

REPORT OF THE MARKET DYNAMICS AND COMMODITIES AD-HOC COMMITTEE

PURPOSE:

This report proposes a comprehensive market-shaping strategy for key health products financed by the Global Fund and resulting recommendations as agreed by the Market Dynamics and Commodities Ad-hoc Committee (MDC) at its 4th meeting on 4-5 April 2011. The report proposes decision points on the implementation of this strategy, which will initially be applied to antiretroviral medicines, and on the transition of fixed-dose combinations of artemisinin-based combination therapies (ACTs).

EXECUTIVE SUMMARY

Background: The Global Fund Board created the Market Dynamics and Commodities Ad-hoc Committee (MDC) at its Nineteenth Meeting to better leverage the institution's massive investments (roughly 37 percent of its USD 21.9 billion committed) in health products. Following 18 months of work with partners and country representatives, the MDC has developed an ambitious "market-shaping" strategy that can dramatically improve the health impact and value for money achieved from funding for health products. This report provides an overview of the proposed strategy and its initial application to antiretroviral (ARV) medicines for decision by the Board.

Strategy Overview: The MDC has determined there is limited opportunity for the Global Fund to increase the value for money realized from its current passive approach; it must actively shape markets to significantly improve the price, quality, design, and availability of products. The strategy will enable the Global Fund to realize that goal by pursuing four objectives: 1) accelerate introduction of new, superior products; 2) ensure recipients procure the most cost-effective product options; 3) strengthen countries strategic procurement capacity; and 4) ensure sustained availability and affordability of products with challenging market conditions.

Working with partners, the Global Fund will use in-depth analysis of product markets to determine those markets that need to be actively shaped in order to realize major additional benefits ("high opportunity") or prevent major disruptions ("high risk"). The Global Fund will then develop and implement interventions that will effectively resolve the challenges in the limited number of markets that require shaping.

This strategy has several advantages compared to alternative approaches:

1. *Focused* - The Global Fund will only employ alternative procurement approaches in markets that represent a small proportion of the products countries purchase with Global Fund resources.
2. *Time-limited* - Many interventions will be phased out once the targeted market challenge has been resolved.
3. *Flexible* - Global Fund interventions will be carefully tailored to the specific challenges in each target market rather than one-size-fits-all.
4. *Complementary* - The Global Fund will only intervene in markets not addressed by partner actions and will work closely with partners such as UNITAID to implement market-shaping interventions.

Strategic Interventions: The strategy provides the MDC and Secretariat with a "toolkit" of interventions to shape target markets. Some of these new interventions will require changes to procurement-related policies and processes for the limited number of relevant products. The most notable changes are:

1. The VPP or a consortium of procurement agents can be set as the required procurement channel for a targeted product. Countries will be able to provide a strong justification to purchase the product through an alternative channel; and

2. Countries will need to provide a strong justification to procure products that are found to provide significantly lower value for money than direct alternatives (for example, justification would be needed to procure a first-line ARV regimen that is found to be less cost-effective than a clinically comparable alternative).

Other interventions included in the “toolkit” include: 1) improved strengthening of country procurement capacity; 2) expedited grant reprogramming to facilitate switches to superior products; 3) creating a joint new product introduction program with UNITAID; and 4) strengthening the VPP to reduce risk of stock-outs and enable it to shape markets.

Expected Impact: The MDC has determined that the initial application of this strategy to ARVs can generate the following impact for countries and people living with HIV/AIDS:

1. Improve health outcomes, including increasing patient survival, reducing side-effects, and delaying resistance;
2. Savings of up to USD 500 million globally (USD 250 million of Global Fund resources) over 5 years;
3. Enable 60-90,000 HIV+ children to receive ARV treatment over 4 years;
4. Significantly reduce risk of stock-outs of ARVs and other medicines.

If approved, the strategy would be subsequently applied to markets for other AIDS, tuberculosis, and malaria products, with the potential for further substantial impact on health outcomes and value for money.

