from 2012-2018 [26], so it is likely that GDF's total market share is higher today than in 2012. In 2018, 87 countries procured TB products from GDF with funds from sources other than the Global Fund; 42 countries procured TB products via GDF with domestic funds, while 45 countries procured TB products from GDF using funds provided by nine other donors, six non-governmental organizations, and 16 clinical research programs.

GDF also established and chairs the TB Procurement and Market-Shaping Action Team (TPMAT), which comprises the following members: Treatment Action Group (serving as Vice-Chair), CHAI, the Global Fund (Sourcing Department and TB Advisor), MSF Access Campaign, PAHO, UNDP, UNITAID, UNICEF, Bill & Melinda Gates Foundation, USAID, WHO Essential Medicines Department, WHO Prequalification Programme, WHO Global TB Programme, South Africa Head of National Procurement, TB Community Representatives, TB Clinical Experts, TB Researchers, KNCV Tuberculosis Foundation, the International Union Against Tuberculosis and Lung Disease, and the

Elizabeth Glaser Pediatric AIDS Foundation. TPMAT takes an end-to-end approach to conduct market stewardship activities for TB markets across the entire product value chain and lifecycle. GDF and TPMAT have conducted numerous market-shaping activities [26]. Examples of these activities include advocating for a waiver of WHO-PQ fees for TB medicine formulation, since introduction of WHO-PQ fees could have created a risk that TB medicines suppliers would not go through WHO-PQ process and/or would cease production of low-volume medicines; creation of the TB medicines Dashboard, which aims to provide a starting point toward improved alignment among global actors for TB medicines, and; expansion of the number of countries eligible for concessional prices for the MGIT System, a TB diagnostic.

The GDF model takes a number of steps which aim to optimize procurement and supply for TB products. These include GDF-specific packaging for all TB medicines in four languages; the management of a Strategic Rotating Stockpile (SRS) that aims to reduce delivery lead time and smooth supplier production cycles; the maintenance of a flexible procurement fund (FPF) which fronts funds to countries that cannot comply with supplier pre-payment requirements; and prioritization and rationing of medicines during global supply constraints in order to prevent stockouts.

GDF also complements its global market-shaping activities with regional and country-level technical assistance (TA) and capability-building. GDF works with the Global Fund, in-country partners, such as WHO, KNCV Tuberculosis Foundation, the International Union Against Tuberculosis and Lung Disease, and USAID staff, to ensure that its TA is aligned with organizations supporting TB program implementation [26]. Examples of key activities and results include: TA and capacity-building to countries on the use of the GDF-managed QuanTB Tool; creation and management of a GDF Global Early Warning System (EWS) that combines data provided from more than 45 national-level EWS; and support for the introduction of new tools. GDF's global EWS facilitates development of global forecasts and supports production planning with suppliers.

### 4.7.3 Assessment of Global Fund efforts in market-shaping for TB

As already mentioned, the focus of this assessment is on the Global Fund's role in market-shaping for TB products, including coordination with partners. Some of these findings also have relevance for other product categories, while others are specific to TB.

The Global Fund has no market-shaping strategy or institution-wide technical perspective on market dynamics issues for TB medicines or diagnostics. This lack of a strategy or institution-wide technical perspective limits the Global Fund's ability to proactively contribute to market-shaping for these products. Global Fund colleagues across multiple teams stated that they do not have sufficient visibility into or engagement with GDF to understand the current state of TB markets, how GDF complements (and differs from) the Global Fund model, or how to engage with GDF to influence its priorities and approach. One should note that formal updates to the Board on market-shaping have been limited to HIV and malaria, and have not included TB.

Many of the objectives taken by GDF for market-shaping align closely with the objectives laid out in the Global Fund's overall MSS. The four GDF-related KPIs (and associated performance) reported to the Stop TB Coordinating Board are as follows [72]:

- Number of GDF TB market roadmaps endorsed by stakeholders ("market coordination")
    - 2018 Performance: six roadmaps endorsed (target of six)
- Percentage of tracer medicines with accurate demand forecasts ("forecast accuracy")
    - 2018 performance not publicly listed in the last Stop TB Coordinating Board meeting
- Percentage of On-Time In-Full (OTIF) deliveries for second-line drugs (SLDs) ("delivery performance")
    - 2018 performance: 66% (compared with target of 75%)
- Country uptake of bedaquiline, delamanid, and new pediatric formulations ("uptake")
    - 2018 performance: 24 target countries had placed orders for these products (compared to target of 25 countries for bedaquiline and new pediatric formulations, and target of 26 countries for delamanid)

Beyond these KPIs, GDF tracks a wide range of metrics related to market-shaping, procurement, and sourcing, and reports these metrics to its main donor, USAID, as well as other forums.

The Global Fund participates in TPMAT, the global leading bodies for market-shaping related to these products. However, there is no formally documented alignment on strategy, market-shaping approaches, or KPIs/metrics between the Global Fund and GDF or TPMAT. Because the Global Fund does not have an institution-wide technical perspective on market dynamics for TB products, it cannot systematically and proactively contribute to market-shaping on these topics.

The formal Global Fund-GDF relationship is managed via an MoU between the two organizations [73]. A recent OIG report highlighted limitations in the relationship between the two organizations and emphasized that this area "*needs significant improvement" [5].* Since the release of the OIG report, the Global Fund SSC Team and GDF have developed a workplan to collaborate on four distinct workstreams:

- API / Key Supplier Management (KSM) mapping aims to optimize templates and approaches to map, interrogate, and respond to reported "API alerts" and supplier performance
- PSA selection tender workstream aims to use relevant lessons from the recent Global Fund PSA tender to inform upcoming GDF PSA tender
- KPI methodology alignment aims to align KPI and measurement methodology for reporting OTIF, cost savings, and reference pricing
- Aligning on approaches to measure on-shelf availability

The Global Fund's data systems are not currently configured to track spend through GDF. The Global Fund has no ability to separate out payments made to GDF from other payments made to UNOPS. Data on procurement through GDF is available through PQR, but, as mentioned earlier, there is often a delay between the execution of transactions and data entry into PQR (for all products, not just those procured through GDF), so this tool does not necessarily provide the Global Fund with up-to-date data on health product spend.

The quality assurance (QA) work of GDF also sits within this MoU. GDF has aligned its QA policy with the Global Fund and works closely with the Global Fund QA team to address and resolve any quality issues that arise. GDF defers to the Global Fund QA team for final decisions related to quality issues for products GDF procures with Global Fund funds. The Global Fund and GDF are in the process of a joint tender to select a quality control agent to conduct quality testing on behalf of both organizations. Another example of collaboration with the QA teams is the development and management of a prioritization system for the Global Fund Expert Review Panel (ERP) Expression of Interest (EOI). GDF leads on the drafting of the priority list and then works through TPMAT to get alignment across all TB stakeholders on products to list and prioritize on Global Fund ERP EOIs.

Outside of the areas described in the MoU, the Global Fund Country Teams and GDF have collaborated on different topics. As noted earlier, GDF serves as the lead organization to coordinate TA on TB procurement and supply planning, working closely with the WHO Regional Green Light Committees and implementing partners. GDF, therefore, works with select Global Fund Country Teams on Terms of Reference for missions and action plans that result from missions. GDF also works closely with country teams to validate quantification for orders placed with GDF and address urgent issues that arise in the procurement process. The Global Fund TB Disease Advisors and GDF have also collaborated on topics such as the the co-development of "Frequently Asked Questions" to provide information to countries about the 2018 changes to WHO MDR-TB treatment guidelines, and with the Global Fund STC Team to provide guidance to Country Teams on issues related to increased domestic financing and procurement of TB products.

Despite the frequent interactions between Global Fund teams and GDF, the Global Fund's role in market-shaping related to TB products faces two key challenges. First, without a product-specific approach for market-shaping related to TB products or visibility into TB markets, the Global Fund cannot proactively engage in market-shaping in a coordinated way. This limits the ability of the Global Fund to systematically identify ways that it can contribute to market-shaping for TB products, including by expanding some of its existing market-shaping tools (e.g., reference pricing) to TB products.

Second, GDF lacks a key partner or focal point for broader market-shaping topics which span multiple Global Fund teams. Therefore, it can be challenging to get cross-Global Fund alignment across, market-shaping issues and approaches that span multiple teams. The recent merging of Sourcing and Supply Chain Teams into one department will help with decision-making across these topics, but there is still a need for broader engagement and processes to move forward on MSS objectives that involve decisions from other Global Fund departments. This challenge in getting cross-Global Fund alignment poses a particular problem with regard to assessing and mitigating risks associated with increased domestic financing for procurement, a topic which has no single "owner" or strategy at the Global Fund. (The Global Fund's approach to addressing challenges related to sustainability and increased domestic financing for procurement is discussed further in other Section 4.11.)

## 4.8 Cross-cutting objective: Quality

### 4.8.1 Context

Although the Global Fund is not a regulatory authority, its positioning as a large procurer gives the Global Fund a unique role in promoting quality-assurance along three key dimensions, both through pooled and non-pooled procurement channels:

- Marketing Authorization (MA)/Registration: The Global Fund mandates stringent regulatory approvals for core products[n] procured with its grants (Stringent Regulatory Authority – SRA –, WHO-PQ or ERP/ERPD approval); for non-core products, the Global Fund only requires that they comply with national regulations (with the exception of In-Vitro Diagnostics products for which Quality Management System certification [ISO 13485] is required) [74, 75]
- Quality control in the supply chain: PRs are required to conduct quality control tests along the supply chain for randomly selected core and non-core products procured with Global Fund grants to ensure product authenticity and quality
- Post-marketing surveillance (including PV - pharmacovigilance): PRs are required to report back to the Global Fund any PV incident for core and non-core products procured with Global Fund grants (the Global Fund, through its Country Teams, is in a position to capture adverse events and report them to appropriate authorities in a timely fashion). By no means may this mechanism be a substitute to national mandatory requirements.

WHO is currently engaged in an effort to broaden the concept of SRA to encourage country regulatory systems strengthening. The Stringent/National Regulatory Authority (SRA/NRA) split is considered judgmental by many countries and criteria to qualify as an SRA lack transparency. WHO is therefore considering the introduction of the concept of WHO-Listed Authorities (WLAs) along with a stringency scale from 1 to 4, 4 being the level a regulatory authority needs to reach in order to qualify as a WLA. Countries are invited to benchmark their NRAs against WHO's Global Benchmarking Tool [76]. While still at the public consultation stage, this process is expected to launch in 2020 [76].

While partners broadly accept the notion of SRA for pharmaceuticals and diagnostics, no such concept exists for vector control tools (including LLINs). Therefore, the global health community usually considers WHO-PQ to be the most stringent authority for these tools. PMI, however, has taken a different approach for vector control tools, as it does not mandate that the LLINs they procure be WHO-PQ-listed. Instead, PMI commissions its own trials to demonstrate the safety, efficacy, and quality of vector control tools it intends to procure.

