

34th Board Meeting

Market Shaping Strategy

Annex 1 to GF/B34/17 – Revision 1
Board Decision

PURPOSE: To present the full amended and restated Market Shaping Strategy as an Annex to the Board decision paper.

Acronyms

ACT	Artemisinin-Based Combination Therapy
ARV	Anti-Retroviral
BMGF	Bill and Melinda Gates Foundation
CHAI	Clinton Health Access Initiative
COIM	Co-Infections and Co-Morbidities
CPP	Coordinated Procurement Planning
DFID	United Kingdom Department for International Development
EID	Early Infant Diagnosis
ERP	Expert Review Panel
FIND	Foundation for Innovative New Diagnostics
FOPC	Finance and Operational Performance Committee
GDF	Global Drug Facility
HPM	Health Product Management
IRS	Indoor Residual Spraying
KPI	Key Performance Indicator
LFA	Local Fund Agent
LLIN	Long-Lasting Insecticidal Net
MDC	Market Dynamics Committee
MEC	Management Executive Committee
MOU	Memorandum of Understanding
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
P4i	Procurement for Impact
PAHO	Pan-American Health Organization
PAPWG	Paediatric ARV Procurement Working Group
PDP	Product Development Partnership
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PFSCM	Partnership for Supply Chain Management
PMI	U.S. President's Malaria Initiative

PPM	Pooled Procurement Mechanism
PQR	Price and Quality Reporting
PR	Principal Recipient
PSM	Procurement and Supply Management
RDT	Rapid Diagnostic Test
SIIC	Strategy, Investment and Impact Committee
TERG	Technical Evaluation Reference Group
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
VL	Viral Load
VPP	Voluntary Pooled Procurement
WHO	World Health Organization
WHOPES	WHO Pesticide Evaluation Scheme

Definitions¹

Diagnostic product –any durable or non-durable in vitro diagnostic product and microscopes and imaging equipment used in Global Fund-financed programs for diagnosis, screening, surveillance or monitoring purposes.

Expert review panel (ERP) – a panel of independent experts to review the potential risks/benefits associated with the use of finished pharmaceutical products or diagnostic products, and to make recommendations to the Global Fund as to whether such products may be procured with Global Fund grant resources. The panel is hosted by the World Health Organization's (WHO) Quality and Safety of Medicines department in the case of pharmaceutical products.

Finished pharmaceutical product (FPP) – a medicine presented in its finished dosage form that has undergone all stages of production, including packaging in its final container and labeling.

Fixed dose combination (FDC) – a combination of two or more active pharmaceutical ingredients in a fixed ratio of doses.

Health products – includes: (i) pharmaceutical products; (ii) durable and non-durable in vitro diagnostic products, microscopes and imaging equipment; (iii) mosquito nets; and (iv) consumable/single-use health products (including condoms, insecticides, therapeutic nutritional support, general laboratory items and injection syringes), which are financed out of grant funds.

Innovation – the process of creating new compounds, therapeutic models, products, or formulations. This can range from basic research that results in new scientific principles or the discovery of new biological pathways to the translation of these conceptual advances into “first-in-class” products to adapting and improving existing products (especially relevant for use in low-resource settings).

Long-lasting insecticidal mosquito net (LLIN) – is a factory-treated mosquito net made with netting material that has insecticide incorporated within or bound around the fibers. The net must retain its effective biological activity without retreatment for at least 20 WHO standard washes under laboratory conditions and three years of recommended use under field conditions.

Manufacturer – means any natural or legal person with responsibility for design and/or manufacture of health products with the intention of making it available for use, under the Manufacturer's name; whether or not such a Diagnostic Product is designed and/or manufactured by the Manufacturer itself or on its behalf by another person(s).

Pharmaceutical products or medicines – means an active pharmaceutical ingredient that is intended for human use.

Pharmaceutical and other health products management country profile and procurement plan – or procurement and supply management plan refers to the set of documents that recipients intending to procure health products with grant funds must submit to the Global Fund for approval. These documents are intended to provide information on the procurement and supply management processes and systems, any strengthening measures for the procurement and management of health products, a complete list of health products to be procured using grant funds, associated costs, and all assumptions used for quantification.

Procurement – The process of purchasing or otherwise acquiring any health product for human use. For the purpose of this document, procurement means the pre-selection of products and manufacturers through a procedure of qualification, including prequalification (see below) and continuous monitoring

¹ Definitions drawn from the Global Fund's existing Quality Assurance Policies for Pharmaceutical Products (December 2010) and Diagnostic Products (February 2014), as well as its Guide to Global Fund Policies on Procurement and Supply Management of Health Products (June 2012).

thereafter, purchase of the prequalified products from prequalified manufacturers (linked to the specific product) through defined purchasing mechanisms, storage and distribution.

Procurement and supply management – refers to all procurement, supply and distribution activities required to ensure the continuous and reliable availability of sufficient quantities of quality-assured, effective products to end-users, procured at the lowest possible prices in accordance with national and international laws.

Product formulation – an active pharmaceutical ingredient (or combination of ingredients), dosage form and strength. Note: different FPPs may exist for the same product formulation.

Quality assurance – is the totality of the arrangements to ensure that health products are of the quality required for their intended use, including quality monitoring.

Quality control – part of quality monitoring and includes all measures taken, including the setting of specifications, sampling, testing, and analytical clearance, to ensure that health products conform to established specifications.

Quality monitoring – all activities undertaken to ensure that health products continue to conform to the manufacturer's established quality specifications during the storage, distribution and use of such products, including quality control in a laboratory.

Malaria Rapid Diagnostic Test – means immuno-chromatographic lateral flow devices for the detection of malaria parasite antigen, and designed to provides a result timely enough to inform immediate treatment (e.g. within 60 minutes).

Recipient – means any entity that receives grant funds (such as a Principal Recipient, sub-recipient, sub-sub-recipient or procurement agent), as the context may require.

Stringent pharmaceutical regulatory authority (SRA) – means a regulatory authority participating in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Sustainability – the ability of a health program to reach and maintain service coverage at a level that will provide continuing control of a health problem even after the removal of external funding.

Total cost of ownership – the total amount of all direct and indirect monetary costs related to the procurement, storage and distribution of a diagnostic product by a recipient, including the price of the product itself, any reagents and other consumables, transportation, customs clearance, insurance, in-country distribution and storage, quality assurance (including quality monitoring, training, and validation of new diagnostic algorithms), and, as applicable, operating costs including cost of installing, servicing, commissioning and maintaining equipment.

Transition – the mechanism by which a country moves toward fully funding and implementing its health programs independent of donor support (financial or otherwise). For the Global Fund, transition includes transition from support altogether or to a decreased level of support due to income classification change.

WHO Prequalification Programme – means the programme managed by WHO which prequalifies: (a) pharmaceutical and other health products that are considered to be acceptable for procurement by the United Nations and specialized agencies; and (b) laboratories for quality control of such products.

Annex 1: Amended and Restated Market Shaping Strategy

I. Introduction

1. The Global Fund plays a significant role in global markets for health products related to HIV/AIDS, tuberculosis and malaria as a financing institution and by negotiating procurement terms for a portion of the health products it finances through its Pooled Procurement Mechanism (PPM). In 2013, approximately 45% of the USD \$3.9 billion disbursed by the Global Fund was used to finance the procurement of health products.² This is consistent with the Global Fund's financing of health commodities in earlier years.³ Of the nearly USD \$1.8 billion used to finance health products in 2013, about 60% or approximately USD \$1.1 billion was financed through the PPM. Access to these critical health products is a key dimension of sustaining the progress achieved over recent years in the fight against HIV/AIDS, tuberculosis and malaria.

2. As a large financing institution that also negotiates procurement terms on behalf of some countries through the PPM, the Global Fund will impact markets simply by interacting with them, both on the supply and demand side. However, the Global Fund also has the opportunity to leverage its unique market position to improve access to health products, though this requires careful consideration of the potential unintended consequences of its actions.⁴ As part of the 2011 Market Shaping Strategy, the Board "further emphasized its desire for the Global Fund to more actively shape the markets for health products to optimize price, quality, design and sustainable supply."⁵ The Global Fund's recent market shaping efforts and its strategy going forward reflect this mandate.

3. In order to achieve its overall mission and strategic objectives, as well as reflect the evolution of the Global Fund's sourcing capabilities and approach, the Global Fund is revising its Market Shaping Strategy. 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.

4. The **second** section of this document reviews the Global Fund's historical market shaping efforts, including implementation of the 2011 Market Shaping Strategy, and provides an overview of the current context for this strategy. The **third** section discusses the vision, guiding principles and scope of the Market Shaping Strategy, while the **fourth** addresses the Global Fund's market shaping approach, including its conceptual framework, relevant tools and foundational elements. The **fifth** section lays out the objectives of the strategy, including highlighting how the Global Fund's tools are likely to be applied and identifying initiatives that apply across product categories. Finally, the **sixth** section discusses implementation of the strategy, including sequencing and timeline, resource requirements and evaluation plan.

II. Background

5. The Global Fund has a history of deliberately leveraging its position to shape markets for health products, contributing to improved health outcomes, increased value for money and more stable product availability. As early as 2004, the Global Fund supported a more rapid transition from

² GF/SIIC15/06: "Procurement for Impact." June 2015.

³ GF/B23/9: "Report of the Market Dynamics and Commodities Ad-Hoc Committee." May 2011.

⁴ "Unintended consequences" refers to the risk of undesirable market outcomes that can arise due to inherent trade-offs between different dimensions of market health or between short-term and long-term objectives. Managing these risks is discussed further in Section VI.

⁵ GF/B23/9: "Report of the Market Dynamics and Commodities Ad-Hoc Committee." May 2011.

suboptimal therapies for the treatment of malaria to highly effective artemisinin-based combination therapies (ACTs).⁶ Working closely with the World Health Organization (WHO), the Global Fund facilitated countries to rapidly switch to more effective ACTs. Distribution of ACTs increased from less than 1 million treatments in 2003 to 190 million from 2004 – 2007. Competition in the market increased and the price fell more than 50 percent over five years.

6. In 2007, the Board approved the Global Fund's first Market Shaping Strategy, calling for the Global Fund to play "a deliberate and strategic role in improving the impact of grants by influencing market dynamics."⁷ This strategy also resulted in the creation of the Voluntary Pooled Procurement (VPP) and Price and Quality Reporting (PQR) mechanisms to support this strategy. Since then, the Global Fund has partnered with other international actors on a number of market shaping initiatives, including (but not limited to) the examples described below. These initiatives directly contribute to improving health outcomes, for example by increasing the number of people protected from malaria by long-lasting insecticidal nets (LLINs) or ensuring a secure supply of anti-retroviral medicines (ARVs) for children with HIV.

- a. Coordinating the Paediatric ARV Procurement Working Group (PAPWG) and its Procurement Consortium, in partnership with UNITAID, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), CHAI, UNICEF, the Partnership for Supply Chain Management (PFSCM), Supply Chain Management Systems (SCMS), the Pan-American Health Organization (PAHO), the Organization of Eastern Caribbean States, and several large country buyers (Kenya, Ethiopia). This has effectively consolidated its members' procurements in the fragile paediatric ARV market around an optimal formulary list and reduced lead times for many products;
- b. Implementing Quality Assurance policies for pharmaceutical and diagnostic products, which ensure that the nearly USD \$1.8 billion in health products financed by the Global Fund are available at an internationally recognized standard of quality;
- c. Improving demand forecasting for LLINs, ACTs and ARVs (in partnership with other large financing institutions, such as PEPFAR and the President's Malaria Initiative [PMI], as well as UNITAID and WHO), and leveraging those forecasts to make volume commitments through a pooled procurement mechanism, which are projected to result in significant savings over two to three years;
- d. Consolidating demand around optimized specifications for LLINs for many recipients, resulting in significant savings which could be used to extend coverage. For example, in one large country, savings were used to fill a coverage gap of over 1 million LLINs;
- e. Stabilizing price volatility for LLINs of the same specifications through long-term supplier agreements and a price adjustment mechanism based on underlying raw material costs, reducing price variance in 2014 and 2015 by over 70 percent compared to 2010 – 2012; and
- f. Responding to potential stock-outs and emergency orders for core ACTs and ARVs, preventing potential supply disruptions in two countries during the first six months after implementing contractual provisions for vendor-managed inventory.

7. In 2011, the most recent Market Shaping Strategy was developed by the Board's Market Dynamics Committee (MDC). It included a framework to categorize markets and determine the appropriate interventions, applying the framework to the ARV category, generating a set of specific

⁶ Ibid.