Proposed Decisions: The MDC recommends that the Board approve the proposed market-shaping strategy and initial interventions in ARV markets. The strategic interventions will be implemented by the Secretariat, with oversight by the MDC. Interventions related to pediatric ARVs will be prioritized given the present risks of treatment disruption. The decision delegates application of the strategy to additional products to the MDC (or another relevant body). The Secretariat will require modest additional capacity to implement the strategy and achieve the targeted savings and impact.

The report also proposes a decision point to expedite the transition to fixed-dose combinations of artemisinin-based combination therapies (ACTs) as requested by the Board at its Nineteenth and Twenty-Second Meetings (GF/B19/DP27 and GF/B22/DP11).

PART 1: INTRODUCTION

1.1 The Market Dynamics and Commodities Ad-hoc Committee (MDC) met in Geneva on 4-5 April 2011 for its 4th meeting. The Chair was Mr. Oliver Sabot (Private Foundations constituency); the Vice-Chair was Ms. Shanelle Hall (UNAIDS constituency).

1.2 Items for Board Decision included in this report are as follows:

- i. Part 2: Global Fund market-shaping strategy, and its initial application to ARV markets
- ii. Part 3: Expediting transition to fixed-dose combinations of (FDC) artemisinin-based combination therapies (ACTs)
- iii. Part 4: Other matters

PART 2: GLOBAL FUND MARKET-SHAPING STRATEGY AND ITS INITIAL APPLICATION TO ARV MARKETS

For decision

2.1 The Global Fund Board has recognized the need for the organization to ensure that it is achieving the greatest value for money with its investments in light of global resource constraints and the substantial unmet needs of countries fighting the three pandemics.¹ Shaping the market dynamics of the health products that make up a substantial proportion of the Global Fund's investments can play a critical role in that effort.

Background and objectives

2.2 Approximately 37 percent² of the Global Fund's USD 21.9 billion portfolio committed to approved proposals is invested in the procurement and management of health commodities. The Global Fund is one of the largest financiers of ARVs globally, supporting 3 million patients on treatment in over 90 countries, and is the largest financier of other key products such as long-lasting insecticide-treated nets (LLINs) and tuberculosis medicines.

2.3 To leverage the Global Fund's unique market share and access to information, an initial market dynamics strategy was launched in 2007, creating two new mechanisms, the Voluntary Pooled Procurement (VPP) and Price and Quality Reporting (PQR)³. A progress update on these ongoing initiatives is available in documents GF/MDC04/04 and GF/MDC04/02 listed in Annex 2 of this report.

¹ GF/PSC14/6: An agenda for a more efficient and effective Global Fund

² 2009 EFR figures ; 2010 EFR breakdown expected first week of May

³ GF/B15/DP15: "Market Dynamics and Voluntary Pooled Procurement"

2.4 While the VPP, the quality assurance policies, and the PQR have made important progress, they are responding to a pre-existing market situation. In its third report to the Board, the MDC noted that relatively modest opportunities existed to increase the value for money realized from spending on health products within current Global Fund strategies and policies and that the Secretariat was already pursuing.⁴ The MDC has therefore determined that additional, more active “market-shaping” strategic interventions are required to enable the Global Fund to significantly improve the value for money achieved with health products.

2.5 In 2009, the Board recognized the urgent need to address this strategic gap. The MDC was created, to identify ways to better influence health product market dynamics. The Board also made two other decisions related to shaping markets for health products: to accelerate the introduction of effective new HIV/AIDS technologies⁵ and expedite transition to more effective formulations of artemisinin-based combination therapies (ACTs) for malaria.⁶

2.6 The MDC engaged experienced consultants to conduct an in-depth analysis of ARV markets, building on extensive existing work in this area by partner organizations such as UNITAID, WHO, and CHAI, and to identify additional roles and opportunities for the Global Fund to shape those markets. The MDC relied on in-depth analysis of relevant product markets and consulted extensively with partner organizations, technical experts, and country representatives. This consultation process included an intensive meeting on market dynamics technical issues hosted by the Vice Chair in Copenhagen⁷ and the 4th official meeting of the MDC, which was attended by WHO and UNAIDS experts, and all MDC members, including all four recipient constituency representatives.

2.7 Following a review of the market factors and challenges for the major products financed by the Global Fund, the MDC selected antiretroviral drugs (ARVs) as the focus for its initial detailed development of market interventions. Anti-tuberculosis medicines, long-lasting insecticide-treated nets, and diagnostics were identified as potential focus products for the next period of the MDC’s work.