One should note that an assessment of the full global system for QA is out of scope for this review. However, it is worth noting that, in a recent report, the Centre for Global Development has identified opportunities for improvement, including the expansion of WHO efforts to facilitate

[n] As mentioned in the Introduction, core products refer to health products used to prevent, diagnose, or treat the three diseases. Non-core products refer to essential medicines used to treat adjacent diseases, e.g., antibiotics or antifungals.

common drug registration at the country level and the update of WHO guidance related to pharmaceutical policy and procurement [77].

### 4.8.2 Marketing Authorization/Registration

For a summary of the description of marketing authorization/registration requirements for Global Fund-funded products by channel and product type, as well as the level of product quality risk for each product type/channel, see Figure 21.

Through PPM, countries/PRs may only procure core products from quality-assured suppliers that have SRA, WHO-PQ, or ERP/ERPD approval (~57% of Global Fund spend is for core products procured through PPM). The Global Fund SSC Team directly enforces the Procurement and Supply Management (PSM) policy for core products procured through PPM, thereby limiting the risk of procuring low-quality products.

Through other global procurement channels, countries/PRs are also required to procure core products from quality-assured suppliers that have SRA, WHO-PQ, or ERP/ERPD approval (~23% of Global Fund spend for core products procured through other global procurement channels). However, the lack of comprehensive visibility into this spend may limit the assessment and complete enforcement of compliance with this policy. The risk is still low as organizations managing other global procurement channels have similarly strict requirements in terms of MA and quality control to those included in the Global Fund's PSM policies [78-80].

For non-core products (which can be procured through any channel), the Global Fund's PSM policies are not as stringent. Procurement Service Agents (PSAs) and National Procurement Agents (NPAs) may procure any product compliant with national laws and national regulatory guidelines. PSAs face another requirement for non-core products procured through PPM and other pool channels: compliance with WHO's Model Quality Assurance System mandating prequalification of manufacturing sites. This limits to some extent the risks for non-core products procured through PPM and other global procurement channels (2% of procurement spend).

The procurement of core and non-core products through national channels (~17% and ~1% of procurement spend, respectively) presents the highest risks. Core products procured through national channels have the same requirements as for pooled procurement, but this is not fully enforced nor enforceable due to the incompleteness of PQR data, which serves as the source for the Global Fund QA Team to check compliance with procurement policies. Non-core products procured through national channels also present a high level of risk since the policy for non-core products is less stringent and there is limited oversight on spend going through national channels. Additionally, there are no requirements for PRs to report transactions for non-core products procured through domestic channels in PQR. Anecdotal evidence has shown that some countries favor local procurement, sometimes at the expense of quality

To limit the risks, the QA Team performs quarterly QA verifications of the transactions based on PQR reporting. PQR data incompleteness limits the thoroughness of these verifications. In Q4 2017, the Global Fund QA Team identified two issues of non-compliance for the procurement of medicines.

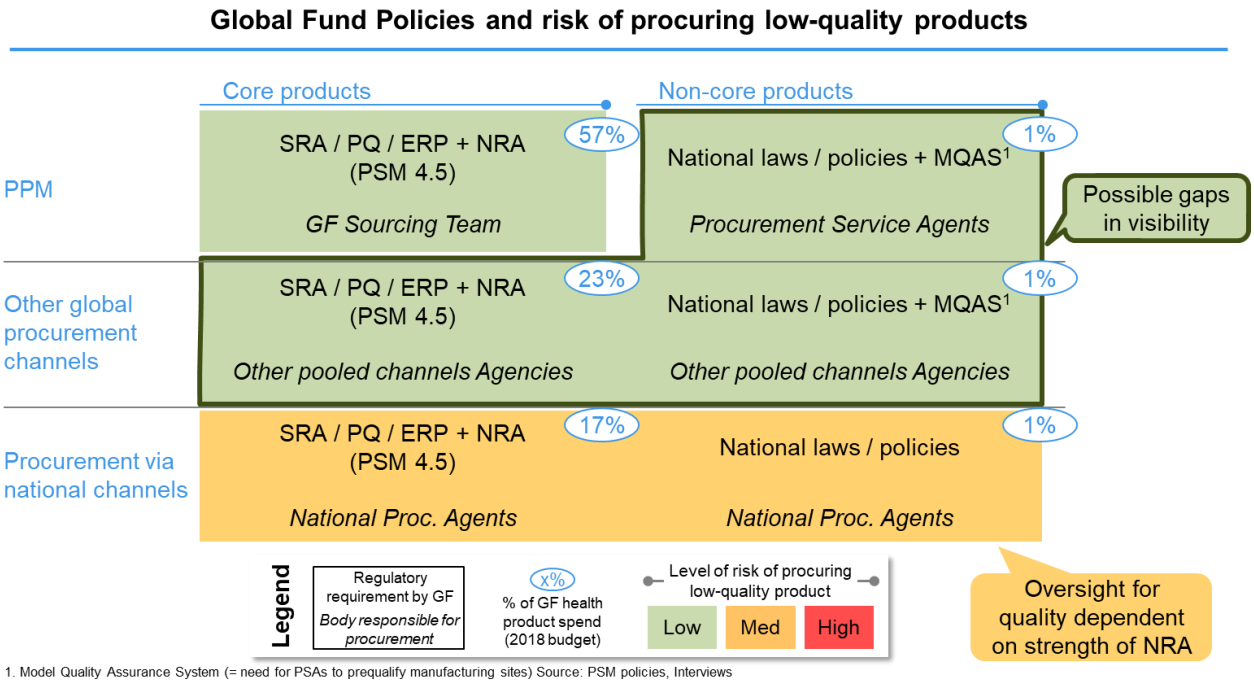



Figure 21 - Risks of procuring low-quality products with Global Fund grants

The Global Fund uses the ERP/ERPD mechanism to facilitate access to products for which there are two or fewer quality-assured suppliers. Mitigating actions are in place to compensate for higher risks compared with SRA approval or WHO-PQ listing:

- Pre-shipment inspection, sampling, and testing are mandatory for all orders of ERP-approved products (all batches are tested for the first five batches, then 20% of batches as long as there are no quality problems or 100% of batches for certain ERP products [81])
- Countries procuring ERP/ERPD-approved products need to make a special request in writing to the Global Fund
- ERP/ERPD approvals are by definition time-limited

Partly because of these mitigating actions, the procurement of ERP/ERPD-approved products has remained limited. Indeed, if at least one SRA-approved or WHO-PQ-listed product exists, PRs will typically prefer it over the ERP/ERPD-approved product, as countries face challenges registering ERP/ERPD products in the absence of a full assessment report provided by WHO-PQ. ERP-approved products also take more time to procure due to pre-shipment inspection, sampling and testing, which can create an eight-week lead-time. Additionally, for the first ERP approval, there is a requirement to complete a method transfer with the engaged laboratory, which adds approximately two to four months' lead-time to the ERP process. The ERP process as it is today is therefore not fit for rapid and massive scale-up of new products.

To reduce lead-times for ERP approvals, the Global Fund introduced the concept of "ad-hoc" ERPs in January 2018. Ad-hoc ERPs may be convened anytime outside the submission window of regularly planned ERPs when there is an urgent need for a given product formulation.

Additionally, these ad-hoc ERPs feature an abbrevatied review process of four weeks versus six weeks for regular ERPs.

For this mid-term review, we conducted transaction-level analysis of the total procurement of ERP-approved ARVs and ANTMs through PPM. We limited transaction-level analysis of the volume of ERP/ERPD-approved products to ARVs and ANTMs for the following reasons:

- Due to the lack of master data, transaction files needed to be manually mapped to monthly ERP approval lists, a labor-intensive process
- ARVs and ANTMs represent half of Global Fund spend
- Non-core products (e.g., Hepatitis C medicines) are out of scope for this review
- Conversations with the SSC Team indicate that the volume of diagnostics procured through ERPD is very low (although of critical importance, including for products such as G6PD tests, CD4 count tests and syphilis diagnostics)
- The Global Fund has limited transaction data readily available for TB products except for GeneXpert reagent reported in transaction files.

The analysis shows that the spend on ERP-approved products peaked at 5% of ANTM spend in 2017, mostly driven by the procurement of AQ+SP for SMC. See Figure 22 for a summary of PPM spend for ERP-approved ANTMs. There was no procurement of ERP-approved ARVs in 2014-2018, although the initial intent was to use the ERP process to rapidly scale up TLD. The lead-time generated by the ERP process, even reduced through the new ad-hoc ERP mechanism, would have hindered the rapid scale-up of TLD. As it turned out, the safety signal on TLD allowed suppliers to obtain FDA approval or WHO-PQ listing while demand for TLD had slowed down, which removed the need to procure ERP-approved TLD. Nevertheless, one benefit of the ad-hoc ERP process is that it allowed more suppliers to be eligible to participate in the tender for TLD (i.e., eight instead of two), which increased price competition.

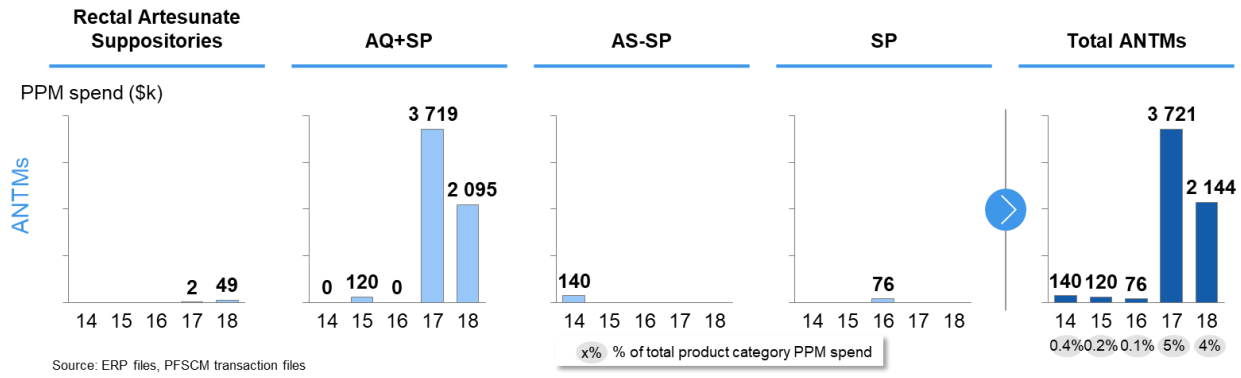



Figure 22 - PPM spend for ERP-approved ANTMs

Key informant interviews also indicate that the ERP/ERPD mechanism acts as a stimulus that encourages suppliers to go through the WHO-PQ process. An ERP/ERPD approval of a product is a sign of good faith that the Global Fund will procure the product once it gets WHO-PQ-listed. An ERP/ERPD approval is also a first step toward WHO-PQ listing and streamlines the subsequent WHO-Prequalification process. However, going forward, there would be value in investigating whether some steps in the ERP/ERPD process could be conducted in parallel.