⁷ GF/B14/DP15: "Role of the Global Fund in Market Dynamics." November 2006.

recommendations to sustain supply in the fragile paediatric market, introduce new ARVs and optimize value for money across products. It also emphasized the importance of the VPP as a market shaping tool, incorporating a number of policy changes to allow the VPP to more effectively pool volumes, coupling this with investment in building country procurement capacity.⁸

01 Context for the revised Market Shaping Strategy

8. Past market shaping efforts by the Global Fund and its partners have yielded significant impact, particularly in promoting greater availability and affordability for a core set of products. However, there are still market factors that prevent access to affordable, quality-assured products or the introduction and adoption of needed new products. There are various root causes, including limited market information, small size, low growth or returns in a given market, high barriers to entry or high transaction costs. Without intervention, this frequently leads to lack of product availability and supply disruptions, unaffordable prices, slow introduction and adoption of new products in some markets, and a lack of products designed to meet the needs of low- and middle-income countries.

9. The landscape reports regularly published by UNITAID provide a comprehensive overview of current market shortcomings across preventive, diagnostic and treatment products.⁹ In addition, the Global Fund has conducted its own analyses of current challenges in the markets for LLINs, ACTs, ARVs, and viral load and early infant diagnostic products to inform its procurement strategies to-date. Both the landscape reports and the Global Fund's analyses highlight challenging market dynamics for products such as new first-line ARVs, paediatric tuberculosis formulations, and products for the treatment of severe malaria. Current challenges are not limited to these products, but this provides a glimpse into the cross-cutting nature of market shortcomings yet to be resolved.

10. It is also important to place these market challenges in the context of the global strategies and targets for HIV, TB and malaria which anchor the work of different actors, especially as many of these strategies have recently undergone or will undergo revision. These include the End TB Strategy (2016-2035), the Global Technical Strategy for Malaria (2016-2030), the UNAIDS Fast Track Strategy and 90-90-90 targets, and the WHO HIV strategy to be presented to the World Health Assembly in May 2016.¹⁰ These strategies lay out the global goals and targets which the Global Fund's market shaping efforts ultimately support, as well as driving certain market implications. For example, the 90-90-90 initiative and the emerging thinking described in the Vancouver Consensus from the International AIDS Society Conference in 2015 are likely to drive increased demand for HIV diagnostics, ARV treatment and pre-exposure prophylaxis.¹¹ Market shaping efforts can support product selection decisions as countries determine how to implement this approach and facilitate the availability and affordability of critical products to maximize funding envelopes. Likewise, market shaping interventions could further the objectives of the Global Technical Strategy for Malaria. For example, efforts to accelerate product introduction would support the call for the "development and adoption of innovative solutions ... to respond to the spread of insecticide resistance and residual transmission".¹²

11. The Global Fund also supports countries in obtaining quality-assured products at the lowest cost and supports the use of TRIPS flexibilities in compliance with national laws and international obligations to protect public health, as set out in the Global Fund's Framework Document and the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (2012). The

⁸ Implementation of the 2011 Market Shaping Strategy was the subject of an independent evaluation commissioned by the Global Fund's Technical Evaluation Reference Group (TERG). It was also separately discussed in a prior paper to the SIIC and the FOPC (GF/FOPC15/07: "Market Shaping Strategy Development Update." July 2015.)

⁹ See: <http://www.unaids.org/resources/publications/technical-reports>.

¹⁰ "End TB Strategy: Global strategy and targets for tuberculosis prevention, care and control after 2015." World Health Organization, 2015. "Global Technical Strategy for Malaria: 2016-2030." World Health Organization, 2015. "Fast-Track: Ending the AIDS Epidemic by 2030." UNAIDS, 2014.

¹¹ Ibid. <http://www.vancouverconsensus.org>.

¹² Ibid.

Global Fund does not prescribe how countries implement their obligations and flexibilities under TRIPS, as those decisions remain the responsibility of each country.

12. The Global Fund faces the unique challenge of working in a broad variety of product and country markets. It has nearly 500 active grants to over 140 countries across three diseases and health systems strengthening. It finances the procurement of hundreds of health products within eight core categories¹³, as well as other health products.¹⁴ Compared to other financing institutions that can engage in market shaping, this is a broad scope.¹⁵ While this presents a tremendous opportunity for impact, it also increases the complexity of the Global Fund's market shaping efforts. It is critical that the Global Fund take a nuanced approach to market shaping and tailor its interventions to the dynamics of the specific product or country.

13. This complexity extends to the channels through which Global Fund-financed products are procured, which also has substantial implications for the Global Fund's ability to shape markets. Figure 1 provides an overview of the Global Fund's different procurement channels. The Global Fund will have greater ability to shape markets through the PPM, which is described further in Section IV. Where products are procured directly by recipients or through Procurement Service Agents (PSAs) acting on behalf of recipients, the Global Fund is primarily engaged on the demand side of the market. This is similarly the case for tuberculosis products, where recipients manage their own procurements and the Stop TB Partnership's Global Drug Facility (GDF) are more involved on the supply side. A Memorandum of Understanding (MOU) is under development between the Global Fund and GDF that will more specifically describe the relationship between the two organizations with regards to market shaping and procurement of Global Fund-financed tuberculosis products.

14. While the Market Shaping Strategy looks primarily at ways to increase access to health products, resilient systems for health are also critical to ensure these products are delivered effectively. To this end, the Global Fund is separately developing an investment strategy for in-country supply chain management. However, the Market Shaping Strategy is also a vehicle to deliver on the Global Fund's mandate to build resilient and sustainable systems for health. Most directly, one of the strategic objectives discussed in Section V focuses significantly on capacity-building and strengthening in-country procurement and supply management (PSM) capacity, as well as strengthening regulatory institutions. In addition, investments in PSM systems have been identified as a priority area for grant-making to support resilient and sustainable systems for health. Other strategic objectives may also contribute to building resilient systems for health and this will be noted where applicable.

15. To inform the Market Shaping Strategy revision process, the Global Fund Secretariat undertook a consultative process that incorporated input from over 30 partner organizations, civil society, donors and the private sector. In addition, the strategy revision was informed by a Thematic Review conducted by external consultants commissioned by the Global Fund's Technical Evaluation Reference Group (TERG). Finally, the Secretariat conducted additional analysis of the implementation of the 2011 Market Shaping Strategy, the market shaping partner landscape and the current status of foundational elements for market shaping.¹⁶ This was informed by review of relevant documents and resources developed by partner organizations, such as UNITAID's technical landscape reports and USAID's Market Shaping Primer and Introduction and Scale Guide.¹⁷

¹³ ACTs, ARVs, LLINs, rapid diagnostic tests for HIV and malaria, other HIV diagnostics, tuberculosis medicines and tuberculosis diagnostics.

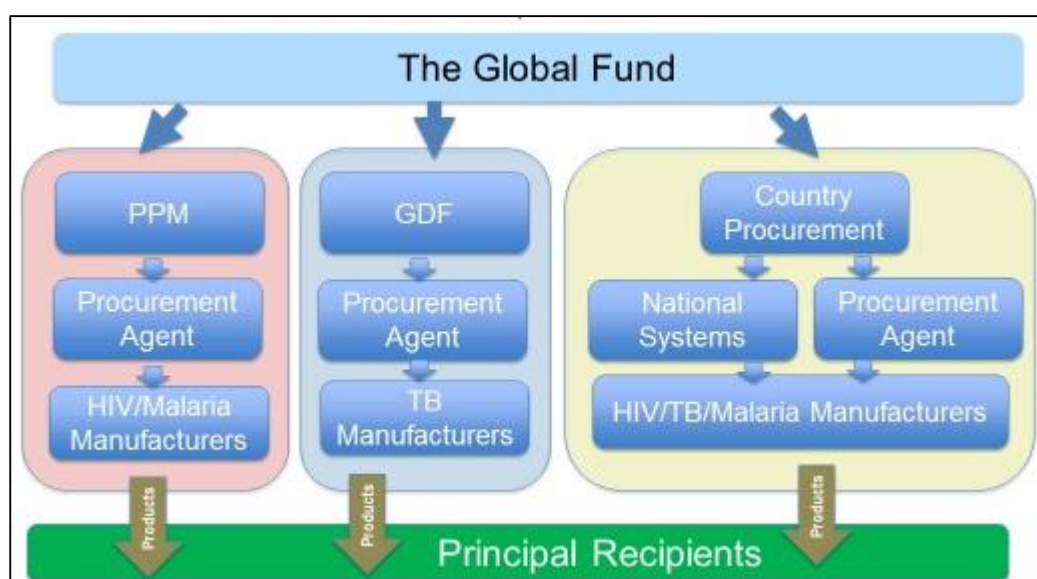
¹⁴ Such as condoms, drugs for opportunistic infections and laboratory supplies.

¹⁵ For example, according to its website, the Gavi Alliance works in one product category (vaccines) across 69 countries. Likewise, websites for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the President's Malaria Initiative (PMI) indicate that they support 31 countries and four regions or 19 countries and one sub-region, respectively.

¹⁶ GF/FOPC15/07: "Market Shaping Strategy Development Update." July 2015.

¹⁷ <http://www.unitaid.org/resources/publications/technical-reports/>. "Healthy Markets for Global Health: A Market Shaping Primer" and "Idea to Impact: A Guide to Introduction and Scale." USAID Center for Accelerating Innovation and Impact. Available at <http://www.usaid.gov/cii/>.

Figure 1: Global Fund procurement channels



III. Vision, guiding principles and scope

16. This section describes the parameters which define the Market Shaping Strategy, including the overall vision and guiding principles for the Global Fund's market shaping efforts, followed by the strategy scope.

01 Vision

17. The Global Fund plays a proactive, deliberate and strategic role in shaping markets to facilitate access to products and improve health outcomes for people living with HIV/AIDS, tuberculosis and malaria. Its efforts are grounded in the Global Fund's overall mission of making a sustainable and significant contribution in the fight against AIDS, tuberculosis and malaria in countries in need.¹⁸ Through the Market Shaping Strategy, the Global Fund will contribute to health outcomes by leveraging its position to facilitate healthier global markets for health products, today and in the future. This vision reiterates the importance of a proactive approach and emphasizes the linkage between the Global Fund's market shaping efforts and its focus on health outcomes. It also highlights that the Global Fund will consider market health more broadly than focusing solely on its own outcomes and will take both a short-term and long-term view in its strategies.

02 Guiding principles

18. As with all of the Global Fund's work, its market shaping strategy is anchored in the core principles that form the foundation of the Global Fund's Framework Document.¹⁹

19. In addition, there are several guiding principles that describe how the Global Fund will approach market shaping. When applying the Market Shaping Strategy to specific product categories or cross-cutting initiatives, the Global Fund will be:

- a. **Focused.** As described below, the Global Fund will limit the scope of its market shaping efforts. It will focus on health product markets that are related to the three

¹⁸ "The Global Fund Strategy Framework 2012 – 2016: Investing for Impact." <http://www.theglobalfund.org/about/strategy>.

¹⁹ "The Framework Document of the Global Fund to Fight AIDS, Tuberculosis and Malaria." 2001.

diseases and where the Global Fund has sufficient leverage to shape the market or could play a catalytic role.

- b. **Sustainable.** The Global Fund will address the impact of its market shaping interventions on country capacity and long-term market viability. It will also assess the implications of country transition on market dynamics. The Global Fund will seek to limit the need for its ongoing intervention to sustain a market, though recognizing that this may not be possible for certain fragile or neglected markets (such as paediatric tuberculosis medicines).
- c. **Flexible.** Within the scope of this strategy, market shaping interventions will be tailored to the specific needs or challenges faced in global, regional or country markets.
- d. **Complementary to partners.** The Global Fund will focus its market shaping interventions on areas that are not already addressed by partner activities and leverage its comparative advantage, as well as joining with partners to enhance the effectiveness of collaborative market shaping efforts. It will work closely with a range of partners to design and implement market shaping interventions.
- e. **Balanced.** While striving to resolve a specific market shortcoming, the Global Fund will also seek to avoid unintended consequences on other dimensions of market health or other market segments.²⁰

20. Given the diversity of organizations whose work shapes or influences global markets for health products (such as UNITAID, WHO, PEPFAR, PMI, GDF and many others) and the complexity of the partner landscape, it is worth outlining where the Global Fund will partner with other organizations in a complementary way. The Global Fund will generally focus its market shaping efforts “downstream” on products that are at growing, mature or declining stages of the product life cycle. This role is aligned with the Global Fund’s role as a financing institution and its capabilities in sourcing, gathering market information and informing product selection.²¹ It will align and collaborate with other large financing institutions on issues related to forecasting, product selection and strategic sourcing, such as PEPFAR, PMI, UNICEF and GDF. On product selection issues and especially cost effectiveness analysis, the Global Fund will also partner with organizations that have expertise in health technology assessment (HTA), such as the United Kingdom’s Department for International Development (DFID), NICE International and other technical assistance partners, as well as in-country HTA agencies, such as Thailand’s Health Intervention and Technology Assessment Program (HITAP). It will also partner with organizations like the Clinton Health Access Initiative (CHAI) and WHO on forecasting and other market analysis.

