34th Board Meeting

Market Shaping Strategy

GF/B34/17 – Revision 1
For Board Decision

PURPOSE: To present the amended and restated Market Shaping Strategy to the Board for decision. This decision paper is accompanied by the full amended and restated strategy in Annex 1.
I. Decision Point

1. Based on the rationale described below, the following decision point is recommended to the Board:

<table>
<thead>
<tr>
<th>Decision Point: GF/B34/DP08: Approval of the amended and restated Market Shaping Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Based on the recommendation of the Strategy, Investment and Impact Committee, the Board approves the amended and restated Market Shaping Strategy, as set forth in Annex 1 to GF/B34/17 – Revision 1 (the “Amended and Restated Market Shaping Strategy”).</td>
</tr>
</tbody>
</table>

The budgetary implications to fully implement this decision will be six additional full-time equivalent positions and USD 3.9 million over the six-year period of calendar years 2016-2021, which will be included in each year’s operating expenses budget. Additionally, a one-time investment of USD 10 million is required to continue the revolving fund beyond calendar year 2016, as described in the Amended and Restated Market Shaping Strategy. The source of such funds will be confirmed by the Finance and Operational Performance Committee, or its successor, prior to the next allocation period that starts in calendar year 2017.

II. Relevant Past Decisions

2. Pursuant to the Governance Plan for Impact as approved at the Thirty-Second Board Meeting,¹ the following summary of relevant past decision points is submitted to contextualize the decision point proposed in Section I above, and is required in documents presenting decisions only.

<table>
<thead>
<tr>
<th>Relevant past Decision Point</th>
<th>Summary and Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>GF/B32/DP08: Market Dynamics Oversight (November 2014)²</td>
<td>The Board agreed to dissolve the Market Dynamics Advisory Group and allocated oversight responsibilities with respect to market dynamics activities to both the Finance and Operational Performance Committee (FOPC) and Strategy, Investment and Impact Committee (SIIC). The FOPC is responsible for oversight of the implementation of strategic policies, including the financial and operational aspects of related sourcing and procurement initiatives. The SIIC is responsible for guiding and overseeing the development and updating of strategic policies related to market-dynamics matters,</td>
</tr>
</tbody>
</table>

¹ GF/B32/DP05: Approval of the Governance Plan for Impact as set forth in document GF/B32/08 Revision 2.  
² http://www.theglobalfund.org/Knowledge/Decisions/GF/B32/DPo8/
such as the Market Shaping Strategy for recommendation to the Board by its November 2015 meeting. The committees collaborate and coordinate on overlapping issues as appropriate.

GF/B25/DP05: The Global Fund Strategy (November 2011)

The Board approved the 2012-2016 Strategy Framework, including a statement that the Global Fund should exploit its scale to more proactively secure optimal prices, quality, design and sustainable availability of health commodities. The strategy also referenced implementing the Market Shaping Strategy, strengthening voluntary pooled procurement, setting voluntary pooled procurement as the default channel for targeted products or countries, and creating a joint new product introduction program with UNITAID.


The Board acknowledged the Global Fund’s critical role in shaping markets to maximize global access to health products and further emphasized its desire for the Global Fund to more actively shape markets for health products to optimize price, quality, design and sustainable supply. The Board approved the market-shaping strategy recommended by the Market Dynamics Committee, including a set of specific interventions for anti-retroviral medicines (ARVs). This strategy superseded the Market Shaping Strategy approved in 2007 (GF/B15/DP15). Approval of the decision point presented in the current paper will supersede GF/B23/DP21 and the Market Shaping Strategy approved under it.


The Board recognized that the Global Fund is well-positioned to drive value for money and leverage its role as the primary financier of essential health products to improve quality, price, design, and sustainable supply. The Board asked the Market Dynamics Committee to propose expanded uses of the Global Fund’s market dynamics “toolkit”. Among other directives, it also requested the Secretariat to take all necessary and appropriate measures to fully implement voluntary pooled procurement and aggressively execute the Market Dynamics Committee recommendations.

GF/B15/DP15: Market Dynamics and Voluntary Pooled Procurement (April 2007)

The Board adopted the objective and guiding principles for market shaping set out at the 14th Board meeting and amended at this meeting. In addition, the Board decided to pursue voluntary pooled procurement as the first element of its market dynamics strategy. It also determined to strengthen the “Price Reporting Mechanism” (now the Price Quality Reporting Mechanism) and enter into contracts to provide procurement capacity-building services to Principal Recipients.