### 4.8.3 Quality Control (QC)/Post-Marketing Surveillance (including Pharmacovigilance - PV)

National Regulatory Authorities are responsible for quality control and post-marketing surveillance activities. For a given country, there will be specific regulatory requirements that organize the flow of information for adverse effects (e.g., a safety signal on a medicine), in which the Global Fund does not play any role beyond allowing grant funds to be budgeted for these activities. Several studies have pointed to a lack of emphasis placed on post-marketing surveillance activities by countries/PRs [82, 83]. Consequently, the Global Fund revised its QA policies in 2017 [19, 84]. In addition to the national flow of information, Global Fund PSM policies now mandate that QC/PV incidents for all health products procured with Global Fund grants be reported to the Global Fund. The information flows both ways, as the Global Fund may also communicate to PRs information provided by SRAs or WHO-PQ that might impact health products they have procured. The Global Fund QA policy and Global Fund Country Teams also provide guidance to PRs to support these QC/PV activities. A new indicator measuring the "Percentage of health product batches for the three diseases tested for quality in line with Global Fund QA Policy" was included in the "modular framework", a list of indicators from which KPIs may be selected for specific grants. If used, this KPI will help improve visibility into quality control, especially for national procurement channels.

There are no standard operating procedures to report incidents uncovered through these activities to the Global Fund, which means some incidents are probably not reported [83]. For pharmaceuticals, the usual, although informal, channel to report incidents is through Global Fund Country Teams (HPMs, FPMs), who then inform the Global Fund's QA Team. However, there have been instances where Country Teams have dealt with incidents directly, without reporting them to the Global Fund QA Team. For diagnostics, incidents usually come from SRAs. For vector control products, incidents come mostly from PSAs and Quality Control Laboratories. The QA Team does not have a centralized tool for tracking the status of each incident brought to their attention. The QA Team stated that all incidents were closed; however, it was not possible to verify this as the QA Team currently does not maintain a central database of all quality incidents that includes information on source and closure. One should note that there is ongoing work by the QA Team to reinforce these processes. For instance, the QA Team intends to develop templates for reporting incidents to ensure that complete information is included in incident reports. The QA Team will also be working on improving its core processes through the PnA Framework in the next 12 to 18 months.

In addition to the lack of formalized reporting, the role and mandate of the Global Fund QA Team vis-a-vis WHO-PQ and Stringent/National Regulatory Authorities for the assessment and resolution of QC/PV must be better defined. The lack of a formal decision-making process to resolve QC/PV issues can lead to inefficient processes and suboptimal decisions, such as:

- Delays in actions by PQ/PR regulatory authority due to their being looped in later than they should have been
- Decisions by the Global Fund that may not involve the necessary expertise given the team's small size
- Parallel investigations potentially leading to contradictory decisions or duplication of efforts

There is ongoing work as part of the OIG's Agreed Management Actions plan to clarify roles and responsibilities, in particular for making decisions about and closing quality incidents [85].

Note that alignment between the Global Fund QA Team and regulatory bodies is not always easy to achieve, as the QA Team has to provide immediate advice to countries while WHO-PQ/SRAs will take time to investigate. Also, risk appetite may differ depending on the institution considered. WHO-PQ will provide advice to procurers, but the eventual responsibility to act upon this advice lies with the procurers [86].

### 4.9 Cross-cutting objective: Innovation

As noted in the MSS, the Global Fund can drive innovation through "push mechanisms," by which the Global Fund influences the innovation activities of partner organizations, or through "pull mechanisms," by which the Global Fund directly incentivizes innovation by suppliers.

For "push mechanisms," the Global Fund primarily partners with Product Development Partnerships (PDPs) and Unitaid. Although Global Fund individuals and teams have perspectives on innovation needs, the Global Fund does not have an institution-wide, documented perspective on this topic that it can use to influence partners. Further, providing systematic input on innovation requirements to partners would require input and decisions on country-level, technical, and sourcing topics, and the expertise for these topics is split across three Global Fund teams: GMD, TAP, and SSC. The Global Fund has no formal governance, process, or accountability across these three teams for influencing innovation priorities of partners, although individuals from these teams do often engage with partners on these topics.

Because market-shaping activities for innovation and new product introduction exist on a continuum, and Unitaid is one of the main partners for the Global Fund on new product introduction topics, we provide further detail on this partnership in Section 4.10.

The Global Fund's main "pull mechanism" to stimulate innovation by suppliers is to include innovation as an evaluation criterion in its tenders. This recognition of innovation helps innovative suppliers compete in the tender process against generics/non-originator suppliers, who typically have lower prices, by granting them points for their innovation activities. Innovative suppliers noted that they appreciated this recognition of their activities in the tender, but also noted that this mechanism in and of itself is insufficient to drive innovation, especially in highly commoditized markets (e.g., LLINs). Dedicating funds for evidence-generation work (e.g., late-stage product evaluation to obtain a WHO policy recommendation), such as in the New Nets projects, is a more comprehensive way to promote innovation. Suppliers participating in the New Nets project expressed support for this approach, as it helped them continue their innovation activities.

Another "*pull mechanism*" is the flexibility that the Global Fund has with its tenders and associated implementation period of long-term framework agreements to include new innovative products and/or additional suppliers for existing products in the "catalogue" of available products. This mechanism was used for TLD, Injectable Artesunate and Rectal Artesunate Suppositories. The Global Fund kept some volume for suppliers in anticipation of the WHO-PQ listing of these

suppliers. This contributed to increasing the supplier base for these new products, as suppliers received assurance from the Global Fund that they would get some volumes.

## 4.10 Cross-cutting objective: New product introduction/product selection

### 4.10.1 Partnership with Unitaid on new product introduction

Market-shaping activities to successfully introduce new products often include:

- Evidence generation: identifying evidence gaps that would slow a WHO recommendation or the adoption of new products, funding clinical trials, epidemiological research or operational research to address these gaps
- Early adoption: developing and running pilot programs to assess the feasibility and impact of a new product, and to understand key lessons for its planned scale-up
- Market preparation for scale-up
    - Supplier-facing activities: ensuring supplier base readiness (including regulatory approvals at global level and in target countries), preparing production capacity, collaborating on procurement with other large buyers
    - Country-facing activities: promoting the inclusion of the new product in national guidelines, generating demand at local level, demand forecasting, ensuring supply chain readiness

Unitaid is the Global Fund's key partner for market-shaping activities related to the innovation/new product introduction continuum. Unitaid and the Global Fund have distinct mandates along the product lifecyle. As described in the Strategic Framework for Collaboration between the Global Fund and Unitaid, Unitaid "*funds critical steps on the pathway to accelerating access to innovation in low- and middle-income countries, and the Global Fund funds programmes and activities to accelerate the end of the HIV, TB and malaria epidemics by scaling up access to diagnosis, treatment and prevention services*" [87].

The Global Fund and Unitaid collaborate on innovation and new product introduction, through their joint presence at the various forums dealing with these topics, and also through frequent direct interactions. The Global Fund and Unitaid are in the process of formalizing these interactions, as testified by the Strategic Framework for Collaboration signed by both organizations in May 2019 [87]. Although this strategic framework lays out principles to govern engagement between the two organizations and areas for collaboration, it does not lay out detailed responsibilities for individual Global Fund or Unitaid teams. The two organizations plan to develop a matrix to guide collaboration based on this strategic framework.

Our review identified two opportunities where the Global Fund can further strengthen its coordination with Unitaid on innovation/new product introduction.

First, as already mentioned in the previous section, the Global Fund lacks a systematic, documented, institution-wide perspective on innovation/new product introduction requirements that takes into account country-level, technical, and sourcing perspectives. Although Global Fund staff do frequently engage with Unitaid as it sets its priorities and grants, this lack of an

institution-wide perspective limits the Global Fund's ability to take a proactive role in shaping Unitaid's priority-setting (e.g., through its "disease narratives" process).

Second, Global Fund colleagues indicated that the process for "hand-off" from Unitaid to the Global Fund for pilot products, by which an intervention or product shifts from Unitaid-funded grant funding to Global Fund-funded funding, is currently unclear. This applies both to the decision whether to continue scale-up in pilot countries, and for the introduction/scale-up in new countries. The Global Fund lacks clear criteria or decision points for whether and how to scale interventions and associated products. It is not currently clear what results from a pilot project would result in a decision not to scale. Further, because the Global Fund operates on the principle of country ownership, it cannot unilaterally decide on behalf of PRs/countries to select certain products, and it therefore does not have full accountability over product scale-up. The Global Fund has an opportunity to strengthen its alignment with Unitaid on what it means for the Global Fund to scale an intervention/product in the context of its principle of country ownership.

One should note that the recently developed Unitaid Mid-Term Strategy Review also highlights coordination with scale-up partners such as the Global Fund as a priority area [88].

The MSS specifies that the Global Fund and Unitaid, along with other partners, are to develop "*high-level strategic 'roadmaps' to bring key products to scale, outlining key barriers, necessary actions, the organization(s) responsible and the timeline*." These roadmaps are to include a "*holistic set of activities and milestones required for product uptake, including (but not limited to) clinical and regulatory requirements, country registration, health technology assessment, integration in country treatment guidelines and priority-setting, quality assurance, and mechanisms for financing and sourcing.*" To date, the Global Fund has not formally developed these joint roadmaps, but if it does for new products in the future, they could include the criteria and decision points for scale-up described above.

### 4.10.2 Product selection

Because the Global Fund operates on the principle of country ownership and does not select products for countries, the role of the Global Fund Secretariat is to help PRs / countries optimize product selection. PRs / countries can only procure WHO-recommended products which have a WHO-PQ, ERP, or SRA-approved manufacturer.

In instances where there is clear WHO guidance or another justification to use one product over another, even if WHO approves multiple products, the Global Fund proactively helps prepare the supplier base for product introduction and influences countries to select these products [89]. The Global Fund Secretariat is taking this approach for the replacement of LNZ with TLD/TLE, and the replacement of the non-dispersible formulations of pediatric AL with dispersible formulations. Tools to proactively drive PRs to switch products include guidance provided during the grant-making process and the de-listing of products from the PPM catalogue (e.g., adult LNZ and NVP-200 were delisted in March 2019). Further, SSC will sometimes "intercept" orders for non-optimal products, a process by which SSC identifies an order for a non-optimal product and coordinates with the Country Team to advise the PR that they can switch to a different product. In some cases, PRs/countries may take years to stop procuring old products, although this may be

due to implementation constraints (e.g., in-country distribution challenges, inability to retrain clinicians on new regimens), rather than poor product selection by the PR. For instance, LNZ stopped being the preferred first-line ARV in 2013 but still accounted for ~5% of the ARV spend through the Global Fund in H2 2018 – however, countries need to go through a formal approval process to procure it now [89].

In instances where WHO does not specify a preferred product or where limited cost-effectiveness data exists, the MSS notes that the Global Fund, in consultation with technical partners can "*define a standard of evidence that must be met to justify purchase of significantly more costly products.*" Additionally, the Global Fund may commission cost-effectiveness studies centrally, where gaps in guidance exist, or allow PRs to fund such analyses from their grants: "*If sufficient evidence does not exist, recipients may fund research and technical assistance to provide sufficient evidence from their grant allocations, including in-country cost effectiveness analysis.*" The Global Fund would share the results of such analyses with the global health community. Despite the lack of cost-effectiveness data for core products procured using Global Fund grants (e.g., pyrethroid-PBO nets vs. LLINs, DHA-Piperaquine vs. AL), our review found no examples of use of either of these mechanisms, with the exception of planned analyses for the New Nets project, which aims to generate cost-effectiveness data (among other objectives). One likely root cause for the Global Fund not undertaking these activities is that it would require input and decisions from country-level, technical, and sourcing perspectives, and these three topics sit across three different Global Fund teams (GMD, TAP, and SSC, respectively).