21. For products that are emerging, the Global Fund will work closely with UNITAID and other technical and development organizations that focus further “upstream”, collaborating to ensure that products are effectively introduced and scaled. The Global Fund also relies on technical and development partners to drive market shaping activities for products further upstream in the pipeline. For example, UNITAID provides expertise on new product introduction, demand generation and intellectual property. Likewise, the Bill & Melinda Gates Foundation (BMGF) has expertise in product introduction, as well as research and development and the creation of target product profiles. WHO also plays a key role in informing and synthesizing ongoing research, shaping product selection through its Essential Medicines Model List, developing treatment guidelines, and quality assurance. Organizations like the Medicines for Malaria Venture (MMV), the TB Alliance, and the Foundation for

²⁰ “Unintended consequences” refers to the risk of undesirable market outcomes that can arise due to inherent trade-offs between different dimensions of market health or between short-term and long-term objectives. Managing these risks is discussed further in Section VI.

²¹ GF/FOPC15/07: “Market Shaping Strategy Development Update.” July 2015.

New and Innovative Diagnostics (FIND) are also critical actors in driving research and development. PEPFAR is also involved in funding research and development and product introduction planning.

22. Furthermore, the Global Fund's implementation of the Market Shaping Strategy will follow several additional operational guidelines, including:

- a. The Global Fund will assess the risks and benefits of potential market shaping interventions and actively manage these risks on an ongoing basis. More detail on the risk management approach for market shaping is described in Section VI, which will also make use of the Global Fund's existing risk management tools.
- b. It will also provide visibility into its own market shaping efforts and promote visibility across stakeholders.
- c. The Global Fund will leverage external expertise and diverse perspectives. While the Global Fund's Board and its committees will continue to provide oversight for market shaping (as discussed in Section VI)²², the Secretariat will implement mechanisms to solicit expertise and input from stakeholders.
- d. The Global Fund will apply a consistent set of criteria to prioritize among market shortcomings to address, including the potential for impact, the Global Fund's ability to effectively influence the market, and any risks or benefits with regards to long-term market viability. In addition, it will consider the Secretariat's capacity to implement new interventions.

03 Scope

23. The Market Shaping Strategy will cover an implementation period that begins at the start of 2016 and concludes upon the end of the final year of the Global Fund's organizational strategy, subject to a mid-term review conducted by the TERG and reported to the SIIC. However, the approach and some strategic actions also consider needs and challenges beyond this period. Recognizing that the dynamics of individual product markets change rapidly, this strategy lays out an approach that can guide the Global Fund's market shaping efforts across categories, as well as a set of tools and cross-cutting strategic actions that can strengthen or enable its work across categories. It does not discuss market shaping strategies or interventions for specific products or categories. These will be developed through product- or category-specific strategies, referenced throughout the strategy and described further in Section VI.

24. The Market Shaping Strategy is focused on medicines or technologies that prevent, diagnose or treat the three diseases and where the Global Fund can reasonably expect to influence the market. This includes health products currently financed in large volumes, such as ARVs, ACTs, LLINs, tuberculosis medicines, rapid diagnostic tests (RDTs) for HIV and malaria, and diagnostic products for HIV and tuberculosis. It also includes health products where the volumes financed by the Global Fund may be small, but they represent a large proportion of the market, such as fragile or declining markets. Given the Global Fund's relationship with the GDF for the procurement of tuberculosis medicines, it will likely be less directly involved in shaping markets for these products than for those related to HIV, malaria or tuberculosis diagnostics.

25. The Global Fund may also shape markets for new products that represent a smaller proportion of the health products financed by the Global Fund. Because such products may have a smaller overall market size, the Global Fund can potentially play a catalytic role in the further growth and maturation of these products. Some examples of these products could include (but are not limited to) point-of-care

²² GF/B32/DPo8: "Market Dynamics Oversight." November 2014.

HIV diagnostics, new paediatric formulations of tuberculosis medicines or new anti-malarial medicines. For these products, the Global Fund will engage closely with technical and development partner organizations that focus on product development, product introduction and market creation (such as UNITAID, BMGF, PEPFAR and others) to ensure that its efforts are complementary and support the work of these organizations.

26. Historically, the Global Fund has financed products related to both co-infections and co-morbidities²³ (COIM) and for distribution in the private retail sector.²⁴ These products are not a focus for new market shaping activities as part of this strategy. However, if specific market shortcomings are identified which the Global Fund could address, it may implement targeted interventions on an ad hoc basis (within its mandate and without detracting from other market shaping efforts). In particular, the Global Fund will monitor the demand for COIM products and the associated need for market shaping interventions as the Global Fund's policy on financing COIM interventions is implemented. It should be noted that the Global Fund's supply chain strategy may place a greater emphasis on the inclusion of private sector mechanisms. Furthermore, countries may continue to request the use of approved grant funds for private sector distribution of ACTs via the Co-Payment Mechanism.²⁵ Given the Global Fund's existing policy on financing COIM interventions, proposed interventions in these markets will be approved by the SIIC prior to implementation. Proposed interventions in private sector markets will be reviewed by the SIIC and recommended to the Board for approval until such time that a broader policy on financing private sector interventions is developed.

27. Several areas are defined as outside the scope of the Market Shaping Strategy. While the Global Fund finances the procurement of non-health products and services, these are not in scope. Strategies related to in-country supply chain and product delivery are addressed through other areas of work by the Global Fund.

IV. Market shaping approach

28. This section outlines the Global Fund's approach to market shaping, including a framework to describe market health, the tools that the Global Fund can currently use to shape markets, and foundational elements that are necessary for the Global Fund to effectively implement the Market Shaping Strategy. These elements provide a conceptual structure for the Market Shaping Strategy and support its implementation.

01 Framework for market health

29. Given the close collaboration between UNITAID and the Global Fund on market shaping, both organizations recognize the value of harmonizing existing frameworks and arrive at a common definition of optimal market conditions to support health outcomes. Historically, UNITAID and the Global Fund each used its own framework to identify market shortcomings, which can result in the two organizations using different language to describe the same issue or using the same language when referring to two different market shortcomings.

30. This harmonized framework is intended to help identify specific challenges or opportunities in a given market by envisioning the optimal state as a basis for comparison. It does not replace the need for quantitative indicators. For example, to assess and monitor affordability, the Global Fund might track product prices, as well as contributing factors such as competition in a given market or the price and availability of active pharmaceutical ingredients. Figure 2 lays out the harmonized framework for the dimensions of market health developed jointly by UNITAID and the Global Fund.

²³ GF/B33/DPo8: "Policy on Co-Infections and Co-Morbidities." April 2015.

²⁴ "Affordable Medicines Facility-malaria: Phase 1 Independent Evaluation." October 2012.

²⁵ GF/B28/DPo6: "Integration of the Lessons from the Affordable Medicines Facility – malaria." November 2012.

Figure 2: Harmonized dimensions of market health

Dimension	Definition
Innovation	There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers.
Availability	New and/or superior evidence-supported, quality-assured products are rapidly introduced in the market and made available to those in low- and middle-income countries. Adequate and sustainable supply exists to meet global needs.
Demand and adoption	Countries, programmes, providers (e.g., healthcare providers, retailers), and end users rapidly introduce and adopt the most cost-effective products (within their local context).
Quality	Medicines and technologies are available at an internationally-recognized standard of quality, and there is reliable information on the quality of the product. This includes not only the quality of the final, finished product, but also the quality of starting and intermediary materials used to manufacture the final product. ²⁶
Affordability	Medicines and technologies are offered at the lowest possible price that is sustainable for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals, or other payers.
Delivery	Supply chain systems (including quantification, procurement, storage, and distribution) function effectively to ensure that products reach end users in a reliable and timely way. ²⁷

31. This framework will be applied to markets for medicines or technologies to effectively prevent, diagnose or treat a particular disease or condition. Market-shaping efforts should ensure that interventions focused on one dimension do not have negative long-term consequences on other dimensions. In addition, the goal of long-term market viability with limited intervention from international public actors should be considered in any market shaping intervention. However, this may not be applicable to fragile or neglected markets, such as medicines for paediatric tuberculosis.

02 Market shaping tools

32. The Global Fund currently has seven primary “tools” it can use to implement market shaping interventions. Many of these can contribute across multiple dimensions of market health described above. When implemented, the e-marketplace may also support the objectives of the Market Shaping Strategy. Current “tools” include:

- a. The **Price and Quality Reporting** mechanism (PQR), a public database that captures transaction-level procurement data on core health products financed by the Global Fund;

²⁶ For the Global Fund, this is operationalized through its existing Quality Assurance policies. Global Fund Quality Assurance Policy for Pharmaceutical Products, December 2010. Global Fund Quality Assurance Policy for Diagnostic Products, February 2014.

²⁷ For the Global Fund, delivery shortcomings are primarily addressed by HPM Specialists within the Grant Management Division. A separate strategy focused on supply chain investment is currently in development.

- b. The Global Fund's **Quality Assurance** policies for pharmaceutical products and diagnostic products²⁸, and its quality requirements for other health products. This also includes the **Expert Review Panel** to accelerate the procurement of products for which there are few quality-assured suppliers;
- c. The **Pooled Procurement Mechanism** (PPM), through which the Global Fund can consolidate recipient demand for health products and negotiate procurement terms on behalf of recipients. The PPM is also a vehicle to deploy a variety of strategic procurement practices, as described in Section V. Examples could include (but are not limited to) demand forecasting, variant reduction, split tenders, framework contracts, and volume commitments;
- d. A limited **revolving fund** to support new product introduction;
- e. The Global Fund's **Guide to Procurement and Supply Management (PSM) Policies**,²⁹ which details the legal obligations that apply to Global Fund-financed health products, as well as other strongly recommended best practices for PSM;
- f. Guidance provided by the Grant Management Division's **Health Product Management Specialists** (HPM Specialists), who interface with Principal Recipients (PRs) on PSM topics throughout the grant-making and grant implementation process, as well as monitoring grant compliance with the procurement policies described above; and
- g. **Cost-effectiveness analysis** commissioned by countries with Global Fund financing or centrally via the Global Fund's Value for Money special initiative, which can inform country priority-setting and selection of health technologies.

03 Foundational elements for market shaping

33. In addition to the market shaping tools described above, there are a set of foundational elements that must be in place for the Global Fund to effectively implement the Market Shaping Strategy and specific interventions. For example, the 2011 Market Shaping Strategy included substantial emphasis on the policies and processes associated with the VPP. Foundational elements include:

- a. **Mandate:** A clear mandate for market shaping that is consistent with and supported by the Global Fund's governance and core documents (including its Charter and Framework Document), as well as the most impactful role the Global Fund can play within the partner landscape and with available tools.
- b. **Team and capabilities:** Sufficient human resource capacity with the right mix of capabilities is in place to execute the strategy. Clear roles and responsibilities for market shaping initiatives are defined within the organizational structure.
- c. **Data:** Data is available to enable a holistic understanding of key markets (including supply and demand). It is accessible, updated regularly and easy to use, with one sole source of truth.
- d. **Processes and policies:** Efficient and effective processes exist to incorporate market shaping into strategy development, implement key initiatives, monitor outcomes and

²⁸ GF/B20/DP13: "Quality Assurance Policy for Pharmaceutical Products." November 2009. GF/B22/DP10: "Quality Assurance Policy for Diagnostic Products." December 2010.

²⁹ "Guide to Global Fund Policies on Procurement and Supply Management." June 2012.

provide appropriate oversight. Policies in place enable the Global Fund to leverage its tools and capabilities to facilitate healthier markets.

- e. **Systems and tools:** Systems or tools exist to manage, standardize and automate key processes to the extent possible.
- f. **Partnerships:** The Global Fund maintains strong relationships with core partners working on topics related to market shaping, such as UNITAID, the WHO, PEPFAR, PMI and others. There is clear understanding of partner initiatives and potential intersections with the Global Fund's efforts, as well as regular opportunities to coordinate and collaborate.