3 http://www.theglobalfund.org/Knowledge/Decisions/B25/DP05/
6 http://www.theglobalfund.org/Knowledge/Decisions/GF/B15/DP15/
The Board endorsed the recommendation of the Policy and Strategy Committee that the Global Fund assume a deliberate and strategic role in improving the impact of grants through influencing market dynamics. The Board reviewed a related objective and guiding principles, asking the Committee to further explore the topic and provide any additional matters, including potential modifications.

III. Action Required

3. This paper presents the revised Market Shaping Strategy developed by the Secretariat under the direction of the SIIC and with substantial input from the FOPC. The SIIC recommends that the Board approve the Market Shaping Strategy set forth in Annex 1.

4. Should the Board adopt the revised Market Shaping Strategy, the Secretariat will be directed to implement the strategy for products and categories considered in scope. The Secretariat will report to the SIIC, the FOPC and the Board on key topics and aspects of strategy implementation as outlined in the amended and restated Market Shaping Strategy in Annex 1 (Section V.8). For example, the Secretariat will share the results of product- or category-specific strategies developed to implement the Market Shaping Strategy, as well as performance against key indicators. In addition, the SIIC and the FOPC, or their successors, and the Board will approve the implementation of specific market shaping efforts based on their respective mandates. For example, this could include expansion into market shaping activities pertaining to markets for products related to co-infections or co-morbidities of the three diseases, private sector delivery of health products or additional support for transitioning countries to address market challenges. This is also outlined in Annex 1, Section V.8.

IV. Executive Summary

5. Past market shaping efforts by the Global Fund, other international financing institutions, and partner organizations have yielded significant impact, particularly in promoting greater availability and affordability for a core set of health products. However, there are still market factors that prevent access to affordable, quality-assured products or the introduction and adoption of needed new products. In addition, new global strategies and targets will both have implications on the market for health products and can be supported by market shaping efforts.

6. 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.” Given continued challenges in product markets related to the three diseases, there remains a need for the Global Fund to play an active role in shaping market dynamics to increase access to health products, working in a manner that is complementary to and coordinated with other organizations with a market shaping mandate, such as UNITAID. Between this continuing need, the recent transformation in the Global Fund Secretariat’s Sourcing Department and the ongoing development of the Global Fund’s next organizational strategy, the Board called for a revised Market Shaping Strategy to be presented for its approval at its 34th Meeting in November 2015.

---

7 http://theglobalfund.org/Knowledge/Decisions/GF/B14/DP15/
7. Under the direction of the SIIC and the FOPC, the Secretariat assembled a cross-functional team to revise the Market Shaping Strategy. To inform the strategy revision, the Secretariat undertook a consultative process with over 30 technical and development partner organizations, civil society, donors and the private sector, as well as Board constituencies and committees. This consultation consisted of in-person discussions, as well as the opportunity for Board constituencies and partner organizations to provide written feedback on the draft revised Market Shaping Strategy. In addition, a Market Shaping Thematic Review was commissioned by the Global Fund’s Technical Evaluation Reference Group (TERG), which included further consultation with Principal Recipients, partner organizations, civil society and the private sector. The findings and recommendations of this review were incorporated in the development of the revised Market Shaping Strategy. A draft report on this review was shared with the SIIC and the FOPC with the draft Market Shaping Strategy and the TERG presented full results to the SIIC at its 16th meeting in October 2015.

8. At the 15th SIIC meeting in June, 2015, the committee discussed the approach, vision and scope of the revised Market Shaping Strategy, as well as planned consultations. At the 15th FOPC meeting held in July, 2015, the committee reviewed core elements of the revised strategy, including guiding principles, the Global Fund’s role in market shaping and draft strategic objectives. At the 16th SIIC meeting in October, 2015, the committee reviewed and discussed the full revised Market Shaping Strategy. The FOPC Chair and one of the FOPC focal points for market shaping also participated in the SIIC discussion. Furthermore, the FOPC discussed the full revised Market Shaping Strategy via phone consultation prior to its 16th meeting. Given the joint oversight role of the SIIC and the FOPC, materials prepared for each in-person committee meeting were shared with both committees for information and input. Both committees also provided written feedback on the draft revised Market Shaping Strategy prior to their 16th meetings in October, 2015.