### 4.10.3 Other activities to drive new product introduction/product selection

In addition to the partnerships and activities mentioned above, the MSS specifies two other approaches to drive new product introduction/product selection.

First, the ERP mechanism aims to accelerate the introduction of new products pending SRA approval or WHO-PQ listing. As mentioned in Section 4.8.2, the analysis of ARVs and ANTMs procured through the ERP mechanism shows that the procurement of ERP-approved products accounted for up to 5% of the ANTM annual PPM spend in 2017-2018 when AQ+SP was introduced for Seasonal Malaria Chemoprevention. This allowed for AQ+SP to be rolled-out one year before the first supplier became WHO-Prequalified. As already mentioned, other than this example, there has been limited procurement of ERP-approved products, and no procurement of ERP-approved ARVs (although the Global Fund initially intended to use ad-hoc ERPs to increase the number of quality-assured TLD sources). In the diagnostics space, some procurement of ERP-approved products has happened (e.g., G6PD tests, CD4 count tests, and syphilis diagnostics).

The MSS also recommends the use of a revolving fund to make volume guarantees to suppliers for new products to reduce their prices and stimulate future demand. However, the use and expansion of a revolving fund was never implemented, as it required approval from the Finance and Operational Performance Committee to make exceptions to Global Fund finance policies (i.e., revolving fund money would not be tied to grants), and changes in institutional leadership since the development of the MSS prevented the execution of this plan. A revolving fund could be useful in making volume guarantees, especially as products move from a "pilot" phase to an "early commercialization/scale-up" phase and require increased volumes. The Global Fund could

consider piloting this approach next time SSC recognizes that it could help achieve price-breaking volumes for a new product.

## 4.11 Cross-cutting objective: Sustainability of health product procurement

### 4.11.1 Context

The sustainability of public health programs as countries move away from donor financing is an important topic for the Global Fund, and for the broader global health community. For example, the current Investment Case aims to spur increased domestic investment of around $46 billion over the period 2021-2023 for the fight against the three diseases and the pursuit of Sustainable Development Goal #3 [90]. Similarly, a recent publication by the Working Group on the Future of Global Health Procurement highlighted three key transitions that will impact the future of global health procurement: the transition away from donor aid, the epidemiological transition, and the transition in health system organizations away from vertical programs to universal health coverage (UHC) [77, 91].

Given these challenges, the MSS includes an objective to "*prepare for country transition and long-term market viability.*" As stated in the MSS, "*the strategic actions described under this objective are cross-cutting initiatives aimed at preparing for country transition and ensuring that countries retain access to affordable, quality-assured health products.*" However, one should note that this section applies to all countries in the Global Fund portfolio, not just those in the formal transition projection cohort. Therefore, in consultation with internal stakeholders working to implement the STC Policy (including the Sustainability, Transition, and Co-Financing [STC] Senior Project Lead at the Global Fund), we have chosen to refer to this section as "Sustainability of Health Product Procurement." As defined by the Global Fund's STC Policy, sustainability refers to "*the ability of a health programme or country to both maintain and scale up service coverage to a level, in line with epidemiological context, that will provide for continuing control of a public health problem and support efforts for elimination of the three diseases, even after the removal of external funding by the Global Fund and other major external donors* [92]." Referring to sustainability, rather than transition, emphasizes the fact that this objective and the actions contained therein will apply to all countries, regardless of their formal transition status.

Countries increase their domestic financing for procurement (and other activities related to public health) for many reasons, including as a response to the implementation of the Board-approved STC Policy, which specifically mandates that the Global Fund work with countries to take up programatic costs. This policy reflects the recognition that the Global Fund must be a catalyst for increased domestic financing, and that the gradual uptake of key interventions is essential to the continued scale-up of national disease programs.

Of course, moving to increased domestic financing, including for health product procurement, also has risks. In particular, shifting health product procurement to domestic financing or domestic channels may introduce three types of risks. Detailed examples of the first two types of risks can be found in the TERG STC Policy Review [3].

First, countries may have weak procurement systems, weak regulatory agencies, or policies and laws which lead to sub-optimal performance of health product management. Procurement systems conduct functions such as product selection, development of category strategies/category management, demand forecasting, tendering, supplier relationship management, and transaction management [93]. Regulatory agencies conduct functions such as marketing authorization/product registration, licensing, inspection, quality control, pharmacovigilance, control of promotion, and control of clinical trials [94]. Weaknesses in the capabilities of these functions, or specific laws and policies applying to these functions, can lead to sub-optimal outcomes in terms of health product management. Recent examples of these types of issues from various countries include:

- Viet Nam currently plans to domestically finance procurement of all ARVs via Social Health Insurance. However, the country currently has limitations in its ability to procure ARVs due to strict marketing authorization requirements, which has resulted in an inability to procure from these suppliers [95, 96].
- South Africa's national regulatory authority, SAHPRA (South African Health Products Regulatory Authority), was created in 2017. SAHPRA inherited a backlog of ~16,000 applications – over 8,000 new registration applications and just under 8,000 variation applications. This backlog has delayed registrations in the country [97].
- As noted in the recent TERG review of the STC Policy, many countries face procurement challenges associated with limitations in public financial management systems [3].

Second, countries with low volumes or value of spend may have trouble successfully conducting tenders for health products because, when these products are not locally available, their low volumes generate little interest from private sector suppliers on international markets.

Third, as countries increase domestic financing and procurement of health products, markets for specific health products may face unique challenges. For example, the market for quality-assured TB medicines is highly fragile due to low overall demand for these products and fragmentation of the supplier base [26]. For ACTs, as products move through various distribution channels, the market may face risks related to counterfeit products and supply diversion [98].

### 4.11.2 Global Fund efforts to address these risks

To address these risks, the MSS specifies that the Global Fund will "*incorporate market shaping, procurement and supply management considerations in country transition planning and grant development, ideally beginning well before countries are on the verge of transition.*" Solutions to these risks may not only sit at the individual country level, but also in cross-cutting activities. Therefore, the MSS also specifies "*the Global Fund Secretariat will undertake additional analysis and consultation to identify further risks of country transition from a market shaping perspective. This will inform the development of options for the Global Fund to address these challenges. This process will be led internally by three focal points designated from among the Sourcing Department, HPM Specialists within the Grant Management Division, and the Policy Hub.*"

The Global Fund currently has a number of initiatives to address the risks associated with sustainability of health product procurement as domestic financing increases:

- Engagement by GMD Country Teams and HPMs

    - Currently, Country Teams for "priority" and "high-impact" countries use the Key Risk Matrix tool (and other tools) to assess risks associated with Procurement and Supply Chain Management topics, among others. In transition projection countries, the transition readiness assessment typically includes a section on PSM. These tools are designed to highlight issues related to sustainability of health product procurement and to facilitate inclusion of these topics in the Country Dialogue and grant priorities.
    - As partners to countries and other organizations supporting countries, the Country Teams and Project Implementation Units for PRs also often support countries as they deal with issues related to sustainability of health product management. For example, in Armenia, the Global Fund-funded Project Implementation Unit supported the revision of procurement processes and regulations after a failed tender for first line TB drugs to help increase the likelihood of success of a future tender [99]. Vietnam currently faces challenges shifting the funding of its procurement of ARVs from Global Fund grants to the national Social Health Insurance, and the Country Team is advising on this shift [96].
- Financing of TA through grants and strategic initiatives
    - In some cases, the Global Fund provides grant funding for PRs/countries to address these topics. For example, in South Africa, the Global Fund supports the implementation of the country's strategy for increasing medicine availability (SIMA) by paying salaries for ten procurement experts and five demand planners [100]. Ethiopia has a specific Resilient & Sustainable Systems for Health (RSSH) grant which includes efforts to strengthen procurement systems, the national regulatory authority, and supply chain management [101].
    - There is an ongoing strategic initiative to strengthen PSM in 16 priority countries, which mostly focuses on in-country supply chain and logistics (which are out-of-scope for the MSS), but which occasionally includes strengthening some procurement functions such as demand forecasting.
- Guidance from STC on issues related to sustainability of health product procurement
    - The STC Team, SSC Team, HPMs, and partners are in the process of finalizing an HPM STC Guidance Note Annex and a TB STC Guidance Note Annex on how to address the challenges associated with sustainability of health product procurement.
    - Formal trainings on STC include a focus on PSM challenges (led by Senior HPM Specialist). More than 150 Global Fund staff members have now attended, including almost all FPMs from transition preparedness countries (and others from across the portfolio).
- Partnerships at country and regional levels. A non-exhaustive list of partnerships on this topic include:
    - Collaboration between the SSC Team and the PAHO Strategic Fund on the tendering process for ARVs (see Box 16 on this topic for more details on how PAHO and the Global Fund combined their ARV volumes for increased commercial leverage)
    - Partnerships with UNICEF and the German Society for International Cooperation in the Eastern Europe and Central Asia region
    - Participation in the Interagency Pharmaceutical Coordination (IPC) group

    - Participation in TPMAT, the global market-shaping forum related to TB products
    - Country-level partnerships
- Pilot to expand Wambo to domestically financed procurement
    - The SSC Team is piloting an approach to give countries using domestic financing for procurement access to prices and long-term agreements secured through PPM via Wambo. The initial pilot consisted of ten transactions, and the Global Fund is planning an expansion of this pilot to 50 more transactions. This pilot will help identify the benefits of granting access to Wambo, as well as the regulatory and operational barriers to doing so (e.g., national laws preventing access to pooled procurement, misalignment of payment terms/schedules between suppliers and countries).

### 4.11.3 Opportunities for the Global Fund to further address these risks

There are three areas where the Global Fund could further strengthen its engagement on topics related to sustainability of health product procurement.

First, although individual country teams review country strengths and risks related to PSM topics in the Key Risk Matrix, Transition Readiness Assessment, and other tools, the Global Fund does not have cross-country visibility into the level of risk related to these topics or the effectiveness of Global Fund investments in PSM. The 2019 TERG Review of RSSH excluded PSM because the OIG was conducting an audit related to procurement, but the OIG report only investigated Global Fund procurement processes, not the effectiveness of Global Fund investments in procurement systems/regulatory agencies. The Global Fund also does not have centralized data on the use of co-financing commitments specifically for health product spend. Therefore, it is difficult to assess the level of risk across the Global Fund portfolio (and transitioned countries) and to ensure that the Global Fund is making full use of its suite of tools and capabilities to address these issues in a coordinated manner (while also managing other competing priorities.)