2.8 The MDC has determined that more active market-shaping interventions are required to enable the Global Fund to truly maximize outcomes such as price, quality, and availability for essential health products. The MDC has defined a set of market conditions that the Global Fund and its partners should target to provide optimal and sustainable outcomes for patients and countries. Those five key objectives for market-shaping interventions include:

⁴ See GF/B22/8. An analysis was presented showing that the actual prices countries paid for ARVs results in net savings of USD 42.9 million due a substantial number of countries that paid below international reference prices. However, the analysis also showed that some countries continued to pay above international references, with a total of approximately USD 26.5 million paid as a result of those higher prices. Five countries accounted for 60 percent of the total amount paid above international references.

⁵ GF/B19/DP34: Enhancing the Global Fund’s response to HIV/AIDS

⁶ GF/B22/DP11: Expediting transition to fixed-dose combinations of artemisinin-based combination therapies (ACTs)

⁷ In addition to MDC members, the Copenhagen consultation was attended by relevant experts from the Ministries of Health of South Africa and Zambia and representatives of the following organizations : UNITAID, the Global Fund Secretariat, the World Health Organization, the Bill & Melinda Gates Foundation, Médecins Sans Frontières, OXFAM, USAID, UNICEF, the Clinton Health Access Initiative, Results for Development, and John Snow International. A summary of the consultation is located on the MDC extranet site at http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/MDC%20Copenhagen%20Meeting%20Summary%20DRAFT%205Mar11.pdf.

- i. Consistent product quality in compliance with the Global Fund’s Quality Assurance policy;
- ii. Lowest possible sustainable pricing;
- iii. Sustainable and adequate supply;
- iv. Optimal product presentation to meet the needs of patients and supply chains; and
- v. Rapid availability of new and superior products and/or regimens to developing countries and patients

2.9 By pursuing all of these objectives, the Global Fund will maximize value for money by not only securing optimal prices, but also increasing health impact by financing higher quality, more efficacious, and better-designed products. This approach will also ensure that countries and patients have access to these benefits over the long-term as well as short-term.

Market-shaping strategy

2.10 The MDC proposes a comprehensive and nuanced strategy to make the Global Fund a “market shaper,” actively leveraging the organization’s unique market power, in line with its core principles, the Board’s original market dynamics strategy approved in 2007,⁸ and the mandate of the MDC.

2.11 The MDC developed this market-shaping strategy following consultation with technical experts and partners (e.g., WHO, UNAIDS), other major financiers (e.g., UNITAID, PEPFAR), civil society, and representatives of recipient countries from Western and Southern Africa, Latin America and the Caribbean, Eastern Europe, and the Western Pacific.

2.12 The overall goal of the market-shaping strategy is to dramatically increase the Global Fund’s impact on the three diseases by improving market outcomes of and therefore access to essential health products in line with the organization’s founding principles. The strategy sets out the specific objectives, additional strategic interventions, and guiding principles and analytical tools that the Secretariat and other Global Fund bodies (e.g., the MDC) will use to achieve that goal. The four specific objectives of the strategy include:

- i. Accelerate the introduction and maturation of new, superior products;
- ii. Ensure that recipients procure the most cost-effective WHO-recommended health products or regimens that meet the Global Fund’s quality assurance policies;
- iii. Strengthen countries’ national capacity to implement strategic procurement practices; and
- iv. Ensure the continued availability, affordability, and innovation of products, including those for which there are not sustainable market conditions.

⁸ GF/B15/DP15: “Market Dynamics and Voluntary Pooled Procurement”

2.13 The full market-shaping strategy is described in Annex 1, with its key characteristics and considerations for the Board summarized in this report. The strategy is intended to be implemented by the Secretariat, working with partners as appropriate, with ongoing oversight and guidance by the MDC.

2.14 The strategy centers on the use of rigorous market analysis to determine major challenges that prevent the achievement of the above objectives and implementation of appropriate, focused interventions to address those challenges. The analysis takes into account critical market factors such as market size and supplier power and competition. It will be updated regularly, in collaboration with other partners, to account for the constant evolution of markets. Where the analysis shows that a market can function effectively with little or no intervention, it will be left to do so but will be closely monitored for any adverse changes that may necessitate action.