9. Based on the consultative process described above and with oversight from the SIIC and the FOPC, the Secretariat has drafted a full revised 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. 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.

10. The revised strategy puts forth a set of strategic objectives that leverage the Global Fund’s position over the period from 2016 – 2022 to facilitate healthier markets leading to improved access to affordable, quality-assured products, including innovative products. It also builds for the future by supporting countries transitioning from Global Fund support to address market challenges. In addition, it calls for the Secretariat to strengthen the foundational data systems and partnerships that enable effective market shaping efforts. These strategic objectives are based on a vision and guiding principles that describe the overall direction and parameters for the Global Fund’s market shaping efforts. They will be applied to medicines or technologies that prevent, diagnose or treat the three diseases, including health products where the Global Fund currently finances a large volume of procurements, where its financing represents a large proportion of the market, and where the Global Fund could be catalytic in bringing a product to scale. The full revised Market Shaping Strategy is included in Annex 1, while its key elements are summarized in this paper.

11. The Secretariat has developed an initial plan to guide implementation of the Market Shaping Strategy, assign roles and responsibilities, inform resource requests, manage potential risks and evaluate outcomes of the strategy. In particular, risk management and evaluation will be a strong focus of the Market Shaping Strategy’s implementation, with the Secretariat directed to develop

---

90 GF/SIIC15/07: “Update on Market Shaping Strategy.” June 2012. The cross-functional team assembled by the Secretariat includes representatives from the Sourcing Department, the Health Product Management Hub in the Grant Management Division, the Legal Department, and the Policy Hub.
indicators and reporting for both purposes in consultation partner organizations, implementers, civil society, the private sector and with the TERG. This is described in Section VI of Annex 1 of this paper.

12. Many of the objectives of this strategy can be achieved with the existing level of resourcing at the Secretariat. However, some additional resources will be required to implement new aspects of the strategy. The total incremental resources requested to implement the strategy are 6 full-time equivalent positions and budget of USD 3.9 million over six years. This is 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 studies. In addition, the strategy calls for a one-time investment of USD 10 million to expand the Global Fund’s revolving fund to support product scale-up.

V. Background

01 History

13. 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). For example, in 2013, approximately 45% of the USD 3.9 billion disbursed by the Global Fund was used to finance the procurement of health products such as anti-retroviral medicines (ARVs), artemisinin-based combination therapies (ACTs), long-lasting insecticidal nets (LLINs), tuberculosis medicines, and diagnostic products. 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.

14. 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.” 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, other examples of the Global Fund’s market shaping activities have included (but are not limited to) efforts such as coordinating the Paediatric ARV Procurement Working Group (PAPWG), stabilizing LLIN price volatility through long-term supplier agreements, and responding to potential stock-outs for ACTs and ARVs. These initiatives directly contribute to improving health outcomes, for example by ensuring a secure supply of ARVs for children with HIV/AIDS or increasing the number of people protected from malaria by LLINs.

15. 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 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.

16. In 2013, the Sourcing Department of the Secretariat also launched the Procurement for Impact (P4i) initiative. This transformation includes a new approach to developing and implementing sourcing strategy for health products that builds on the 2011 Market Shaping Strategy, as well as organizational and operational reforms.
02 Context for the Market Shaping Strategy revision

17. 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 interventions. However, there are still market factors that prevent access to affordable, quality-assured products or the introduction and adoption of needed new products.16

18. Given continued challenges in product markets related to the three diseases, there remains a need for the Global Fund to play an active role in shaping market dynamics to increase access to health products. It is also important that the revised Market Shaping Strategy address evolving public health priorities and market dynamics. For example, the Global Fund’s market shaping efforts should support its mandate of building resilient and sustainable systems for health, as well as address the growing need to support transitioning countries in addressing market challenges that can limit access to key health products. In addition, new global strategies and targets focused on HIV/AIDS, tuberculosis and malaria will both impact market dynamics and can be supported by market shaping efforts. Given continuing market challenges, the evolving context, the transformation in the Sourcing Department and the development of the Global Fund’s next organizational strategy, the Board has called for a revised Market Shaping Strategy to be presented for its approval at its 34th Meeting in November 2015.