Second, there is an opportunity to take a more comprehensive and systematic approach to addressing these issues across Global Fund teams. Global Fund Country Teams had variable levels of awareness and engagement on this topic. Additional challenges related to Global Fund engagement include the following:

- In many cases, the Global Fund can influence but not control the outcomes of strengthening of procurement systems/regulatory agencies (e.g., changes to national laws, results of tenders by national procurement agencies, etc.). Addressing these issues requires influencing a broad range of policies, including fiscal, health, and trade policies. In some cases, the role of the Global Fund for influencing these activities and supporting countries/partners is unclear.
- The new Modular Framework for the upcoming grant cycle includes three PSM indicators related to procurement and quality[o], but these indicators only relate to Global Fund-

[o] OTIF ("Percentage of consignments delivered on-time and in-full among the total number of consignments expected to be delivered for the three diseases during the reporting period"); Demand forecast accuracy ("Percentage of health products for Purchase Orders confirmed with suppliers among the projected quantities for the three diseases during the reporting period"); Quality control ("Percentage of health product batches for the three diseases tested for quality in line with Global Fund QA Policy")

funded procurement, and not domestic procurement or strength of country systems. (PSM indicators in the Modular Framework for the last grant cycle, only looked at facility-level availability of health products, not procurement or quality.) [102]

- The role of HPMs versus SSC for providing technical guidance to countries related to procurement systems and regulatory agencies is unclear.
- The strategic initiative to strengthen PSM in 16 priority countries mostly focuses on warehousing, distribution, and logistics, and rarely includes efforts to strengthen procurement systems or regulatory agencies (although some exceptions do exist, including Malawi, Liberia, and Ethiopia).

Third, although the Global Fund's efforts to pilot access to Wambo for countries using domestic financing for health product procurement is a welcome initiative, this effort needs to systematically consider the risks and trade-offs inherent in such an effort for the full range of transaction types that could happen on Wambo in the future. The pilot is currently limited to current Global Fund PRs using domestic funding and is not open to procurement by other entities, such as governments in Global Fund-supported countries where the government is not a current PR, donors funding programs in Global Fund-supported countries, or transitioned countries. Excluding these types of transactions limits the pilot's ability to test how Wambo could work as a platform for procurement outside of PRs. Further, while this pilot is designed to consider the regulatory and operational barriers to opening up Wambo to domestically funded procurement, the evaluation of the pilot should also assess the complex political economy, global governance, and country-level health systems considerations involved, and it should help determine a long-term strategy for Wambo based on these findings. For example, if countries begin to use Wambo for domestic procurement of health products, this could fragment procurement systems within the country (since only a subset of products will be available via Wambo) or lead to a weakening of procurement capacity by countries since they will rely on the procurement capabilities of the Global Fund. Further, procuring through Wambo may give countries access to lower-priced or higher-quality products than they could secure through their own systems, but countries may have an interest in optimizing for other dimensions of health product management, such as procuring from a local manufacturer base in order to support the local economy.

Case study: Partnership between PAHO Strategic Fund and Global Fund PPM

The Pan-American Health Organization (PAHO) conducts pooled procurement for its member states. Originally focused on pooled procurement of vaccines and immunizations, member states chose to expand to other health commodities through the development of a Strategic Fund in 2000. Today, PAHO's Strategic Fund serves as a mechanism for pooling procurement of WHO Essential Medicines including antiretroviral medicines, TB medicines, antimalarial medicines, diagnostics, and vector control products, among other products. Member states can choose to opt in – but it is not mandatory – not all countries participate in this mechanism for all products, and some countries opt in for some products but not others.

While an important initiative, the Strategic Fund initially faced challenges with procurement and supplier performance for certain products, including product availability, inability to secure prices comparable to those of other major procurers, and issues with quality, packaging, on-time in-full delivery, and language requirements. In 2014, while the Global Fund was in the process of developing its current MSS, the Global Fund and PAHO identified a potential opportunity for collaborating on pooled procurement, specifically for ARVs. The Global Fund and PAHO chose to collaborate on ARVs for two reasons. First, PAHO had significant enough volume and spend in this category ($40m in 2018) that it could meaningfully add to the total value of the Global Fund's tender, and improvements in performance (e.g., reduced price, improved supplier performance) could lead to meaningful impacts for members states, including those projected to transition from Global Fund funding. Second, PAHO had small total volumes and value for ARVs compared with those of Global Fund PPM, which totaled approximately $350m in 2018; therefore, PAHO could gain significant leverage and market power by collaborating with the Global Fund for this product category.

In advance of the Global Fund's 2015 tender, PAHO and the Global Fund developed a Memorandum of Understanding which allowed for sharing on reference prices and other information related to pooled procurement. The two organizations identified a significant opportunity for savings through price reductions. PAHO then participated in the Global Fund's ARV joint tender including PAHO volumes in the tendered volumes in order to ensure that it received the same terms and conditions from suppliers as those of the Global Fund. Participating in this tender has generated savings and improvements in OTIF and product lead-times for ARVs for PAHO countries (17 PAHO countries currently procure ARVs through this agreement). PAHO also currently uses the same performance-based approach to managing supplier relationships and allocating volumes to suppliers.

This partnership represents an important model for the Global Fund to address challenges related to sustainability of health product procurement as countries increase domestic financing and procurement of health products. Of the 23 country components formally projected to transition by 2025, ten are in the Latin America/Caribbean region. This initiative provides one example of how the Global Fund can collaborate with other large procurers to grant access to the benefits of its LTAs, and how it can help ensure that small countries, which may have challenges conducting successful tenders on their own, have access to affordable, quality products.

Box 16 - Partnership between PAHO Strategic Fund and Global Fund PPM [103, 104]

## 5. Based on current performance, where should the Global Fund focus its market-shaping efforts in the next two years?

**Key takeaways:** There are four key activities that the Global Fund should undertake by the end of the MSS (end of 2021) to further strengthen its performance on market-shaping and move fully from "smart procurement" to "proactive market-shaping" covering all MSS objectives, procurement channels, and product categories:

A. SSC should **continue to drive value on availability, affordability and quality** by using its strategic sourcing capabilities and leverage with suppliers
B. SSC, GMD, and TAP should **drive stronger health product management across all Global Fund-funded procurement** (not just PPM) by strengthening metrics, tools, and systems that monitor health product spend
    i. The Global Fund should **develop fit-for-purpose tools, master data, and standard operating procedures** to track health product spend, including demand forecasting, transaction management, reporting / resolution of quality incidents
    ii. The Global Fund should **expand its Strategic, Implementation, and Operational KPIs** to cover market-shaping objectives beyond availability and affordability, to cover spend channels beyond PPM, and to include TB products
C. The Global Fund should **drive a stronger institution-wide effort to market-shaping** by ensuring that internal teams and core partners align on issues, priorities, and roles / accountabilities for specific product markets
    i. For specific product categories, **the Global Fund should develop cross-team institution-wide technical perspectives** (with input from partners) that articulate how market-shaping will contribute to fight against the three diseases. TB product strategies should build on an assessment of TB markets, ideally developed jointly with USAID, Stop TB, and Unitaid, and other key partners.
    ii. The Global Fund should also **clarify governance / accountability among SSC, GMD, and TAP** for activities requiring country-level / technical / sourcing input & decision-making (innovation, scale-up, product selection)
D. Key Global Fund teams (e.g., GMD, SSC, and TAP) should help **ensure long-term sustainability of market-shaping successes and reduce likelihood of back-sliding on progress** by developing comprehensive approach to address risks associated with increased domestic financing.

See Figure 23 for for a visual representation of how these actions relate to specific outcome objectives.

Given the strategic importance of proposed actions of Bii, C.i., C.ii., and D., we recommend that these actions are considered in relation to the Global Fund's overall strategy and as part of Strategic Review (SR) 2020.

The Global Fund should make sure to provide adequate resourcing for all necessary activities and avoid diverting resources away from critical ongoing activities to undertake new activities in any way that could put ongoing activities at risk.

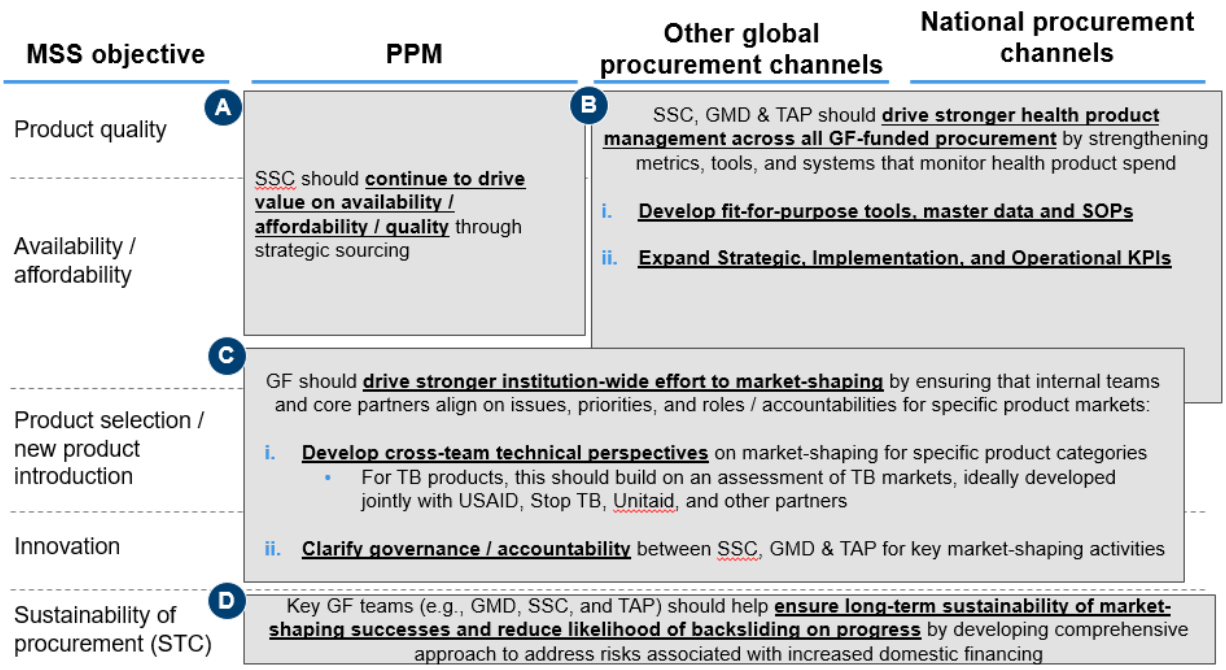



Figure 23 - Summary of proposed actions for the Global Fund to strengthen market-shaping activities

## 5.1 Proposed Action A.: SSC should continue to drive value on availability, affordability, and quality by using its strategic sourcing capabilities and leverage with suppliers

Current state: As mentioned earlier in this report, the Global Fund has achieved success through its various market-shaping activities (see Section 4). This has allowed for the effective execution and oversight for pooled procurement and strategic sourcing to drive the availability of affordable and quality health products. These capabilities include:

- The use of long-term framework agreements to maintain a sustainable and reliable supplier base (see Section 4.1.3)
- The volume reallocation mechanism to reward suppliers based on evaluation criteria linked to the LTA (see Section 4.1.3)
- The Vendor-Managed Inventory feature, paid for by suppliers to fulfill emergency orders in a timely fashion (see Section 4.2.2);
- The target price-setting mechanism to bring prices down based on COGS analyses (see Section 4.2.3)
- Product-specific initiatives like the requirement for Finished Pharmaceutical Product suppliers to procure from a prequalified panel of artemisinin suppliers, or the requirements promoting the use of semi-synthetic artemisinin (see Section 4.3.2)

The Global Fund has established a trusted relationship with suppliers over time and this gives the Global Fund significant leverage to achieve successes on the different aspects of healthy markets.