34. Based on an assessment of the current state of these foundational elements, the Global Fund determined that tools and systems to facilitate forecasting, gathering market information and data management will be a key need going forward. In addition, given the global nature of market shaping, strong partnerships are especially important. A focus on these foundational elements is reflected in the strategic objectives described in Section V. While the Global Fund currently has a strong team in place to support its ongoing activities, there will also be a need for additional resources to fully implement the objectives of the Market Shaping Strategy, discussed in Section VI.

V. Strategic objectives

35. Based on the vision, scope, guiding principles and approach described above, the Global Fund has developed a set of strategic objectives to guide its market shaping work over the span of this strategy. The objectives briefly summarized below and then displayed in Figure 3. They are then detailed further, along with specific actions to achieve each objective. Because some of these actions represent continuing activities while others are new areas of focus, a summary of the new actions is provided at the end of this section, along with relative level of effort. At the highest level, the strategic objectives include:

- a. Ensure continued availability and affordability
- b. Promote consistent quality standards
- c. Support efforts to stimulate innovation
- d. Accelerate the adoption of new and / or cost-effective products
- e. Prepare for country transition and long-term market viability
- f. Strengthen key foundational elements for market shaping

36. Of the objectives laid out above, the first four relate directly to near-term market shaping strategies that the Global Fund will implement across product categories. The Global Fund will develop product and category strategies that lay out how these objectives will be achieved in the context of that specific market. This is discussed further in Section VI. The actions described under each of these objectives indicate how the Global Fund will approach the objectives and how specific tools may be applied.

37. The Global Fund will strive to achieve all of its near-term objectives for each health product within the scope of this strategy. However, based on the dynamics in specific product markets and the Secretariat's capacity, trade-offs may be made between objectives at a given point in time. For example, not every category will have new products being introduced (so innovation might be prioritized and adoption deprioritized) and affordability is not currently an issue for all products. Likewise, trade-offs

will inevitably arise between different dimensions of market health based on category dynamics. For example, in a market with few quality-assured suppliers, the Global Fund might allocate volumes through PPM to a higher-priced manufacturer in order to secure a stable supply base and promote competition in the longer-term. Likewise, in a market where an effective new product was recently introduced, the Global Fund's efforts might prioritize scaling up that product and reducing its cost, rather than incentivizing additional new product development efforts. Priorities for each category will be articulated in the strategies mentioned above and discussed further in Section VI.

38. The fifth strategic objective is focused on preparing for country transition and supporting long-term market viability. It recognizes that the Global Fund's ability to shape markets is necessarily time-limited, especially on a country-by-country basis, and it emphasizes the need to lay the groundwork for the future. 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. The last objective is related to the need to strengthen key foundational elements that support both the Global Fund's ability to shape markets in the near-term and its efforts to facilitate country transitions. The strategic actions described here are also cross-cutting initiatives, rather than being focused on a specific product or category.

39. Many of the strategic actions highlighted under the availability, affordability and quality objectives continue, refine and institutionalize the Global Fund's current market shaping approach and activities. Historically, many of the Global Fund's market shaping strategies have focused on these dimensions, which are strongly aligned with its capabilities. The objective related to innovation also continues and refines the Global Fund's existing approach to creating "pull" incentives for innovation, rather than making significant investments, as this is an area largely outside the Global Fund's mandate. However, achieving the objective related to product adoption will also support innovation, as it accelerates and streamlines the route-to-market for new products, reducing risk and increasing demand visibility. This objective and the remaining two objectives, focused on preparing for transition and strengthening foundational elements, will receive increased attention and investment from the Global Fund. Each of the strategic objectives and related actions are displayed in Figure 3 below and then described in further detail.

Figure 3: Market shaping strategic objectives



01 Ensure the continued availability and affordability of health products

40. This objective calls for ensuring the continued availability and affordability of health products. This has historically been a focus of the Global Fund's market shaping efforts and is a key part of ensuring access to key health products and effective grant implementation. It is also aligned with the Global Fund's emphasis on the growing, mature and declining stages of the product lifecycle. It includes four strategic actions, each discussed in order below:

- a. Continue to facilitate market transparency and competition;
- b. Leverage strategic procurement practices in PPM sourcing;
- c. Extend the benefits of market shaping interventions to all countries and PRs; and
- d. Help prevent and respond to potential stock-outs and emergency orders.

Continue to facilitate market transparency and competition

41. A key element of ensuring product availability and affordability is promoting market transparency, such that data on volumes, prices, demand and supply are readily available. This typically contributes to increased competition and enables recipients to better negotiate procurements, providing benchmarks for in-country procurement systems. The Global Fund will continue to support this through the PQR mechanism, discussed above. This will include an assessment of opportunities to strengthen the timeliness and quality of PQR data, as well as to expand the information provided via the PQR (for example, to reflect orders throughout the procurement process). It will also make available non-proprietary and non-commercially sensitive procurement information through a comprehensive web portal (such as category strategies, reference prices, tender documents, and sample contracts). The Global Fund will also continue to support and collaborate with WHO on strengthening and exchanging information for the Global Procurement Reporting Mechanism (GPRM). Specifically with regards to price transparency, the Global Fund will publish updated reference prices for core health products on a quarterly basis. As noted above, the Global Fund will also continue to publish actual prices on specific procurements through the PQR. It is further noted below in Strategic Objective 6 that the Global Fund will explore ways to strengthen this mechanism so that data can be shared earlier in the procurement

process, rather than waiting until products are delivered. Other proprietary or commercially sensitive supplier information may not be publicly disclosed if it compromises the Global Fund Secretariat's ability to execute the Market Shaping Strategy (such as manufacturer target prices, cost data or product development pipelines), is part of an internal deliberative process, or is part of the Global Fund's contractual and legal obligations.

42. In addition, the Global Fund will continue to contribute to global forecasting efforts by consolidating demand forecasts from its PRs and will provide this visibility to suppliers. It will continue to engage in efforts to triangulate forecasts with other actors, such as PEPFAR, PMI, GDF, CHAI and UNITAID, as well as supporting WHO in its coordination effort for global demand forecasts of ARVs and HIV diagnostics. The Global Fund will also coordinate with partners with respect to other types of market data collection and analysis. This occurs through existing working groups (such as the PAPWG, the WHO Technical Working Group on global demand forecasting for ARVs and HIV diagnostics, or the ACT forecasting initiative funded by UNITAID) and could potentially be extended to new channels, such as the formation of a new partner working group focused on market data.

43. As with other international financing institutions, competition is a basic principle for procurements financed by the Global Fund. The Global Fund will continue to encourage market competition through its Procurement and Supply Management policies, which require recipients to "use transparent competitive procedures for the purchase of health products."³⁰ The Global Fund supports efforts to address barriers and practices that prevent access to affordable medicines by promoting generic competition in order to help reduce costs. In addition, in markets where there are few quality-assured manufacturers, the Global Fund Secretariat may apply strategic procurement practices through the PPM to foster competition, such as reserving volume for new entrants in tenders conducted by the Secretariat. Finally, the Expert Review Panel (ERP) is also a mechanism to enhance competition when there are fewer than two quality-assured suppliers of a given product. The ERP is discussed later in this section under Strategic Objective 4: Accelerate the adoption of new and/or more cost-effective products.

Leverage strategic procurement practices in PPM sourcing

44. In addition, the Global Fund will continue to employ strategic procurement practices through PPM to increase or maintain product affordability and availability. PPM will continue to be offered as a value-added service that countries may choose to participate in for some or all grants, as well as a mechanism to mitigate grant implementation risk in some countries. Given the Global Fund's commitment to in-country systems, it is important that the PPM remain primarily a voluntary mechanism (unless implementation risk is a concern). In addition, to support stronger in-country procurement systems, pooled procurement must be accompanied by capacity-building, which is discussed later in this section under Strategic Objective 5.

45. As described in the 2011 Market Shaping Strategy, under extraordinary circumstances where product demand is still developing or where fragile markets make supply security a concern, the Global Fund may choose to coordinate financed procurement of such products through PPM, GDF or another coordinated ordering mechanism on an opt-out basis. In these markets, products may not otherwise be available or affordable and time-limited intervention can make the difference between access or lack of access to critical products.³¹ Employing a coordinated approach similar to that used by the PAPWG for paediatric ARVs can be beneficial for other markets that are similarly challenging. Even in these instances, countries will be able to opt out of pooled procurement by providing a justification that equivalent market outcomes will still be achievable (e.g., based on historical precedent) and if the Secretariat establishes that other countries will still be able to obtain a consistent supply and equivalent prices of the product. Grant funds may be used to finance the preparation of any necessary analysis or

³⁰ "Guide to Global Fund Policies on Procurement and Supply Management of Health Products." June 2012.

³¹ GF/B23/09: "Report of the Market Dynamics and Commodities Ad Hoc Committee." May 2011.

justification. This measure will only be taken after significant consultation with partner organizations and recipients and approval by the SIIC.

46. A number of strategic procurement practices can be applied through the PPM, providing different levers to help achieve market shaping objectives, such as promoting competition, incentivizing innovation, encouraging supplier entry to expand the local or global quality-assured manufacturing base, or enforcing quality assurance measures (for example). Prior to launching a negotiation or tender process with suppliers through the PPM, the Secretariat will develop a product or category strategy that highlights key market dynamics and how the principles and objectives of the Market Shaping Strategy will be implemented for the designated product or category. Section VI provides further detail on the process of implementing the Market Shaping Strategy on a product or category basis. As part of this process, the Secretariat will assess potential risks associated with planned market shaping interventions and determine how these risks can best be managed on an ongoing basis. It will also gather input from partner organizations, the private sector and civil society, as well as providing a post-tender briefing on the results achieved.

47. As described in Section IV, the PPM is one of the Global Fund's core market shaping tools and its effectiveness depends in part on the extent to which recipients participate in this mechanism. If a significant number of countries were to leave the PPM, the Global Fund would need to amend its Market Shaping Strategy and category-specific strategies. For example, it might need to place increased emphasis on coordination with other buyers. However, the Global Fund's recent ARV tender for the PPM demonstrates that it is possible to pursue market shaping objectives without tremendous market share (the PPM represents about 17 to 18 percent of the developing world market for ARVs).

Extend the benefits of market shaping interventions to all countries and PRs

48. It is important that all countries benefit from the Global Fund's efforts to increase affordability and availability of health products, regardless of their participation in PPM. Some interventions will naturally have wider benefits because they act by increasing market transparency, enhancing competition or promoting a stable supplier base. For example, the Global Fund publishes the reference prices negotiated through its long-term agreements with suppliers, thus providing all PRs with insight into prices they could expect. If the Global Fund incorporates provisions into a specific tender to maintain a diversified supplier base, this will also ensure that these suppliers are available to other purchasers.

49. Steps will also be taken to directly extend the benefits of the Global Fund's market shaping efforts more broadly. For example, this could take the form of publicizing information on the total cost of ownership for different viral load technologies, as implemented through the Global Fund's recent tender or extending the option of participating in the Global Fund's long-term agreements to members of the Pan-American Health Organization (PAHO), which has been agreed to by all suppliers. While these are some examples of ways in which the Global Fund actively extends its market shaping strategies already, it will deliberately consider this in the development of new interventions or category sourcing strategies going forward. It will also ensure that available information and resources related to market shaping and procurement are disseminated across countries and PRs through the HPM Specialists embedded with each country team and through regional meetings with in-country stakeholders. This will also provide in-country actors with greater visibility into the Global Fund's activities and may also provide a venue for technical assistance.

Help prevent and respond to potential stock-outs and emergency orders

50. A number of the strategic actions described under other objectives will help prevent stock-outs at the country level. These include potentially expanding the PQR system (as noted above), which could provide greater visibility into the procurement process for recipients not participating in PPM, and likewise the improved forecasting and data management tools noted below. In addition, the

procurement capacity-building described below will include forecasting and order planning, which are key elements of ensuring steady supply. However, these interventions primarily contribute to preventing country-level stock-outs and additional work will be needed by partners focused on the in-country supply chain to ensure this extends to end users. Finally, the Global Fund will continue to employ contractual arrangements for vendor-managed inventory linked to committed volumes to fill short-term orders, thus ensuring sufficient capacity to meet demand and preventing country-level stock-outs of core ARVs and ACTs. The Global Fund will also continue coordinating closely with other financing institutions and partners to prevent and respond to stock-outs. For example, this includes participation on the Steering Committee of the Coordinated Procurement Planning (CPP) initiative for ARVs, the Procurement Consortium of the PAPWG, and the Inter-Agency Procurement Consortium.