19. Under the direction of the SIIC and the FOPC, the Secretariat assembled a cross-functional team to revise the Market Shaping Strategy.17 To inform the strategy revision, the Secretariat undertook a consultative process with over 30 partner organizations, civil society, donors and the private sector, as well as from Board constituencies and committees. In addition, a Market Shaping Thematic Review was commissioned by the Global Fund’s Technical Evaluation Reference Group (TERG), which included additional consultation with Principal Recipients, partner organizations, civil society and the private sector. The results of this review were incorporated in the strategy development process and were presented by the TERG at the 16th SIIC meeting in October, 2015.

20. At the 15th SIIC meeting in June, 2015, the committee discussed the approach, vision and scope of the revised Market Shaping Strategy, as well as planned consultations. At the 15th FOPC meeting in July, 2015, the committee reviewed core elements of the revised strategy, including guiding principles, the Global Fund’s role in market shaping and draft strategic objectives. The FOPC Chair and one of the FOPC focal points for market shaping also participated in the SIIC discussion. Furthermore, the FOPC discussed the full revised Market Shaping Strategy via phone consultation prior to its 16th meeting. Given the joint oversight role of the SIIC and the FOPC, materials prepared for each in-person committee meeting were shared with both committees for information and input. Both committees also provided feedback on the draft revised Market Shaping Strategy prior to their 16th meetings in October, 2015.

VI. Discussion

21. Based on the consultative process described above and with oversight from the SIIC and the FOPC, the Secretariat has drafted a revised Market Shaping Strategy. The revised strategy puts forth a set of strategic objectives that leverage the Global Fund’s position to facilitate healthier markets in the near-term, as well as building for the future by supporting transitioning countries to address market challenges. These strategic objectives are based on a vision, guiding principles and scope that describe the overall direction and parameters for the Global Fund’s market shaping efforts. The full strategy is included in Annex 1 to this paper, while its key elements are summarized below.

---

16 Analysis and discussion of current challenges in markets related to the three diseases can be found in technical landscape reports prepared by UNITAID: http://www.unitaid.org/resources/publications/technical-reports.

17 GF/SIIC15/07: “Update on Market Shaping Strategy,” June 2012. The cross-functional team assembled by the Secretariat includes representatives from the Sourcing Department, the Health Product Management Hub in the Grant Management Division, the Legal Department, and the Policy Hub.
01 Vision, guiding principles and scope

22. As previously directed by the Board, the Global Fund will continue to play an active, deliberate and strategic role in shaping markets to maximize access to health products and improve health outcomes for people living with HIV/AIDS, tuberculosis and malaria. The revised Market Shaping Strategy defines how the Global Fund can contribute to health outcomes by leveraging its position to facilitate healthier global markets for health products, today and in the future. These efforts are guided by five principles: to be focused, sustainable, flexible, complementary to partners, and balanced.¹⁸

23. The landscape of actors in health product markets is complex; at the same time, the Global Fund is committed to working in a way that is complementary to the efforts of partners like UNITAID and WHO whose work shapes or influences global markets. The Global Fund will continue to focus on “downstream” products that are at growing, mature or declining stages of the product life cycle. In this area, it will align and collaborate with other large financing institutions on forecasting, product selection and strategic sourcing, such as the U.S. President’s Emergency Fund for AIDS Relief (PEPFAR), the President’s Malaria Initiative (PMI), and the Global Drug Facility (GDF) of the Stop TB Partnership. On product selection topics 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 Department for International Development (DFID), the National Institute for Health and Care Excellence (NICE) International, and in-country HTA agencies, such as Thailand’s Health Intervention and Technology Assessment Program (HTAP). It will also partner with organizations like the Clinton Health Access Initiative (CHAI) and WHO on forecasting and other market analysis.

24. Emerging products require particularly close coordination to ensure that they are effectively introduced and adopted by countries. The Global Fund will work closely with technical and development partners that focus further “upstream”, especially UNITAID. 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 has expertise in product introduction, 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 assuring quality. Organizations like the Medicines for Malaria Venture (MMV), the TB Alliance and the Foundation for New and Innovative Diagnostics (FIND) are also critical actors in driving research and development. In addition, PEPFAR also funds research and development and engages in product introduction planning.

25. The Market Shaping Strategy also continues to focus specifically on medicines or technologies that prevent, diagnose or treat the three diseases. This includes health products where the Global Fund currently finances a large volume of procurements, such as ARVs, ACTs, LLINs, tuberculosis medicines and diagnostic technologies, or where Global Fund financing represents a large proportion of the market. In addition, market shaping efforts may also include products where the Global Fund does not currently finance a significant volume of procurements but where it could be catalytic in bringing a product to scale. For example, this could include (but is not limited to) new anti-malarial medicines or vector control products. For these products, it is especially critical that the Global Fund partner closely with partner organizations that focus on product introduction, such as UNITAID. The strategy lays out an approach that the Secretariat is directed to apply in developing product- and category-specific strategies that are tailored to each market.