Proposed actions: SSC should continue to drive value on availability, affordability, and quality by using its strategic sourcing capabilities and leverage with suppliers. SSC can also consider adding or expanding the tools it uses to drive performance on strategic sourcing, including activities

described in the Phase 2 Roadmap (e.g., total cost of ownership approach to reducing prices, responsible procurement) and other activities (e.g., purchasing third-party data on market prices to benchmark Global Fund prices).

Potential additional value: These initiatives will continue to drive value by shaping markets across MSS objectives, especially affordability, availability, and quality. The forthcoming tender for RDTs is a new area where SSC can drive value for Global Fund product categories.

Requirements: This action represents continuation of existing SSC activities and requires continuation of existing SSC resources.

### 5.2 Proposed Action B.: SSC, GMD, and TAP should drive stronger health product management across all Global Fund-funded procurement by strengthening metrics, tools, and systems that monitor health product spend

Current state: As detailed in Section 4.1.4, different, non-integrated tools currently exist for various aspects of health product management. Static (non-dynamic) lists of health products sit in the Grant Operating System; information on transactions sits in PSA transaction files and PQR; SSC and Country Teams do not have an integrated way to consolidate demand forecasts; and the QA team tracks quality incidents in an Excel spreadsheet and does not systematically document incident source or outcome in a central database. No master data or approach to data governance exists, which creates complexity for data reconciliation and analysis. Given the evolving priorities for the Gobal Fund (e.g., better demand forecasting, better traceability for quality incident reporting), PQR is no longer fit-for-purpose. As explained in Section 4.8.3, for the resolution of quality incidents, the mandate of the Global Fund QA Team vis-à-vis the PR QA Team/Regulatory Authority, and WHO-PQ is unclear.

The Global Fund currently only reports Board-level metrics / KPIs for availability and affordability of PPM spend, as detailed in Section 4.1.5. There is no Board-level visibility into TB product markets.

Proposed actions: The Global Fund should undertake two key "sub-actions" related to this action:

- The Global Fund should develop fit-for-purpose tools, master data, and standard operating procedures to track health product spend, including demand forecasting, transaction management, reporting/resolution of quality incidents.
- The Global Fund should expand its Strategic, Implementation, and Operational KPIs to cover market-shaping objectives beyond availability and affordability, spend channels beyond PPM, and TB product markets.

**i. The Global Fund should develop fit-for-purpose tools, master data, and standard operating procedures to track health product spend, including demand forecasting, transaction management, reporting/resolution of quality incidents.** This tool would include functions such as maintenance of dynamic health product lists, demand forecasting, transaction reporting, and tracking of quality incidents. Robust master data and data governance systems would underlie this tool and its functionality. Standard operating procedures for key activities, including consolidating demand forecasts, reporting and tracking transactions, and reporting and tracking

quality incidents, would support the use of this tool. Updates to reporting requirements should balance the need for up-to-date visibility into spend with the fact that changing reporting requirements for PRs could create additional administrative burden.

ii. The Global Fund should expand its Strategic, Implementation, and Operational KPIs to cover market-shaping objectives beyond availability and affordability, to cover spend channels beyond PPM, and to include TB products. In particular, SSC, GMD, and TAP could introduce metrics to monitor:

- New product introduction: Product scale-up/phase-out rates, volumes, or number of new countries for products such as new first-line ARV regimens, new DR-TB regimens, pyrethroid-PBO nets/new nets, and RDTs under forthcoming interchangeability guidelines
- Quality: Operational KPIs on quality incident severity level (e.g., recall rate) and closure rate
- Availability: The Board-level KPI/target on the number of quality-assured suppliers (four or more) might need to be revised for some recommended products with low volumes. That target could spread low volumes too thin and remove commercial viability, in line with SSC's plan to propose related revisions to this KPI to the Audit and Finance Committee in Q4 2019

Potential additional value: Stronger visibility into health product spend across all channels and product categories would help guide health product management, decision-making, and priorities by GMD, SSC, and TAP. It would allow for the identification of issues and opportunities, such as: PRs not receiving the best prices for health products; PRs not using optimal channels to procure products, and; PRs facing roadblocks for switching to new products. The Global Fund could then take a more proactive role in addressing these issues, ultimately helping achieve better performance on grant objectives. This proactive role in addressing issues and opportunities could take place in interactions with PRs (e.g., providing guidance on product selection), suppliers (e.g., incentivizing or pushing for better performance), or partners (e.g., influencing/coordinating with partners to take action in areas where partner capabilities complement those of the Global Fund).

The addition of new KPIs/metrics for other MSS objectives and for TB product markets will enable better visibility by management and governance bodies into performance on the MSS, and it will further incentivize the Global Fund Secretariat to optimize performance in these areas.

Requirements: The development and strengthening of tools, data, and analytics could fall under the purview of the SSC Data, Analytics, Processes, and Tools Team. The strengthening of coordination and interactions with Country Teams and PRs could fall under the purview of the SSC PR Services Team. These two teams could lead this action with counterparts from GMD. The appropriate GMD counterparts to lead this effort are likely the Regional HPM Managers. Developing and approving new metrics/indicators may require input from other Global Fund teams, depending on the level at which the metrics are reported (e.g., SSC only, MEC, or governance bodies/the Board).

The Global Fund will require additional resourcing to develop and roll out tools and standard operating procedures for health product management. (This resourcing would include technical

support for underlying IT, development and training on new standard operating procedures, etc.) Delivering impact on other channels will likely require process adjustments since current processes are tailored to PPM. The development of new metrics/KPIs likely does not require additional resourcing.

Both sub-actions in this section will require engagement from the Global Fund leadership, especially at the MEC level, to ensure coordinated messaging, communication, and execution.

### 5.3 Proposed Action C.: The Global Fund should drive a stronger institution-wide effort to market-shaping by ensuring that internal teams and core partners align on issues, priorities, and roles/accountabilities for specific product markets

Current state: As detailed in Section 4, alignment internally and externally with core partners on product-specific market-shaping issues, priorities, and roles/accountabilities varies considerably across product categories. Although SSC defines product category strategies in consultation with other Global Fund teams and partners, they often focus on availability, affordability, and quality (objectives directly related to sourcing functions), and have less of a focus on other MSS objectives (innovation, new product introduction/product selection). These strategies do not ensure accountability for market-shaping activities outside SSC. The lack of a systematic diagnosis of issues affecting product markets across all MSS outcome objectives and potential solutions to address these issues means that there are likely missed opportunities to capitalize on the core capabilities of the Global Fund and partners for market-shaping.

Given the focus of these strategies and SSC's accountability for driving availability, affordability, and quality of products, there are at least three activities related to other MSS objectives where the Global Fund needs to clarify governance/accountability among GMD, TAP, and SSC, as detailed in Section 4.1.2. These are activities that require input from the three teams on country-level, technical, and sourcing perspectives, respectively.

- Influencing partners on innovation (See Section 4.9 for more detail)
- Coordinating with Unitaid on early adoption / scale-up (See Section 4.10 for more detail)
- Providing guidance to PRs on product selection (See Section 4.10 for more detail)

Future actions: The Global Fund should undertake **two major "sub-actions"** related to this action:

i. For specific product categories, the Global Fund should develop cross-team technical perspectives (with input from partners) that articulate how market-shaping will contribute to the fight against the three diseases.
ii. In parallel to developing these product-specific technical perspectives, the Global Fund should also clarify the governance/accountability between SSC, GMD, and TAP for the three activities mentioned above which require input and decision-making on country-level, technical, and sourcing topics.

**i. For specific product categories, the Global Fund should develop cross-team technical perspectives (with input from partners) that articulate how market-shaping will contribute to the fight against the three diseases.** These product-specific perspectives on market-shaping would help ensure all Global Fund teams have a shared understanding of key issues for healthy markets, actions to address these issues, governance, accountability, and milestones to execute these

actions, and agreed-upon measures of success. They can also help the Global Fund communicate its perspectives, drive alignment, and influence core partners. These technical perspectives on product markets can also contribute to broader Global Fund technical perspectives articulating what the priorities in the fight against the three diseases are. They would identify any market-shaping related shortcomings impeding progress on these priorities. If any product strategies include new accountabilities for teams (including SSC, Country Teams, or TAP), these accountabilities should be formally documented and possibly included in teams' performance metrics.

- While current product category strategies developed by SSC can serve as the basis for these technical perspectives on market-shaping, they will have to be expanded to ensure comprehensiveness across the entire product lifecycle (including innovation, new product introduction/product selection), and to drive accountability for actions by Global Fund teams outside SSC.
- The Phase 2 Roadmap developed by SSC in 2017 includes a proposal for a biannual joint stock-take between SSC, GMD, TAP, and partners for new product introduction progress and bottlenecks. Global Fund teams could pilot this approach to drive alignment on any product which faces market-shaping challenges (not just new products).
- Examples of products where this approach could have driven value and could still drive value going forward include:
    a. RDTs: SSC currently has a strategy to drive RDT interchangeability among suppliers through its ongoing tender, as mentioned in Section 4.5.1. A more systematic approach to RDT market-shaping by the Global Fund would also include plans with partners and Country Teams to update national guidelines for testing algorithms and training health workers to ensure efficient rollout of this interchangeability strategy (which could help increase availability and affordability of these products).
    b. ITNs / LLINs: As mentioned in Section 4.4.1, the recent conditional recommendation by WHO to use WHO-prequalified pyrethroid-PBO nets in certain settings while there is unclear epidemiological efficacy data on some of those WHO-prequalified nets, plus the development of innovative new nets through a joint project with partners, has significantly increased the complexity of this product category. As planned by SSC, the Global Fund should develop a "bridging strategy" for the next several years which defines the future outlook for this market and how the Global Fund will drive product selection and allocate volumes among LLINs, pyrethroid-PBO nets, and innovative new nets across geographies.
    c. TB products: Unlike for HIV and malaria, the Global Fund currently has no product-specific strategies for TB products, as specified in Section 4.7.3. Given the Global Fund's limited visibility into TB product markets, increasing visibility into these markets and developing product-specific strategies would help the Global Fund to systematically identify ways that it can contribute to market-shaping for TB products, including by expanding some of its existing market-shaping tools (e.g., reference pricing) to TB products. It would also help with alignment on KPIs across market-shaping objectives. (Currently, the Global Fund and GDF are aligning on KPIs for availability and affordability). This effort will be important as TB medicines markets evolve (with at least one major generic supplier of HIV and malaria medicines entering the TB medicines space), and to address affordability issues related to TB diagnostics. Given the critical role that many partners play in market-

shaping for TB products, any TB product strategies should build on an assessment of TB markets, ideally developed jointly with USAID, Stop TB, and Unitaid, and other key partners.

d. ANTMs: Global health partners need to ensure supply security for ANTMs that have one or two QA suppliers (e.g., Injectable Artesunate, Amodiaquine+SP, SP, DHA-Piperaquine – this may include work to ensure API supply security), as detailed in Section 4.3.4.