02 Promote consistent quality standards

51. Multiple stakeholders have noted the Global Fund's key role in upholding consistent quality standards for health products. This has been a cornerstone of the Global Fund's market shaping efforts since 2007 and it will continue to maintain robust Quality Assurance Policies for preventive, diagnostic and treatment products. It will also continue to leverage these policies and its position as a large financing institution to promote international quality assurance standards. While the Global Fund will continue to uphold quality assurance standards through its policies, it also relies on WHO to set quality standards and evaluate the quality, safety and efficacy of products.

52. The Global Fund's Quality Assurance Policy for Pharmaceutical Products is well-established and tested. Its policy for diagnostic technologies and its quality requirements for other health products are more recent and will continue to be refined and strengthened. The Global Fund will continue to monitor compliance with its Quality Assurance Policies and other requirements, resolving issues as they arise. The Global Fund's Quality Assurance Policies, requirements and other guidance may also be used to inform countries strengthening their own national quality assurance requirements.

53. As discussed above, the WHO's role in assessing and monitoring product quality is critical to the Global Fund as its Quality Assurance policies depend directly on the work of the WHO Prequalification Programme and the WHO Pesticide Evaluation Scheme (WHOPES). The Global Fund recognizes the value of these programmes and urges WHO Member States and the international donor community to continue supporting these mechanisms, including consideration of creation of additional funding mechanisms.³² It also supports the current efforts to strengthen the operations of these programmes. Furthermore, the Global Fund also supports the WHO's Collaborative Registration Procedure to share information on WHO-prequalified products between the WHO Prequalification Programme and national regulatory authorities. This is a key mechanism to accelerate national product registration, contributing to the previous objective on availability and affordability as it can increase the number of suppliers registered in a given country market, as well as the objective below on accelerating the adoption of new products.

03 Support partners' efforts to stimulate innovation

54. The Global Fund relies on its technical and development partners to stimulate innovation through "push" mechanisms, such as directly funding research and development, driving the development of target product profiles, and leading other activities directly focused on creating new medicines and technologies. Given its mandate and core capabilities, as well as its principle of working in a complementary way with partners, the Global Fund does not plan to move into these areas and will continue to rely on partner organizations. The primary way in which the Global Fund can support innovation as a financing institution focused on country programs is by working with partners to facilitate smooth product introduction and scale-up so that there is lower risk of investing in new

³² Draft statement by the Interagency Pharmaceutical Coordination Group on support for the WHO Prequalification Programme.

products and more transparency on the time and process required to scale. The Global Fund's efforts in this area are described in the following strategic objective related to accelerating product adoption.

55. While the Global Fund's direct role in driving innovation is limited, there is still a clear need for new technologies and tools to combat the three diseases. For example, each of UNITAID's recent landscape reports related to medicines for HIV/AIDS, malaria and tuberculosis highlight market shortcomings related to the need for new products.³³ As a major financing institution, it is important that the Global Fund clearly signal its interest in innovation and support technical and development partners working in this area. The Global Fund can support these organizations' efforts to promote innovation by collaborating early in the product life cycle to provide perspective on how to integrate new products into Global Fund-financed procurements and share insight based on country demand and product selection decisions. For example, the Global Fund will continue to engage with WHO as part of its guideline development process. When products are in the pre-commercialization phase, the Global Fund can also work to reduce the risk of market entry. For example, if engaged early, the Global Fund can develop forecasts of PR demand for new products and make them available to manufacturers and other partners. In addition, this allows the Global Fund to begin planning for new product introduction well in advance by sharing information about new products with recipients and building them into Global Fund and PR planning.

56. There are also specific "pull" mechanisms that the Global Fund can implement in its sourcing strategies and procurement policies to incentivize investment in innovation. These mechanisms draw on the Global Fund's position and unique capabilities as a financier of health products, without focusing on larger incentives or subsidies where partner organizations are better suited to play a leadership role. As part of developing disease or category-specific sourcing strategies, the Secretariat will incorporate assessments of needed innovation and products in the pipeline, drawing particularly on analyses by UNITAID, WHO and other technical partners. Based on these assessments and consultation with technical experts, the Secretariat will deploy "pull" mechanisms to recognize the value of innovation in its sourcing strategies, recognizing that the optimal approach will depend on the type of innovation required.

57. These mechanisms will leverage the strategic procurement practices outlined above, including the procurement model, tender allocation model, and value-added services. For example, the Secretariat could continue to incorporate quantitative, external measures of innovation into the allocation criteria for tenders run through the PPM. Where incremental product development needs are identified by partners, the Global Fund may also continue to include collaborative projects with suppliers focused on those needs in its tender evaluations. When market analysis indicates that new products or new entrants are likely to emerge, volume can be allocated for new products and new entrants to allow flexibility and accelerate bringing these products to market. Lastly, when analysis indicates that fundamental innovation in treatment modalities or product categories are needed and funding from public or philanthropic sources are unlikely to meet this need, the Global Fund may engage with originators to explore the volumes required to support continued participation in a market.

58. These "pull" mechanisms will not necessarily be employed in all tenders managed by the Global Fund, but when a specific market challenge related to innovation is identified and prioritized. In addition, the mechanisms at the Global Fund's disposal are likely to be most effective in encouraging incremental or process-based innovation. As noted above, when there is a clear need to encourage more fundamental innovation, the Global Fund has fewer tools suited to resolving this type of challenge and will coordinate with partners that have greater capabilities in this area (such as BMGF, UNITAID or the Product Development Partnerships [PDPs]).

³³ <http://www.unitaid.org/resources/publications/technical-reports/>

04 Accelerate the adoption of new and/or more cost-effective products

59. This objective addresses the Global Fund's efforts to support the introduction and adoption of new products that are identified as high priorities from a public health perspective by technical and development partners, as well as the adoption of the most cost effective products, formulations, and presentations. It includes four strategic actions, which are outlined below and then described further. Many of these actions also align with the prior objective to support innovation, as one of the Global Fund's key mechanisms to stimulate innovation is by facilitating a clear, smooth route-to-market for new products. The strategic actions for this objective are:

- a. Coordinate with partners to develop and implement "roadmaps" for key product needs;
- b. Accelerate the introduction of products for which there are few quality-assured suppliers;
- c. Coordinate with partners to reduce the risk of market entry for high-priority new products; and
- d. Optimize product selection within WHO guidance.

Coordinate with partners to develop "roadmaps" for key product needs

60. The Global Fund must coordinate closely with partners to accelerate the adoption of new and/or more cost-effective products. This is essential to ensure that recipients have access to needed products that can result in the best health outcomes, without gaps in availability or unaffordable prices, as well as to demonstrate the potential for success from ongoing innovation. As part of its strategy and operating model going forward, UNITAID is also committed to transition planning to ensure that the interventions it finances can be taken to scale. These objectives of both organizations are incorporated in the Memorandum of Understanding signed between the Global Fund and UNITAID in 2014.

61. Going forward, the Global Fund will work closely with partners to develop and implement high-level strategic "roadmaps" to bring key products to scale, outlining key barriers, necessary actions, the organization(s) responsible and the timeline. This could include products that have been introduced but where barriers have prevented uptake or products that are in the development pipeline. These roadmaps will consider the 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. In particular, the Global Fund anticipates partnering closely with UNITAID and this effort will be complementary to UNITAID's transition planning and the roadmaps may be an output of that process. As a starting point, the Global Fund, UNITAID, WHO and the Medicines Patent Pool (MPP) will pilot this initiative, working together to assess scale-up challenges for new first-line ARVs that may be incorporated into the WHO's 2015 or 2017 guidelines.

62. In addition, the Global Fund and UNITAID Secretariats will form a joint working group that meets annually to identify priority products for focused collaboration, based on criteria such as alignment with both organizations' missions, potential impact and cost effectiveness of the product, anticipated scale-up challenges and the ability of both organizations to address those challenges. Drawing on UNITAID's transition planning, the working group will align on a joint strategic roadmap for selected products and monitor its implementation. Additional partner organizations and other experts will be consulted or integrated as needed. Roadmaps will be shared at the annual Global Fund Sourcing and Market Dynamics Strategic Review meeting to foster additional input from and collaboration with partners. The Global Fund and UNITAID will jointly report on these efforts to the SIIC, as well as any relevant governance structures at UNITAID.

Accelerate the introduction of products for which there are few quality-assured suppliers relative to demand

63. The Global Fund will also continue to support the Expert Review Panel (ERP) as a way to accelerate the introduction of new, quality-assured products. The ERP provides a mechanism for the Global Fund to procure products with a strong public health need for which there are not yet suppliers who are prequalified or authorized for use by a stringent regulatory authority, or where a limited number exist. This improves both the availability of products that are in the process of being quality-assured and enhances competition in these markets, leading to greater affordability. ERP review can be targeted to products where the Global Fund and its partners are seeking to accelerate introduction and adoption.

Coordinate with partners to reduce risk of market entry for high-priority new products

64. In addition, as discussed in Section IV, the Global Fund currently has a revolving fund (USD \$2 million) available to make advance commitments to manufacturers with the goal of reducing the risk of market entry, thereby resulting in lower prices and stimulating more sustainable demand for new products. When new products are initially introduced, low visibility on demand can lead to higher prices to compensate for this uncertainty. The level of prices at product introduction may also deter countries from purchasing them, which then contributes to uncertain demand and resulting price premiums.

65. While the Global Fund finances significant health product procurements, it is not able to make commitments to purchase new products based on that spend unless the product is already incorporated in countries' grant budgets. Grant reprogramming requests for new products can be expedited, but the ability to commit in reasonable amounts based on the expectation that demand will materialize in time and at lower prices can help reduce the risk of market entry and make new products more affordable. The Global Fund is also uniquely positioned to do this in a sustainable way, as the volumes committed can be back-filled by country purchases from grant budgets as demand emerges or through collaboration with other funding partners. This provides the Global Fund Secretariat with an added incentive to disseminate information about new products and expedite reprogramming if needed, as country demand is necessary to ensure the revolving fund is not exhausted.

66. This kind of fund can both promote innovation by reducing the risk of market entry and facilitating smoother product introduction, as well as accelerating product scale-up. However, the size of the current revolving fund is not sufficient to significantly participate in advance commitments for new products, based on past examples of similar interventions.³⁴ While the Global Fund will seek to apply this fund in concert with other partner organizations, it will also look to expand the size of the revolving fund to USD \$10 million in the next funding period. Even at this size, the revolving fund will be better suited to accelerating new product introduction, rather than incentivizing the development of fundamentally new products. The Global Fund will also leverage these resources by collaborating with partners when using the revolving fund. Deploying the revolving fund will involve some risk, as the purpose of the fund is to be able to make advance commitments before new products are fully incorporated in grant budgets. There is a possibility that demand will not materialize to the extent or as quickly as forecast and a portion of the revolving fund is depleted. However, deployment of the revolving fund will be approved by the FOPC to ensure that risks are being appropriately managed by the Secretariat.

³⁴ For example, in the GeneXpert buydown by UNITAID, the United States government and the Bill & Melinda Gates Foundation, the total commitment was USD \$11.1 million (UNITAID/EB16/2012/R5, June 2012). The Global Fund recently explored using its existing revolving fund for an advance commitment on a new HIV prevention technology where the total commitment would have been USD \$6 million.

Optimize product selection within WHO guidance

67. Among products that have already been introduced, there may be instances when multiple formulations or presentations of the same product exist. This can fragment demand, reducing product availability and affordability. When this challenge arises, the Global Fund Secretariat will proactively engage with countries and share analysis to inform their product selection choices, aiming to consolidate Global Fund-financed procurement toward a set of optimal product specifications. This may include commissioning and sharing evidence on the cost-effectiveness of varying presentations or of consolidating specifications. In some cases, the Secretariat may limit the number of formulation or presentation choices available to recipients in order to optimize procurement and achieve market shaping objectives. In particular, the Secretariat will look for opportunities to improve outcomes for Global Fund recipients as a whole (for example, when volume discounts for all recipients could be achieved if volume levels for a certain set of product specifications are reached). Decisions to limit available product formulations or presentations will be informed by consultation with recipients and technical partners.