26. While not a focus for the Global Fund, it may also consider market shaping activities focused on products related to co-infections or co-morbidities (COIMs), in accordance with the Global Fund’s

recent policy in this area, as well as products delivered via the private sector. Market shaping efforts focused on COIMs will be approved by the SIIC, while interventions in the private sector will be reviewed by the SIIC and recommended to the Board for approval.

02 Approach

27. To identify and articulate market shortcomings, the Global Fund and UNITAID have developed a harmonized framework that describes the optimal market conditions to facilitate access to critical products and support health outcomes. The framework includes six dimensions of market health: innovation, availability, demand and adoption, quality, affordability and delivery. The Secretariat will use this framework to assess product markets and describe challenges that its market shaping efforts are intended to address.

28. The Global Fund will deploy seven primary tools to help resolve market shortcomings and facilitate healthier markets as described above. These tools include: the Price and Quality Reporting (PQR) mechanism, Quality Assurance policies, the PPM, a revolving fund to support new product introduction, the Global Fund’s Guide to Procurement and Supply Management (PSM) policies, guidance provided to recipients by Health Product Management (HPM) Specialists, and cost effectiveness analysis.

03 Strategic objectives

29. 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 efforts (Figure 1 below). The tools noted above will be deployed to achieve these objectives across products or categories.

Figure 1: Strategic objectives

30. The first four objectives are the focus of market shaping strategies that the Global Fund will implement in the near-term across products or categories. Of these, ensuring access to affordable, quality-assured products are consistently core areas of focus for the Global Fund. The first two strategic objectives focus on continuing and refining the Global Fund’s efforts in these areas. For the third objective on innovation, the Global Fund will primarily use its capabilities to support the work of

---

partners, while continuing to recognize the value of innovation in its sourcing strategies. The fourth strategic objective related to accelerating product adoption requires more investment, as well as close ongoing coordination with partner organizations to develop and implement product roadmaps to introduce and scale up new products.

31. Overall, the Global Fund will attempt to achieve each of these near-term objectives for the health products within the scope of this strategy. However, based on the dynamics in specific product markets and the Secretariat’s capacity, certain objectives may be prioritized at a given point in time. This will be outlined in product- or category-specific strategies developed by the Secretariat in consultation with partner organizations, civil society, and the private sector.

32. The Global Fund also recognizes that its ability to shape markets is necessarily time-limited as countries transition from Global Fund support and the fifth strategic objective emphasizes the need to build a strong foundation for the future. The strategic actions described under this objective are cross-cutting initiatives aimed at preparing for country transition, building in-country capacity and ensuring that countries retain access to affordable, quality-assured health products. The last objective includes a cross-cutting emphasis on building the Secretariat’s data systems and strengthening partnerships as key foundational elements that support both the Global Fund’s ability to shape markets in the near-term and its efforts to facilitate country transition.

04 Implementation plan

33. The Secretariat has developed an initial plan to guide implementation of the Market Shaping Strategy, assign roles and responsibilities, inform resource requests, manage potential risks and evaluate outcomes of the strategy. In particular, risk management and evaluation will be a strong focus of the Market Shaping Strategy’s implementation, with the Secretariat directed to develop indicators and reporting for both purposes in consultation with partner organizations, implementers, civil society, the private sector, and the TERG. This is described in Section VI of Annex 1.

34. Many of the objectives of this strategy can be achieved with the existing level of resourcing at the Secretariat. 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 now require fewer resources to maintain. However, some additional resources will be required to implement new aspects of the strategy. The total incremental resources requested to implement the strategy are 6 full-time equivalent positions and budget of USD $3.9 million over six years. This is 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 analysis and health technology assessment. In addition, the strategy calls a one-time investment of USD 10 million to fund an expansion of the Global Fund’s revolving fund to support product scale-up.

VII. Recommendation

35. Based on the discussion outlined above and previous papers prepared for the SIIC and the FOPC, the SIIC recommends that the Board approve the revised Market Shaping Strategy set out in Annex 1 to this paper.

---