- In order to further strengthen the linkage between MSS activities and the Global Fund's overall strategy, the Global Fund may want to consider aligning the timing for developing its next MSS and overall strategy.

ii. In parallel to developing these product-specific technical perspectives, the Global Fund should clarify the governance/accountability between SSC, GMD, and TAP for the three activities mentioned above which require input and decision-making on country-level, technical, and sourcing topics. If this effort results in any new accountabilities for teams (including SSC, Country Teams, or TAP), these accountabilities should be formally documented and possibly included in teams' performance metrics.

- Influencing partners on innovation: Developing clear perspectives on innovation requirements will help the Global Fund influence partner R&D priorities, influence target product profiles, generate evidence, and perform other upstream activities in the product lifecycle.
- Coordinating with Unitaid on early adoption/scale-up: for Unitaid projects where the Global Fund may be expected to scale the intervention/associated products, the Global Fund and Unitaid should align on the definition of success and quantified conditions for scale up. The Global Fund should provide systematic input into the design of Unitaid's grant, including on grant KPIs, if that is identified as a limitation to the strength of the proof of concept. If the Global Fund identifies meaningful barriers to scale-up based on the design or execution of the Unitaid pilot, it should clearly communicate these challenges, and, if these disagreements cannot be resolved, the Global Fund should communicate that it may not be able to drive scale-up. The Global Fund (Country Teams, SSC, TAP) should work with PRs and Unitaid to set criteria and decisions for determining whether and how to scale-up new products piloted by Unitaid (both in countries where pilots take place, and in new countries). These decisions need to acknowledge that the Global Fund operates on the principle of country ownership, and therefore cannot unilaterally decide on behalf of countries to scale products. In certain cases, failure to meet certain criteria at the end of the pilot could result in a proactive decision not to scale certain products/interventions. There may be additional root-causes for scale-up shortcomings that Unitaid and the Global Fund will have to jointly identify and mitigate against. One should note that the recently developed Unitaid Mid-Term Strategy Review also highlights coordination with scale-up partners such as the Global Fund as a priority area [88].
- Providing guidance to PRs on product selection: When gaps exist from partners on guidance for product selection, especially for cost-effectiveness analysis, the Global Fund should fill these gaps so that it can provide appropriate guidance to its grantees. The Global Fund could do this either by developing guidance when sufficient evidence exists, or by commissioning research (e.g., cost-effectiveness studies) to fill gaps in the evidence

base. Examples of products that could potentially benefit from cost-effectiveness research include HIV facility-based versus self-test diagnosis strategies (see Section 4.5.5), pyrethroid-PBO nets (as part of an ITN / New Nets strategy, see Section 4.4.5), and ANTMs (e.g., DHA-Piperaquine vs. AL, see Section 4.2.5).

Potential additional value: Driving agreement between core partners and Global Fund teams on market-shaping priorities would lead to more effective collective action. In particular, more systematically defining issues, priorities, and roles for specific product categories would help increase the likelihood of fully addressing these issues, especially for objectives related to innovation and product introduction/selection, where multiple Global Fund teams beyond SSC, and core partners, have important roles to play.

Requirements: Leading the process for developing cross-Global Fund technical perspectives on specific product markets falls under the purview of SSC's Strategic Sourcing Team. Developing these technical perspectives will require input from GMD, TAP, and partners. For RDTs, ITNs/LLINs, and ANTMs, these technical perspectives can likely build on existing product category strategies. This will require incremental effort but likely does not require significant incremental resourcing. On the other hand, given the complexity of TB markets and the Global Fund's historically limited engagement with them, developing a Global Fund perspective will likely require more technical expertise on TB markets than the Global Fund has. As described, any TB product strategies should build on an assessment of TB markets, ideally developed jointly with USAID, Stop TB, and Unitaid, and other key partners.

Determining the accountability for innovation, new product introduction, and product selection across SSC, GMD, and TAP likely does not require incremental resourcing, but it may require a "facilitator" outside these three teams to manage the process.

Both sub-actions in this section will require engagement from the Global Fund leadership, especially at the MEC level, to ensure coordinated messaging, communication, and execution.

### 5.4 Proposed Action D.: Key Global Fund teams should help ensure long-term sustainability of market-shaping successes by developing a systematic approach to addressing these issues

Current state: As detailed in Section 4.11.2, several initiatives are underway to drive sustainability of procurement as domestic financing and procurement increases. These efforts include: new guidance to country teams on these types of risks; country-/region-level efforts and partnerships to strengthen systems; and the ongoing pilot to expand access to LTA suppliers/prices for domestically financed procurement via Wambo. These efforts represent a starting point for the Global Fund to address sustainability issues, and the Global Fund could progress further in its approach to mitigating potential risks. In particular, the Global Fund could strengthen its approach to addressing these topics by developing: a systematic assessment of risks/priorities across countries; more comprehensive engagement on this topic, and; an expansion of the Wambo pilot to domestically financed procurement by entities other than PRs, coupled with a rigorous evaluation and long-term strategy. Current restrictions on the Wambo pilot (e.g., which entities can procure on Wambo using domestic financing) limit its ability to comprehensively assess potential future scenarios for its use.

Future actions: The Global Fund should develop a comprehensive proposal for how to address risks associated with sustainability of health product procurement. This proposal should include:

- Benchmarking information (new or already existing) on the ability of country procurement systems to conduct relevant functions (including tendering, category management, and executing transactions) and the strength of regulatory agencies (i.e., using the new WHO Global Benchmarking Tool) to systematically assess risks and bottlenecks, and prioritize solutions.
- A proposal for how to organize Global Fund activities to address these issues. This should address questions including whether the Global Fund should: use only existing grant funds versus adding a new strategic initiative; develop new RSSH expertise versus leveraging the existing SSC team to provide TA; how best to incorporate activities into grant objectives where Country Teams can influence but not control outcomes; and how to coordinate among SSC, GMD, and any other relevant teams to address these topics.
- A plan to expand the Wambo pilot granting access to LTAs for domestically financed procurement to assess its value, operational barriers, and long-term potential risks to country systems. This pilot should inform a long-term strategy and governance model for Wambo and its potential impact on health product markets at the global level. A long-term strategy for expanding Wambo would consider topics like its potential impact on country-level procurement systems, its potential impact on global markets for health products, and its value proposition for countries and suppliers as compared to other global/pooled procurement channels. The Global Fund should lift certain restrictions on which entities can procure through Wambo for the pilot (e.g., governments in Global Fund-supported countries where the government is not a current PR), in order to ensure that the types of purchases through the pilot are similar to those which could be part of a longer-term strategy for Wambo.

One should note that this proposed action is generally aligned with recommendations in the recent TERG review of the STC policy (draft as of July 19, 2019), which states that the Global Fund should *"urgently expand efforts to address systems constraints in… national procurement and supply chain management,"* and should "p*rovide access to wambo.org or other pooled procurement mechanisms post-transition, especially for countries that lack the capacity or purchasing power to procure efficiently in global markets" [3].* We believe it is important to address these topics in one comprehensive plan in order to ensure aligned approaches and priorities across the Global Fund, especially between GMD and SSC.

Potential additional value: This action will help ensure that the Global Fund identifies, plans for, and develops an approach to address/mitigate risks associated with increased domestic financing for health products. Taking a more systematic approach to addressing these issues will increase the likelihood that previous and forthcoming successes in improving availability, affordability, quality, and optimal product selection are maintained over time.

Requirements: Developing a comprehensive proposal for how the Global Fund can organize and address topics related to sustainability of health product procurement will likely require dedicated, incremental resourcing and engagement across Global Fund teams and at the country level. This proposal will require engagement with Secretariat staff, partners, countries, and topic

experts. The execution of the Wambo pilot can likely be executed by existing teams, but the development and execution of a rigorous evaluation of its long-term implications may require expertise on global market dynamics (e.g., from industrial organization economists[p]), global governance for health, health systems, and other topics.

This action will require engagement from the Global Fund leadership, especially at the MEC level, to ensure coordinated messaging, communication, and execution.

### 5.5 Summary of proposed actions which would likely require incremental resourcing/additional expertise

This section summarizes the proposed actions above which would likely require additional resourcing or expertise. Of course, the decision to dedicate incremental resourcing to these efforts is dependent on many factors beyond the scope of this review, including the capacity of Global Fund teams, other Global Fund priorities, and resources to address other priorities not related to market-shaping. The Global Fund should make sure to provide adequate resourcing for all necessary activities and avoid diverting resources away from ongoing activities to undertake new activities in any way that could put ongoing activities at risk.

- Proposed Action B.i. - The Global Fund should develop fit-for-purpose tools, master data, and standard operating procedures to track health product spend, including demand forecasting, transaction management, reporting / resolution of quality incidents. The Global Fund will likely require additional resourcing and expertise to develop these tools (e.g., technical support for underlying IT, development and training on new standard operating procedures, etc.)
- Proposed Action C.i. - For specific product categories, the Global Fund should develop cross-team technical perspectives (with input from partners) that articulate how market-shaping will contribute to the fight against the three diseases. Given the complexity of TB markets and the Global Fund's historically limited engagement on these markets, developing a Global Fund perspective on them will likely require new technical expertise on TB markets which the Global Fund currently does not have. Given the critical role that many partners play in market-shaping for TB products, any TB product strategies should build on an assessment of TB markets, ideally developed jointly with USAID, Stop TB, and Unitaid, and other key partners.
- Proposed Action D. - Key Global Fund teams should help ensure long-term sustainability of market-shaping successes by developing a systematic approach to addressing these issues. Developing a comprehensive proposal for how the Global Fund can organize and address topics related to sustainability of health product procurement will likely require dedicated, incremental resourcing and engagement across Global Fund teams and at the country level. This proposal will require engagement with Secretariat staff, partners, countries, and experts on various topics (e.g., on industrial organization economics, global governance, and health systems).

[p] Industrial organization/economics is a field dealing with the organization of specific industries and markets.

## 6. How aligned are the mid-term review recommendations with the initiatives listed in the Phase 2 Roadmap?

Key takeaways:

- In Q4 2017, the Global Fund developed a Phase 2 Roadmap for the implementation of the MSS by consulting and aligning internally and externally with partners.
- Due to changes in institutional leadership after the development of the Phase 2 Roadmap, it was never fully implemented, although the SSC Team has undertaken select activities.
- The proposed actions from this Mid-Term Review identify two actions not included in the Phase 2 Roadmap, three actions that are partially aligned to the Phase 2 Roadmap but which have a broader scope or different approach, and one action that is closely aligned with the Phase 2 Roadmap.

In Q4 2017, the SSC Team developed a Phase 2 MSS Implementation Roadmap with internal and external consultations, which consisted of six priorities. In general, these priorities are efforts to strengthen or refine approaches to existing activities, rather than moving into new market-shaping activities:

- Leverage impact by coordinating and sharing information with other buyers
- Use a total cost approach to identify opportunities for price reduction
- Support new product introduction
- Incorporate responsible procurement (i.e., focus on economy, ecology, society, and business) into sourcing
- Share market information by strengthening PQR and market intelligence capabilities
- Strengthen quality assurance through in-country capacity-building, information sharing, and formalizing Global Fund decision-making for quality incidents

Due to changes in institutional leadership after the development of the Phase 2 Roadmap, it was never fully implemented, although the SSC Team has undertaken select activities.