68. There may also be instances where multiple products with different technical attributes are treated as equivalent by the WHO and other technical partners, with limited guidance on when to deploy one product vs. another. This may also occur in the context of new product introduction. In some instances, these products may also have significant price differences. For example, prior to its 2013 treatment guidelines, WHO did not provide a clear recommendation on its preferred first-line ARV regimen. Currently, there is limited technical guidance on the use of synergistic LLINs, which are treated as equivalent to other LLINs in WHOPEs' list of recommended LLINs and currently have a significant price premium. This makes it challenging to effectively assess when it could be more cost effective to procure products with different technical attributes, even at a higher price.

69. In these instances, the Global Fund Secretariat, in consultation with technical partners, will define a standard of evidence that must be met to justify purchase of significantly more costly products. If a body of evidence already exists widely, recipients may specify the product requirements that best meet their technical needs. In instances where there is minimal or no difference in price but material differences in technical attributes, the standard of evidence required to differentiate between products will reflect the lower threshold needed to ascertain cost effectiveness. However, in all instances, potential trade-offs of segmenting demand will be considered (e.g., limiting the potential supplier base and therefore competition, reducing volume leverage).

70. The Global Fund will continue to support technical assistance to recipients to aid them in the selecting among interventions and products during the grant-making process. In addition, it will proactively engage with recipients to share relevant analyses and information about likely product costs and comparative health technology assessments. 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. Through the continuation of its Value for Money initiative, the Global Fund Secretariat will also maintain relationships with experts in the field of cost effectiveness modelling and health technology assessment. It will connect recipients with these resources to inform country-driven health technology assessment. Engaging in this process can also be an opportunity to build country capacity for health technology assessment and how to incorporate this into product selection decisions. In addition, the Global Fund will fund cost effectiveness studies centrally to address product selection questions, especially those which are raised across multiple recipients. The results of these assessments will be proactively shared with recipients and used to inform the Global Fund's procurement policies. Finally, the Global Fund will continue to explore the contribution of health technology assessment and the fit with ongoing processes via the Secretariat's current effort to develop a set of options and technical recommendations on this topic.

71. In addition, the Global Fund Secretariat will engage with WHO and other technical partners to highlight where there are needs for additional technical guidance. Any research or evidence generated

through Global Fund funding will also be provided to relevant technical partners for their review and consideration. In the event that WHO or another technical partner designated by WHO reaches a recommendation on a particular set of products, the Global Fund will adopt these recommendations. Recipients will transition to WHO-recommended products within a reasonable period of time and the Global Fund Secretariat will expedite grant reprogramming requests related to recipients adopting WHO recommendations.

05 Prepare for country transition and support long-term market viability

72. According to analysis prepared by the Bill & Melinda Gates Foundation (BMGF), 24 countries can be expected to transition from Global Fund support over the next 15 years based on projected economic growth and current eligibility policies, representing four percent of total Global Fund investment.³⁵ While this represents a small proportion of financing, the Global Fund has determined that investing in sustainability is critical to protecting gains made in the fight against the three diseases at the country level. Further, setting countries up for sustainability requires advance planning, so efforts will benefit countries transitioning in the longer-term as well.

73. In addition, several specific implications of transition for market health at the country level have been identified. First, country capacity to effectively set priorities, target investments and regulate domestic markets will continue to be critical. Second, countries need procurement and supply management capacity in place, as well as well-functioning national drug regulatory authorities, in order to effectively assure quality and apply strategic procurement practices. Third, smaller countries that transition from Global Fund support may not have sufficient volumes and market leverage to maintain product affordability and availability once they begin sourcing on their own. Fourth, countries may struggle to provide attractive payment terms to manufacturers, irrespective of size. Fifth, middle-income countries may not be able to access the prices or licensing arrangements provided to lower-income countries. Sixth, once countries transition, they may not have access to information about prices paid by comparable countries (as the PQR and other transaction reporting databases cover only donor-funded procurements). There are likely additional challenges faced in the transition to domestic financing, but these alone have the potential to significantly disrupt the availability and affordability of quality-assured products for transitioning countries, as well as their access to new products.

74. The Global Fund can take several steps to address these dynamics. First, it 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. Secretariat focal points for transition and market shaping issues will be established to provide an expert resource to country teams working on transition plans. The Global Fund will also continue to invest in strengthening countries' procurement and supply management institutions and support technical assistance in these areas through funding to build resilient and sustainable systems for health, as well as national drug regulatory authorities. Throughout the first five application windows of the New Funding Model, approximately one-third of proposals have included modules related to procurement and supply management systems strengthening, totaling approximately USD \$113.1 million.

75. The Global Fund Secretariat will also explore specific in-country capacity-building initiatives, starting with procurement. A cross-functional team within the Secretariat will be established to assess capacity needs, in close consultation with countries, other in-country actors including civil society, and partner organizations working on in-country capacity-building. The assessment will consider areas related to skill sets or required knowledge, but also topics like human resource policies, leadership and governance. Based on this assessment, a procurement capacity-building program will be designed and implemented. While capacity-building is especially critical in the context of transition and sustainability, country ownership is also fundamental prior to transition and the program will not be limited to transitioning countries; nor will it be specific to health products financed by the Global Fund.

³⁵ Global Fund presentation: "Sustainability and Successful Transitions" presented at Policy Forum, May 2015.

In addition, the Global Fund's capacity assessments and capacity-building program will build on and coordinate with tools and approaches developed by partners. Should the Global Fund's capacity-building efforts prove effective, the Secretariat will consider expanding its programming to additional areas of capacity-building related to market dynamics (such as supply chain management).

76. Finally, the Secretariat will explore other ways to provide continued access to long-term agreements negotiated through the PPM to transitioning countries or regional bodies engaged in pooled procurement. For example, the Secretariat recently signed a Memorandum of Understanding with the PAHO Strategic Investment Fund to provide access to its long-term agreements for ARVs, to which all suppliers have agreed.

77. These actions will start the process of facilitating country transition and sustainability from a market dynamics and product access perspective. However, there are challenges that may limit their effectiveness. For example, manufacturers may not provide access to prices negotiated by the Global Fund to transitioning countries if they are not able to meet the same terms provided by the PPM. In addition, it may be difficult for transitioning countries to coordinate access to these agreements in settings where procurement has been decentralized. Moreover, there may be additional interventions that deliver further benefits or address some of the challenges described above.

78. Therefore, as part of its overall efforts to support country transition and sustainability, 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. For example, this could consider the Global Fund's potential to facilitate regional procurement of low volume products, promote harmonized regulatory systems or explore the establishment of guarantees that improve countries' credit terms. It might also examine the role of the private sector in creating sustainable in-country capacity or the use of innovative financing mechanisms.

79. 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. Recommendations will be made to a Steering Committee representing the departments named above and representatives of key partner organizations, including at least one civil society and one private sector member. Specific interventions or programs will be approved by the SIIC prior to implementation, with budgetary implications approved by the FOPC. This effort will build from existing work, such as the case studies of transitioning countries conducted this year as part of the Global Fund's Strategic Review 2015 and similar work recently conducted by the Gavi Alliance. It will also be informed by close consultation with industry, in-country recipients and civil society organizations.

06 Strengthen key foundational elements

80. As noted in Section IV above, the Global Fund has identified two foundational elements that are critical to its effectiveness in shaping markets and require further investment and strengthening. First, the Global Fund will prioritize investing in needed tools and systems to support forecasting, market information and data management. Accessible, current, complete and holistic data is critical to design, implement and evaluate effective market shaping interventions. It also facilitates market transparency and visibility into the Global Fund's market shaping efforts. However, while many of the Global Fund's tools and systems to capture, produce or analyze this data have improved, they are still highly manual and fragmented. The Secretariat will undertake an effort to assess its market shaping data needs and appropriate solutions, considering data related to supply, demand and specific products and connected to the evaluation plan outlined in Section VI. In addition, the Global Fund will collaborate with UNITAID, the WHO and other partners to leverage joint systems or databases where possible.

81. The Global Fund engages closely with partners in a number of areas related to market shaping, which is critical to gather expert perspectives and coordinate activities. For emerging products, it is particularly important that there be close coordination to ensure successful introduction and scale-up. The Global Fund also relies on partners to incentivize new product development, provide technical guidance and assure quality, among other areas. Likewise, partners leverage the Global Fund's financing and procurement scale to expand access to products. The Global Fund will continue to strengthen and operationalize its relationships with partners. This will include (but is not limited to) strengthening its strategic alignment with UNITAID, engaging with the WHO in its development of target product profiles, clinical guidance and treatment guidelines, supporting the WHO prequalification programme, engaging with civil society organizations, participating in multiple working groups and forecasting consortia³⁶, and coordinating with other financing institutions and purchasers, such as PEPFAR, PMI, DFID, GDF, UNICEF and other large government purchasers. In particular, it will define and strengthen its relationship with GDF, which will be formalized in a joint Memorandum of Understanding. It will also continue to engage with suppliers through its commercial processes and frequent supplier conferences.

82. The Global Fund Secretariat will continue to convene multiple forums for regular coordination, consultation and planning among partner organizations, the private sector, civil society and government representatives. It will continue to hold annual Strategic Review meetings to gain input on Global Fund strategies and coordinate with a broad range of partner organizations, the private sector, civil society, recipients, and technical experts. In addition, as category or product strategies are developed, it will proactively seek input from suppliers, partner organizations, civil society, recipients and technical experts through joint consultative meetings. For example, the Secretariat recently convened manufacturers of HIV and malaria rapid diagnostic tests (RDTs), PMI, PEPFAR, WHO, CHAI, MSF, BMGF, FIND, UNICEF, UNAIDS, PFSCM, and several recipient countries (Ghana, Nigeria, Uganda) in order to consult on the development of its strategy for HIV and malaria RDTs. The Global Fund will also hold briefings for partner organizations, manufacturers and civil society on the results of any tenders conducted through the PPM, as well as informing participating suppliers through individual notifications and discussions. The Secretariat will also engage with suppliers on a monthly basis to manage ongoing commercial relationships and conduct quarterly contract performance reviews. Finally, it will re-introduce regional meetings for in-country partners, including recipients, Local Fund Agents (LFAs), civil society, and technical partners, as a means to share information and gather country input on market shaping and procurement matters. The Global Fund will also continue to participate in similar events for coordination and consultation convened by partner organizations, such as UNITAID's Market Fora and WHO's annual supplier meetings.

07 Summary: New strategic actions and investments

83. This section has described the objectives of the strategy and actions related to achieving each objective. As noted above, some of these actions are continuing, while others represent new areas of investment. Figure 4 below summarizes which strategic actions represent continuing activities and which are new investments. It also highlights relative level of effort required for each strategic action.

³⁶ Such as the ACT forecasting consortium sponsored by UNITAID, forecasting conducted by the PAPWG, and forecasting efforts sponsored by the WHO's AIDS Medicines and Diagnostic Services programme.

Figure 4: New strategic actions and level of effort

Strategic objective	Continue, refine, institutionalize	Invest going forward
Ensure the continued availability and affordability of health products	a) Continue to facilitate market transparency b) Leverage strategic procurement via PPM c) Prevent and respond to potential stock-outs & emergencies	d) Extend benefits of market shaping
Promote consistent quality standards	a) Continue to define & enforce quality standards for Global Fund-financed products b) Support the WHO prequalification programme and collaborative registration	c) Strengthen quality standards for diagnostics & other non-pharmaceutical health products
Support efforts to stimulate innovation	a) Recognize value of innovation in sourcing strategies, with differentiated approaches	
Accelerate the adoption of new and/or more cost-effective products	a) Accelerate the introduction of products for which there are few QA'd suppliers	b) Proactively optimize product selection within WHO guidance c) Coordinate with partners to develop and implement roadmaps for key product needs d) Coordinate with partners to reduce risk of market entry
Prepare for country transition and support long-term market viability	a) Invest in strengthening in-country PSM systems and national regulatory authorities	b) Build in-country PSM capacity c) Incorporate market health in transition plans d) Assess additional market implications of transition and develop interventions
Strengthen key market shaping enablers	a) Continue to strengthen and operationalize partnerships	b) Strengthen tools and systems for forecasting, market intelligence and data management
Investment already made, limited additional required	Substantive upfront or some ongoing investment	Significant initiative over period of strategy

08 Actions required

84. As noted throughout Section V, the Secretariat will have primary responsibility to implement the Market Shaping Strategy, applying it to products or categories in scope as outlined in Section VI. However, a number of activities or decisions must be approved by the SIIC, FOPC or Board prior to implementation. In addition, the Secretariat will provide certain information to the SIIC and the FOPC to keep the committees apprised of progress in implementing the Market Shaping Strategy. Figure 5 outlines specific decisions and information to be brought to the Board, the SIIC or the FOPC with regards to implementation and what implementation authority is delegated to the Secretariat. These responsibilities and authorities apply also to any successors to the SIIC and the FOPC.