This strategy has several principal advantages over alternative approaches:

- i. It is focused. That is, the Global Fund will only employ additional interventions for a limited number of health products that present particular risks or opportunities. As a result, the initial application of the strategy to ARVs (see Section 5 of Annex 1) would result in changes to procurement channels for a limited portion of the total ARVs and other health products that countries purchase with Global Fund resources.
- ii. Its interventions will usually be time-limited. Each intervention addresses specific market challenges and will be phased out as soon as analysis indicates that those challenges have been resolved.
- iii. It is flexible. The Global Fund will tailor its interventions to the specific challenges in each product market.
- iv. It is complementary to other partners' initiatives. The Global Fund will focus its interventions in markets that are not already adequately addressed by partner actions and will work closely with a range of partners such as UNITAID and UNICEF to design and implement those interventions.

2.15 As a result, it is expected that this strategy will have minimal impact on the volume of products purchased through national procurement systems, while maximizing the impact and value for money achieved with the Global Fund's investments in health products. By targeting products that will not otherwise be available or affordable and time-limited interventions, this strategy focuses the choice of whether to pursue additional market action as between **access or lack of access to life-saving products** instead of between local ownership and optimal value for money.

2.16 Once a target market for an effective product has been identified, the strategy will enable the Secretariat to implement a set of strategic interventions to resolve the identified challenges and improve market outcomes. These interventions will be determined by the MDC (or relevant replacement body) based on a technical analysis of the interventions best suited to address the specific challenges of the target market and the assessment of those interventions against five key principles: 1) the potential total impact; 2) the implications for country capacity; 3) the increase in value for money; 4) the fit with existing processes and potential additional administrative burden; and 5) complementarities with actions of other partners. By analyzing potential interventions against these principles, the MDC will ensure that the Global Fund's actions are coordinated with and fully additional to other partners. This coordination is facilitated by the active engagement of key partners such as UNITAID, USAID, UNICEF, and WHO on the MDC.

2.17 The “toolkit” that the Global Fund will have available to address market challenges will include the following primary interventions:

- i. **Enhance selection of value for money products** (see Section 3.3.1 of Annex 1)
 - Working with partners such as WHO, the Global Fund will commission rigorous analysis comparing the cost-effectiveness of clinically comparable products and treatment regimens.
 - Countries will have to provide a strong rationale for procuring a product or regimen with Global Fund resources that is found to be significantly less cost-effective or is not included in relevant international guidance (e.g., WHO guidelines and international formularies).
 - The contracted analytical partner will provide countries with support to conduct local cost-effectiveness analysis as appropriate and country requests to use alternative products will be reviewed by relevant technical experts identified by the Secretariat.
- ii. **Consolidate new product demand** (see Section 3.1.1 of Annex 1) -
 - To accelerate availability and optimal pricing of critical new products, the Global Fund can pursue several actions, including consolidating initial demand and strategically employing those volumes to engage and negotiate with suppliers. To achieve this demand consolidation, the Voluntary Pooled Procurement (VPP) mechanism can be set as the default procurement channel for the new product until targeted market conditions are achieved.
 - Countries will have the opportunity to justify not using the VPP for these products based on criteria such as the ability independently to achieve equal or better market outcomes (i.e., price and availability).
- iii. **Coordinated procurement** (see Section 3.2.1 of Annex 1) -
 - To ensure regular and secure availability of ‘high risk’ products, the Secretariat can require countries to use a consortium of a limited number of procurement agents, including the VPP, that will coordinate order timing to create sufficient demand for suppliers to produce the products.
 - Countries may choose to decline to procure through this consortium if they and other countries will still be able to obtain a sustained supply of the high risk products as determined by the Secretariat.