One should note that the Phase 2 Roadmap does not explicitly link the proposed priorities to the six objectives in the MSS. Any decisions to execute activities in the Phase 2 Roadmap and associated communication to Global Fund teams, partners, and Global Fund governance bodies should clearly articulate how the activity will drive value with regard to MSS objectives or other emerging priorities.

This section summarizes the alignment between the recommended actions coming out of this review, and the priorities identified in the Phase 2 Roadmap.

| Proposed action in Mid-Term Review | Related actions in Phase 2 Roadmap |
|---|---|
| A. SSC should continue to drive value on availability and affordability by using its strategic sourcing capabilities and leverage with suppliers | Aligned and important to continue as part of ongoing work of SSC<br>• Priority activities in the Leveraging Impact action of the Phase 2 Roadmap include work on coordination with other buyers and tender approaches to deliver on common strategic objectives<br>• The activities included in the Total Cost Approach and Responsible Procurement actions are important efforts to continue. Responsible procurement is important for the Global Fund's contribution to other SDGs and can be used to drive value when it aligns with other MSS objectives for specific product categories (as has been done for carton-less ARVs and the stabilization of the artemisinin market in the past) |
| B. SSC and GMD should drive stronger health product management across all Global Fund-funded procurement (not just PPM) by strengthening metrics, tools, and systems that monitor health product spend | *See sub-actions below* |
| • B.i. The Global Fund should develop fit-for-purpose tools, master data, and standard operating procedures to track health product spend, including demand forecasting, transaction management, reporting/resolution of quality incidents. | Very closely aligned<br>• Market Information Sharing action in the Phase 2 Roadmap aims to "evolve tools," and "contribute to forecasting"<br>• Quality Assurance action in the Phase 2 Roadmap aims to "systematize QA information sharing"<br>• The "implement lean opportunities" activity in the Total Cost Approach action aims to improve internal processes and ways of working, with clearer accountabilities<br>• The need for a new, fit-for-purpose tool is clearly identified in the Phase 2 Roadmap |

| | |
|---|---|
| • B.ii. The Global Fund should expand its Strategic, Implementation, and Operational KPIs to cover market-shaping objectives beyond availability and affordability, spend channels beyond PPM, and TB product markets | **Not included or only has very limited activities**<br>• Although the Phase 2 Roadmap emphasizes measurable ways of working with partners, it does not propose any specific KPIs |
| C. The Global Fund should drive a stronger institution-wide effort to market-shaping by ensuring that internal teams and core partners align on issues, priorities, and roles/accountabilities for specific product markets | *See sub-actions below* |
| • C.i. For specific product categories, the Global Fund should develop cross-team technical perspectives (with input from partners) that articulate how market-shaping will contribute to the fight against the three diseases. | **Partially aligned**<br>• The New Product Introduction action in the Phase 2 Roadmap mentions a biannual joint stock-take with partners for new products – this could be extended to any market-shaping challenge (not just new product introduction)<br>• The Market Information Sharing action in the Phase 2 Roadmap includes activities to define an "information sharing framework" with partners<br>• The Roadmap does not call for systematic, comprehensive technical perspectives for specific product categories |
| • C.ii. In parallel to developing these product-specific technical perspectives, the Global Fund should also clarify the governance/accountability between SSC, GMD, and TAP for the three activities mentioned above which require input and decision-making on country-level, technical, and sourcing topics. | **Partially aligned**<br>• The New Product Introduction action in the Phase 2 Roadmap identifies the need to more deliberately push for new products<br>• The Roadmap does not identify all the areas where governance and accountability need to be clarified (innovation, scale-up, and product selection) |

| | |
|---|---|
| D. Key Global Fund teams should help ensure long-term sustainability of market-shaping successes and reduce the risk of backsliding on progress by developing a comprehensive approach to addressing risks associated with increased domestic financing | Not included or only has very limited activities<br>• Quality Assurance action in the Phase 2 Roadmap aims to "foster in-country capacity" with respect to regulatory systems<br>• Other than that, there is no comprehensive action to address the risks associated with increased domestic financing in the Phase 2 Roadmap |

We recommend at least two new actions as part of the Mid-Term Review (Proposed Actions B.ii. and D). Other proposed actions align with priorities included in the Phase 2 Roadmap but have a broader scope or different approach (Proposed Actions A, C.i, C.ii). Proposed Action B.i. aligns closely with the Phase 2 Roadmap. The SSC Team could pursue the "Total cost approach" and "Responsible procurement" initiatives as part of Proposed Action A.

## 7. Where could the Global Fund expand its market-shaping mandate in the long-term?

**Key takeaways:**

- Before expanding its market-shaping mandate, the Global Fund should address the limitations and proposed actions described in previous sections.
- At a later date, if the Global Fund wanted to expand its mandate for market-shaping, it could consider expanding into:
  - New stages of the product lifecycle
  - New product categories within the three diseases or new diseases
  - New market-shaping objectives

We believe that the priority for the Global Fund in the next couple of years is to address the limitations and recommended actions described above. At a later date and possibly for the next MSS, the Global Fund could consider expanding its role, building on its current strengths. As described earlier, the Global Fund currently has effective foundational elements for driving availability, affordability, and quality of products procured through PPM ("smart procurement"), and partially effective foundational elements for achieving broader market-shaping objectives across all procurement channels ("proactive market-shaping"). An expansion of mandate could involve expanding the Global Fund's capabilities and focus into at least three different areas:

- New stages of the product lifecycle (e.g., innovation, new product introduction/product selection) for current product categories by taking additional ownership for market-shaping outcomes in these stages
- New product categories within the three diseases (e.g., Indoor Residual Spray for malaria) or new diseases (e.g., sexual and reproductive health)
- New market-shaping objectives (e.g., economic development of countries through local manufacturing or quality testing)

See Figure 24 for a summary of these potential areas of mandate expansion.

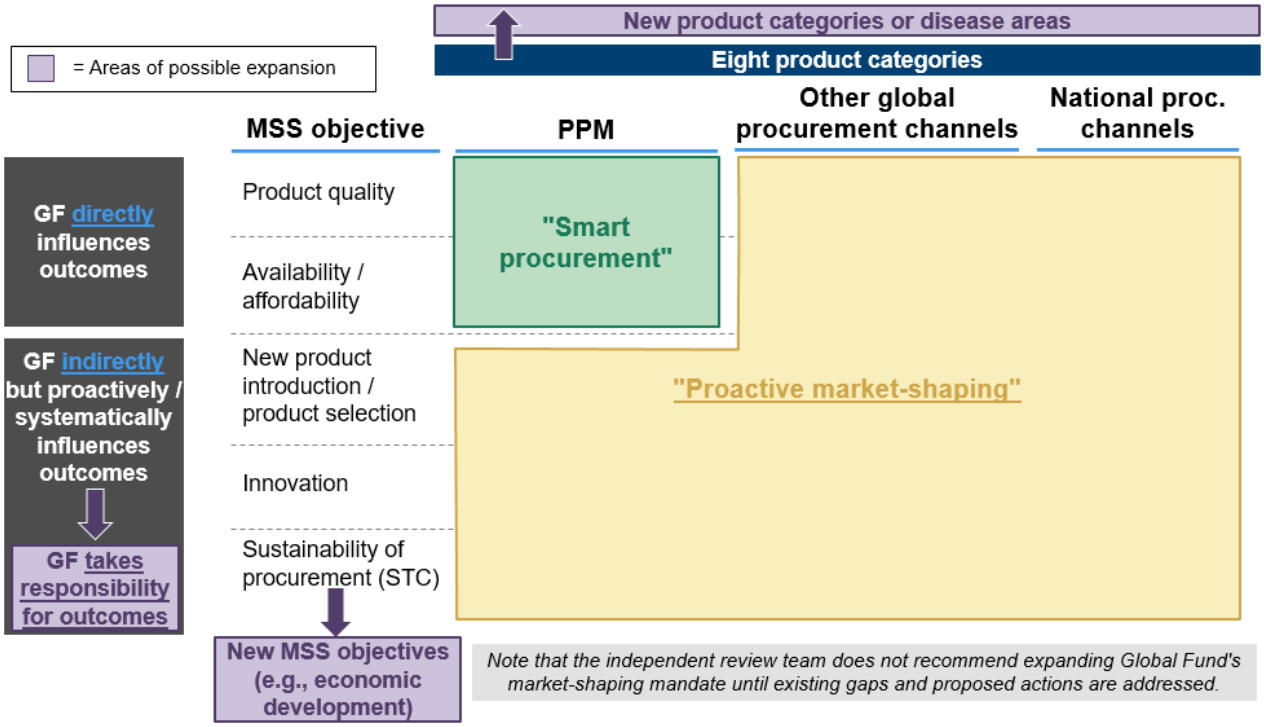



Figure 24 - Potential areas of expansion for the Global Fund

New stages of the product lifecycle: For diseases directly addressed by the Global Fund's market-shaping activities (malaria, HIV), the Global Fund could expand both upstream and downstream along the product lifecycle. Expanding upstream would mean taking on additional influence on product innovation. Expanding downstream would imply playing a more proactive role in product selection to accelerate the phase-out of declining products.

New product categories within the three diseases or new diseases: The Global Fund could decide to use its market-shaping tools for new product categories within malaria and HIV. These could include Indoor Residual Sprays and CD4 diagnostics for already established products and potentially innovative products such as new vector control interventions, e.g., Attractive Toxic Sugar Baits or spatial repellents, in the medium term. The Global Fund could also decide to expand into new diseases. For example, the Global Fund could consider taking a more proactive role in commodities for disease areas such as such as maternal, newborn, and child health and reproductive health (which are closely linked to HIV – the Global Fund already procures some products for Hepatitis B, Hepatitis C, Syphilis), and neglected tropical diseases (which may have similar market-shaping needs as malaria with regard to vector control). This has, in fact, already happened for some diseases with the extension of the ARV tender to Hepatitis B and Hepatitis C medicines.

New market-shaping objectives: Finally, the Global Fund could expand into new market-shaping objectives. These could include: "Economic development" to promote the development of the local economy through local manufacturing, quality testing, etc. (the Global Fund already partly addresses this topic through the African manufacturing footprint criterion is its tenders); "Appropriate design," the degree to which product design maximizes end-user requirements such

as cultural acceptability and ease of use; and "Awareness," the extent to which end-users, health care providers, and key influencers can make informed choices about product use.

As the Global Fund considers new areas for market-shaping, it will be important to consider:

- What gaps exist in the global market-shaping landscape?
- What capabilities would be required to enter that space?
- Does the Global Fund have the appropriate positioning to enter that space?
- What added value could the Global Fund bring to that space?

The Global Fund should not expand its mandate into any areas which would divert resources away from existing market-shaping priorities, possibly putting them at risk.

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