Figure 5: Actions required

Responsible body	Actions required
Board	<ul style="list-style-type: none"> • Approve amendments to the Market Shaping Strategy that result in a significant change to the Global Fund's market shaping mandate • Approve any proposed interventions in markets for products delivered via the private sector (such as the Co-Payment Mechanism) • Review corporate key performance indicators (KPIs) semi-annually • Review the mid-term and final evaluation of the Market Shaping Strategy
SIIC ³⁷	<ul style="list-style-type: none"> • Provide oversight for "guiding and overseeing the development and updating of strategic policies, such as the Market Shaping Strategy"³⁸ • Review product- and category-specific strategies developed by the Secretariat to implement the Market Shaping Strategy for information and comment at bi-annual meetings • Approve any proposed market shaping activities in targeted areas:

³⁷ Or its successor.

³⁸ GF/B32/DPo8: "Market Dynamics Oversight." November 2014.

	<ul style="list-style-type: none"> ○ Interventions to consolidate demand in new or fragile product markets by requiring Global Fund-financed procurements to be coordinated through the PPM, GDF or another coordinated ordering mechanism ○ New interventions to support transitioning countries in addressing market challenges that limit access to quality-assured, affordable health products (beyond those currently included in the Market Shaping Strategy) ○ Interventions in product markets related to COIMs of the three diseases • Review and recommend to the Board for approval any proposed interventions in markets for products delivered via the private sector • Approve material amendments or deviations from the approach laid out in the Market Shaping Strategy; where such amendments would result in a significant change to the Global Fund’s market shaping mandate, recommend to the Board for approval • Review regular reporting on the Market Shaping Strategy’s implementation: <ul style="list-style-type: none"> ○ Semi-annual corporate KPIs ○ Assessments of progress against product- or category-specific strategies conducted by the Secretariat ○ Joint reporting by the Secretariat and UNITAID on the development and implementation of product scale-up roadmaps ○ Mid-term and final evaluations of the Market Shaping Strategy conducted by the TERG • Designate two focal points to engage with the Secretariat on market shaping, procurement and supply chain matters • Review the proposed process to revise the Market Shaping Strategy during its final year of implementation
FOPC ³⁹	<ul style="list-style-type: none"> • Provide oversight for “the implementation of strategic policies, including the financial and operational aspects of sourcing and procurement initiatives”⁴⁰ • Review product- and category-specific strategies developed by the Secretariat to implement the Market Shaping Strategy • Approve any significant budgetary implications of: <ul style="list-style-type: none"> ○ Product- and category-specific strategies developed by the Secretariat ○ Market shaping activities recommended by the SIIC with regards to COIM products, private sector markets or to support transitioning countries in addressing market challenges ○ Material amendments or deviations from the approach of the Market Shaping Strategy recommended by the SIIC • Approve deployment of the Global Fund’s revolving fund to support new product introduction and adoption • Review market risk indicators and approve any required market risk management plans • Review regular reporting on the Market Shaping Strategy’s implementation: <ul style="list-style-type: none"> ○ Semi-annual corporate KPIs

³⁹ Or its successor.

⁴⁰ Ibid.

	<ul style="list-style-type: none"> ○ Assessments of progress against product- or category-specific strategies conducted by the Secretariat ○ Joint reporting by the Secretariat and UNITAID on the development and implementation of product scale-up roadmaps ○ Mid-term and final evaluations of the Market Shaping Strategy conducted by the TERG • Designate two focal points to engage with the Secretariat on market shaping, procurement and supply chain matters • Review the proposed process to revise the Market Shaping Strategy during its final year of implementation
Secretariat	<ul style="list-style-type: none"> • Implement the Market Shaping Strategy as laid out in this document, including: <ul style="list-style-type: none"> ○ The development of product- or category-specific strategies described in Section VI ○ Establishment of a steering committee to develop and recommend additional interventions to support transitioning countries with market challenges, as indicated in Section V ○ Establishment of a joint working group with UNITAID to develop product introduction and scale-up roadmaps • Establish regular consultative forums with technical and development partners, in-country actors, external experts, civil society and the private sector, including: <ul style="list-style-type: none"> ○ Annual strategic review meetings ○ Pre-tender conferences and post-tender briefings ○ Regional meetings of in-country actors ○ Ad hoc consultation as noted in the Market Shaping Strategy and as needed • Assess the risks of implementing product- or category-specific strategies and develop indicators to monitor risks of unintended consequences in the market • Conduct assessments of progress toward achieving the objectives of product- and category-specific strategies prior to revising or updating these strategies • Provide updates to the SIIC and the FOPC on progress in implementing the Market Shaping Strategy, including monthly calls with the SIIC and FOPC's designated focal points and biannual updates at the committees' in-person meetings • Report to the SIIC, the FOPC and the Board as outlined above, including: <ul style="list-style-type: none"> ○ Semi-annual reporting on corporate KPIs ○ Assessments of progress against product- or category-specific strategies conducted by the Secretariat ○ Joint reporting by the Secretariat and UNITAID on the development and implementation of product scale-up roadmaps • Propose a process to revise the Market Shaping Strategy during its final year of implementation
Other	<ul style="list-style-type: none"> • The TERG will conduct two evaluations of the Market Shaping Strategy, at the mid-point and in the final year of strategy implementation

VI. Implementation

85. A strong implementation plan is necessary to ensure the Market Shaping Strategy is operationalized and reaches its full potential. This section provides an overview of roles and responsibilities, how the strategy will be applied to different categories, sequencing and timeline, resource requirements, potential risks and risk management, and oversight. It will also discuss a plan to monitor implementation and evaluate the Market Shaping Strategy.

01 Roles and responsibilities within the Global Fund Secretariat

86. In addition to the collaborations with partner organizations described above, market shaping will require cross-functional cooperation from multiple divisions within the Global Fund Secretariat. Because many of the tools that the Global Fund can use to shape markets are related to sourcing and procurement, the Sourcing Department within the Finance, Information Technology, Sourcing and Administration (FISA) Division plays a lead role. Market shaping activities related to sourcing are implemented through the Procurement for Impact (P4i) initiative, which also addresses other operational procurement initiatives.⁴¹ The HPM Hub and HPM Specialists within the Grant Management Division are also closely involved in setting quality assurance policies, managing the HPM-related aspects of grant-making and grant implementation, and advising recipients on product selection. In the Strategy, Investment and Impact Division, technical advisors for the three diseases and health systems strengthening play an important role in informing product selection and supporting in-country procurement capacity. Finally, the Global Fund's Policy Hub drives the development of the Global Fund's organizational strategy and formulation of specific policies, many of which impact the Global Fund's approach to market shaping, particularly with regards to sustainability and transition.

87. Therefore, while the Sourcing Department will drive many pieces of the Market Shaping Strategy, implementation will be undertaken by multiple divisions. Focal points for Market Shaping Strategy implementation will be identified within the Sourcing Department, the HPM Hub or HPM Specialists, and the Policy Hub. The focal point in the Policy Hub will also be responsible for coordinating work in the Strategy, Investment and Impact Division, given the close collaboration of these units. Overall coordination across divisions of the Secretariat will be the responsibility of the Sourcing Department, with the Procurement and Supply Management Steering Group as a forum for executive coordination and oversight provided by the Management Executive Committee (MEC).

02 Application of the Market Shaping Strategy across categories

88. As noted in Section V, the first four objectives of the Market Shaping Strategy must be applied to individual products and categories. Over the last two years, the Secretariat has implemented a rigorous process to develop product- and category-specific strategies, largely from the perspective of strategic procurement.⁴² At the beginning of each year, the Secretariat will create a work plan for which product- or category-specific strategies will be developed or revised during that year. This could include categories where the Global Fund is already financing products or new product needs identified in collaboration with UNITAID and other partners. Initial thinking on this work plan over the life of the Market Shaping Strategy is described below (based only on strategies currently in place).

89. As strategies are developed, an assessment of market dynamics and specific shortcomings will be integrated in the Secretariat's approach. For example, this 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

⁴¹ GF/FOPC15/07: "Market Shaping Strategy Development Update." July 2015. GF/SIIC15/06: "Overview of the Procurement for Impact Initiative." June 2015.

⁴² GF/SIIC15/06: "Overview of the Procurement for Impact Initiative." June 2015.

particular, these analyses will be used to identify high-risk or high-opportunity markets⁴³ which may especially benefit from intervention, along with other market challenges based on the framework described in Section IV. This assessment will draw on analyses by UNITAID, CHAI, and other partners. In particular, where product- or category-specific strategies address the introduction and scale-up of new products, they will be developed in close consultation with the UNITAID Secretariat. They will also include tailored indicators, as discussed as part of the evaluation plan below.

90. As described in Section V, partner organizations, civil society and the private sector will be consulted while developing each product or category strategy through annual strategic review meetings or focused conferences. Proposed strategies or interventions will be approved by the MEC and shared with the SIIC and the FOPC. Material amendments to or deviations from the approach laid out in the Market Shaping Strategy will be approved by the SIIC. Interventions with any significant new financial or operational implications will be approved by the FOPC. Briefings will be provided to partner organizations, civil society, the private sector; to the MEC; and to the SIIC and FOPC on the progress and outcomes of strategy implementation, including any tender processes managed by the Global Fund and its PSAs.

03 Sequencing and timeline

91. As noted in Section II, the Market Shaping Strategy covers an implementation period that begins at the start of 2016 and finishes at the end of the final year of the Global Fund's organizational strategy. This is likely to be 2016 – 2022, subject to Board approval of 2022 as the final year of the Global Fund's organizational strategy. Recognizing the Global Fund Secretariat's resourcing level and resulting capacity, new investments or activities discussed above will be sequenced over the course of this period, rather than implemented at one time. Continuing activities will proceed as currently implemented. Figure 6 below lays out high-level sequencing and timeline, focused on new initiatives and areas of investment. It also includes when current category- or product-specific strategies will be developed or revised, based on the length of the Global Fund's current or likely long-term framework agreements. These are incorporated because they require significant investment of staff resources, as well as because they are primary points of consultation with stakeholders. Note that products or categories may appear in later years of the timeline if they were the subject of a recent strategy development effort; this does not necessarily indicate a lack of focus on these areas. For example, the Global Fund completed a strategy and tender in viral load and early infant diagnosis in 2015, which is currently in the initial stages of implementation; this would be revised in 2018.

92. This timeline also focuses on the first four years of strategy implementation (2016 – 2019). During 2019, the Global Fund Secretariat will assess progress against strategy implementation, propose any needed amendments to the strategy, and prioritize initiatives for the remaining years. In the final year of strategy implementation, the Secretariat will also undertake a process to revise the Market Shaping Strategy. The proposed process will be reviewed by the SIIC and the FOPC.

⁴³ GF/B23/09: "Report of the Market Dynamics and Commodities Ad Hoc Committee." May 2011.

Figure 6: Year-by-year implementation of new initiatives

	2016	2017	2018	2019
Category strategies	<ul style="list-style-type: none"> • RDTs • ACTs • Multi-category opportunities 	<ul style="list-style-type: none"> • ARVs • LLNs • IRS 	<ul style="list-style-type: none"> • RDTs • ACTs • VL / EID 	<ul style="list-style-type: none"> • LLNs
	Continue engagement with suppliers, partner organizations and civil society on product- and category-specific strategies			
Adoption	<ul style="list-style-type: none"> • Begin to pilot scale-up roadmap for new ARVs • Update PSM Manual and hold regional PR meetings 	<ul style="list-style-type: none"> • Continue ARV pilot; consider additional roadmaps • Hold regional PR meetings 	<ul style="list-style-type: none"> • Evaluate ARV pilot; develop & implement additional roadmaps • Hold regional PR meetings 	<ul style="list-style-type: none"> • Continue to develop & implement roadmaps • Update PSM Manual and hold regional PR meetings
Transition	<ul style="list-style-type: none"> • Incorporate market challenges in transition planning • Assess procurement capacity needs in-country 	<ul style="list-style-type: none"> • Implement procurement capacity building • Assess additional market challenges for transitioning countries and options 	<ul style="list-style-type: none"> • Continue procurement capacity-building • Implement interventions to address 	<ul style="list-style-type: none"> • Evaluate capacity-building; consider expanding • Implement add'l transition initiatives
Data	<ul style="list-style-type: none"> • Assess need for data tools, PQR improvements • Begin to implement new forecasting & data tools 	<ul style="list-style-type: none"> • Continue implementing new forecasting & data tools • Begin implementing steps to strengthen PQR 	<ul style="list-style-type: none"> • Continue implementing new data tools • Implement steps to strengthen PQR 	<ul style="list-style-type: none"> • Assess effectiveness of new data tools • Continue strengthening PQR
Other	<ul style="list-style-type: none"> • Restructure web portal • Implement TB strategy, MOU 	<ul style="list-style-type: none"> • Expand revolving fund for new product introduction 	<ul style="list-style-type: none"> • N/A 	

04 Resource requirements

93. Many of the objectives of this strategy can be achieved with the existing level of human and financial resources, assuming a stable operating budget. This is due to the focus on refining and institutionalizing existing activities, as well as a number of continuing initiatives that required significant start-up investment but are now require fewer resources to maintain at steady-state (such as the Rapid Supply Mechanism or the development of Quality Assurance policies). In addition, the Secretariat has already identified opportunities to re-allocate some existing resources to support the Market Shaping Strategy. However, some additional resources will be required to implement new strategic actions.

94. The total incremental resources requested to implement the strategy are 6 FTEs and budget of USD \$3.9 million over six years, largely to support engagement with in-country stakeholders, an initial procurement capacity-building effort, and studies on 1) market dynamics and country transition, 2) forecasting and data systems, and 3) cost effectiveness and health technology assessment. In addition, the strategy calls for an expansion of the Global Fund's revolving fund from USD \$2 million to USD \$10 million. Because the current revolving fund is supported by special initiative funding which expires at the end of 2016, the full amount of USD \$10 million must be re-appropriated in order to expand the revolving fund. The operationalization of the revolving fund would remain as currently authorized (i.e., approval by the FOPC, or its successor, before utilizing the revolving fund for a particular product).

05 Managing risks

95. Risks associated with the Market Shaping Strategy fall into three primary categories. The first category is risks to the market and to potential health outcomes due to unintended consequences of interventions. These typically arise due to inherent trade-offs between different dimensions of market health or between short-term and long-term objectives. For example, Section III noted the risks that can arise from pooled procurement if the Global Fund is excessively focused on short-term affordability at the expense of securing availability, long-term competition and innovation. Figure 7 illustrates some of the additional trade-offs that must be managed between different dimensions of market health.

Figure 7: Illustrative market shaping trade-offs and unintended consequences⁴⁴

		Dimension that market shaping interventions are trying to maximize				
		Innovation	Availability	Adoption	Quality	Affordability
Potential unintended consequences on other market health dimensions	Innovation		• Could spread supplier base too thin, without enough volume to recoup innovation	N/A	• Overly burdensome or unclear QA processes can deter innovation	• Focus on price may deter innovation by reducing ability to recoup costs
	Availability	• Could result in too many niche products with few suppliers		• If countries scale up together / abruptly, may cause shortages • Registration can be a bottleneck	• Overly burdensome or unclear QA processes can result in too few eligible suppliers	• Low margins could cause suppliers to exit, reducing capacity
	Adoption	• Countries may face increased burden to prioritize new product scale-up	N/A		• Countries may be reluctant to adopt QA products if it is too difficult for local suppliers	N/A
	Quality	• May place increased burden on WHO PQ programme or cause delays	• In capacity-constrained context, QA may become less stringent	N/A		• Suppliers may under-invest in QA if faced with significant price pressure
	Affordability	• New products are often more expensive and value for money may be unclear	• Broad supplier base may reduce potential for volume discounts	• Surges in country demand can also increase prices for API, especially fixed sources	• Expense of quality assurance may result in higher prices	

96. To manage these risks, the Secretariat will identify metrics that allow it to monitor each dimension of market health, as well as risk tolerances which indicate that the Global Fund should assess whether its strategies are having a negative impact on the market. For example, in categories where a significant share of global volumes is managed through the PPM, the Secretariat might monitor the total number of pre-qualified suppliers and the number of Global Fund suppliers by product to ensure they do not fall below a certain threshold. In addition, when the Global Fund Secretariat develops product- or category-specific strategies that implement the Market Shaping Strategy, it will explicitly assess the market risks and potential unintended consequences of any interventions identified. If additional indicators are needed, they will be monitored as well. These metrics and associated tolerances will be compiled on a biannual basis and shared with the FOPC. If there is indication that indicators are outside predetermined risk tolerances, the FOPC will approve a plan to manage or reduce risk. Given the complexity of health product markets and the number of actors, the FOPC may also determine that the Global Fund's actions are not significantly contributing to market risks and limited action is required.

97. In addition, the Global Fund must find the right balance between short-term and long-term objectives. For example, there could be a risk that by over-emphasizing centralized procurement in order to achieve short-term market objectives, countries' domestic procurement capabilities may be diminished in the long-run. This risk is mitigated by the fact that even countries participating in the PPM still procure many health products and other products through in-country systems. Even within a category, some recipients may procure certain products while opting into the PPM for others (such as first-line ARVs vs. second- or third-line ARVs). In addition, this risk is also addressed by the procurement capacity-building program discussed in Section V under Strategic Objective 5, as well as Global Fund grants focused on procurement and supply management systems. Meanwhile, as noted in Section V, there is also a risk that the Market Shaping Strategy may not be implemented in full if a significant number of countries or high-volume countries do not participate in the PPM, reducing the effectiveness of one of the Global Fund's key market shaping tools. As discussed previously, given the Global Fund's commitment to in-country systems, it is important that the PPM remain a voluntary mechanism (unless implementation risk is a concern). However, the Secretariat will monitor PPM

⁴⁴ Figure 7 does not include the Delivery dimension of market health, as this is addressed by a separate Global Fund strategy related to investment in supply chain management. However, the same question with regards to risks and unintended consequences will need to be considered in terms of how the two strategies integrate with each other.

participation and alert the FOPC if it appears that this could materially affect the Secretariat's ability to implement the Market Shaping Strategy. In this event, the Market Shaping Strategy may need to be revised to reflect the Global Fund's evolving capabilities or constraints.

98. The next category of risk pertains to effective implementation of the Market Shaping Strategy. The full potential of the Global Fund as a strategic market actor may not be achieved if the strategy is not fully or consistently implemented. This can occur if the Secretariat is under-resourced compared to its market shaping mandate, if there is insufficient management attention to this area or if roles and responsibilities are not clear. The strategy development process attempted to mitigate these risks by identifying clear resource needs and how the strategy would be scaled back if resources are not available. In addition, to ensure cross-functional engagement on the strategy, its development was led by a team at the Secretariat representing each of the units likely to be involved in implementation. Clear roles and responsibilities for each unit with regards to different strategic actions were also defined.

99. The final category of risks pertains to whether partner organizations are able to fill critical roles. As described previously, the Global Fund relies on partner organizations to take the lead in a range of areas related to market shaping, from setting technical guidance to assuring product quality to investing in research and development. Even if the Global Fund's Market Shaping Strategy is implemented effectively, its impact also relies on these partners. Managing this risk is another reason that it is critical for the Global Fund to engage closely with partner organizations on their work and ensure there is sufficient consultation and collaboration. If this risk poses a barrier to achieving the objectives of the Market Shaping Strategy, the Secretariat may request that the SIIC approve an amendment to the objectives or indicators. In extraordinary circumstances, the Secretariat could also propose an extension of the Global Fund's mandate, following significant consultation with technical and development partners, civil society and the private sector. This would be reviewed by the SIIC and the FOPC, with any proposed changes recommended by the SIIC to the Board for approval.

06 Oversight

100. In November 2014, oversight for market dynamics became the joint purview of the SIIC and the FOPC, with the SIIC responsible for "guiding and overseeing the development and updating of strategic policies, such as the Market Shaping Strategy" and the FOPC responsible for "overseeing the implementation of strategic policies, including the financial and operational aspects of sourcing and procurement initiatives."⁴⁵ To the extent that Global Fund governance mechanisms are restructured, oversight for the Market Shaping Strategy would fall similarly to the successors of the SIIC and the FOPC. The specific responsibilities emanating from this strategy is outlined for both committees by Figure 5 in Section V above. Both committees will review regular reporting and comment on product- or category-specific implementation of the Market Shaping Strategy, as well as reviewing the proposed process to revise the Market Shaping Strategy during its final year. In addition, each committee will have oversight of specific aspects of strategy implementation, as outlined in Figure 5. For example, the SIIC will approve new interventions to support transitioning countries or to shape markets for COIM products. Meanwhile, the FOPC will, for example, approve significant budgetary implications of the strategy and any required risk mitigation plans.

101. Given the close connection between developing and implementing market shaping strategies or policies, documents prepared for either the SIIC or the FOPC will generally be shared with both committees. The market shaping focal points designated by each committee will play a key role in providing ongoing input during strategy implementation through monthly updates with the Sourcing Department. Each committee will receive updates during its in-person meetings and will have the opportunity to provide feedback on materials prepared for the in-person meetings of the other

⁴⁵ GF/B32/DPo8: "Market Dynamics Oversight." November 2014.

committee. SIIC and FOPC members also have the opportunity to consult with external experts or other stakeholders to ensure they have sufficient perspectives on issues raised.

102. Within the Secretariat, management oversight for the Market Shaping Strategy is provided by the Procurement and Supply Management Steering Group and the MEC. The OIG provides additional independent oversight of the Secretariat's various functions. Finally, the TERG provides independent evaluation of the Global Fund's initiatives, including market shaping.

07 Evaluation plan

103. The Global Fund Secretariat will develop a package of indicators and management information to monitor implementation and evaluate success of the Market Shaping Strategy. The corporate key performance indicators (KPIs) developed as part of the next Global Fund strategy will draw from this package and address the intended outcomes of the overall Market Shaping Strategy. These indicators will be presented to the SIIC and the Board as part of the overall Global Fund strategy development process, leading up to the 35th Board Meeting in early 2016. Baselines and targets for these KPIs will be further approved by the Board at its 36th meeting in November, 2016.

104. In addition to corporate KPIs, the package of indicators and management information that the Secretariat monitors will measure both the outcomes of the overall Market Shaping Strategy and the objectives of each product- or category-specific strategy or product introduction roadmap. Market shaping indicators will be developed in consultation with technical partners and experts, civil society, implementers, and the private sector. In particular, the Secretariat will seek to collaborate with other organizations that actively shape markets to align indicators or methodologies where possible. They will also be validated with the TERG. In addition, the Secretariat will develop operational indicators to monitor implementation of specific initiatives or activities related to the Market Shaping Strategy.

105. It is also important to recognize that the Secretariat will monitor additional data and that are not part of its reporting and for which performance targets are not set, but are still critical to understand market dynamics. These could include: the number of manufacturers procured from through PPM, GDF and recipients; comparison of price trends to other benchmark purchasers; and manufacturer product development pipelines. Participation in the PPM will be tracked by category, but specific targets will not be set. If PPM participation falls below a minimum threshold defined by the Secretariat in any given category, revisions to the Market Shaping Strategy may be required as the Global Fund's ability to shape markets in that category will be reduced. If overall cost savings are selected as an indicator, it will be aggregated from product- or category-specific targets so that a nuanced approach to target-setting can be applied, based on projected savings from tenders already conducted.

106. Potential indicators by strategic objective could be applied to the overall Market Shaping Strategy or in some cases to product or category strategies. This may include indicators, which monitor implementation (and can be proxy indicators for desired results), and outcome indicators, which measure results directly.

107. The methodologies and definitions for measuring selected indicators will be clearly documented. Where possible, the Global Fund will seek to collect the same indicators over the course of the strategy so that comparisons can be made over time. It will also seek to harmonize indicators with partner organizations where possible. In addition, in developing indicators, the Secretariat will look for opportunities to compare its performance to a counterfactual scenario in order to estimate the impact of its market shaping efforts, while recognizing that attribution of impact may be challenging.

108. Corporate KPIs will be compiled on a semi-annual basis and reported to the SIIC, the FOPC and the Board. Qualitative information will also be shared by the Secretariat to provide visibility into progress on implementing the Market Shaping Strategy and context for the quantitative indicators.

Before revising a product- or category-specific strategy, the Secretariat will evaluate progress toward the objectives and indicators for that strategy. These evaluations may be conducted by the Secretariat or by external consultants. They will be shared with the SIIC and the FOPC for information, as well as informing an overall evaluation of the Market Shaping Strategy to be conducted by the TERG at the strategy mid-term and during its last year of implementation.