- iv. **UNITAID partnership** (see Section 3.1.2 of Annex 1) - A joint program with UNITAID, which also has a mandate and resources to actively shape markets, to introduce a more cost-effective new product will save funds for both organizations and ensure sustainable impact. The Secretariat is requested to develop a specific joint program with UNITAID, including identifying the new policies that the Global Fund will need in order for a smoother transition of product financing between the organizations to be possible.
- v. **Country capacity building** (see Section 3.3.2 of Annex 1) - Countries will be supported to improve their own procurement capacity by shifting the Capacity Building Services component of the VPP to provide resources directly to country institutions (e.g., drug regulatory authority) rather than through third-party organizations. These direct investments in the capacity of institutions will complement the technical assistance to those institutions provided by other partners.

2.18 In addition to these new interventions, the strategy recommends specific ways for the Global Fund to improve existing interventions to improve market outcomes, including:

- i. Improve the clarity and efficiency of **reprogramming processes** to provide countries with greater incentives to introduce higher value for money products, including through “first right of use” on savings realized because of the use of those products.
- ii. Make **operational and financial policy changes** that are essential to enable the VPP and its agents to effectively pool volumes and shape markets in accordance with Board decisions.
- iii. Mandating the Secretariat to use **additional strategic practices** through the VPP such as volume guarantees, splitting of tenders, and volume-based negotiation to effectively shape markets for relevant products
- iv. Develop a **revolving fund**⁹ that would help the Secretariat, through the VPP, mitigate the impact of financial delays on risk of stock-outs and market-shaping.

2.19 These changes should not alter the voluntary nature of the VPP: even in those cases where the VPP is the set as the default procurement channel for specific products, countries will have the choice to decline participation in the mechanism with appropriate justification.

2.20 The recommendations of only requiring time-limited use of VPP for targeted products, and of increasing the impact of capacity building, are in line with the Global Fund's earlier decision to employ the VPP as a short-term strategy and the capacity-building services/supply chain management assistance as a long-term strategy¹⁰.

2.21 Based on an in-depth analysis of ARV markets, the MDC has identified how the Global Fund can apply this strategy to the following markets by selecting relevant interventions from the “toolkit” described under 2.17:

- i. Pediatric ARVs (see Section 5.2.2 of Annex 1)
- ii. Emerging first line ARVs (Section 5.2.3 of Annex 1)
- iii. First and second line ARVs (Section 5.2.1 of Annex 1)

⁹ The Portfolio and Implementation Committee (PIC) is overseeing a feasibility study on a similar fund.

¹⁰ GF/B15/DP15: “Market Dynamics and Voluntary Pooled Procurement”

2.22 In addition to these interventions, the MDC emphasized the importance of the other cross-cutting components of the strategy such as strengthening the VPP through policy and process changes to improve ARV markets. The Secretariat is accordingly requested to ensure implementation of these cross-cutting components of the strategy before or at the same time as the ARV-specific interventions. Given the expected role of the VPP in procuring pediatric ARVs, which has been identified as the most urgent of the ARV interventions, the Secretariat is requested to prioritize implementation of the policy revisions necessary to ensure the optimal functioning of the VPP.

2.23 If the strategy is approved by the Board, the MDC (or other relevant body) will further work with the Secretariat, partners and independent experts, to apply the strategy to other priority markets such as anti-tuberculosis medicines, long-lasting insecticide-treated nets, diagnostics, and/or other major products financed by the Global Fund. Table 1 provides an overview of the recommended interventions and corresponding implications for the Global Fund.

2.24 The expected impact of these interventions in the ARV market for countries, the Global Fund, other donors, and, most importantly, patients living with HIV/AIDS, will be to:

- i. **Improve health outcomes**, including increasing patient survival, reducing side-effects, and delaying resistance;
- ii. **Potential savings of up to USD 500 million globally** (USD 250 million of Global Fund resources) **over 5 years** by shaping the market for new ARVs and optimizing selection of existing products;
- iii. **Enable 60-90,000 HIV+ children to receive treatment** over 4 years by preventing disruption of the pediatric ARV market;
- iv. **Significantly reduce risk of stock-outs of ARVs** and other medicines.

2.25 Implementation of this overall strategy and specific ARV interventions will not be possible with the current staff and resources available to the Secretariat. As a result, the Global Fund will need to make modest additional investments, starting in 2011, to realize the improved health gains and substantial savings made possible by this strategy. The specific additional investments required are detailed in Table 1.

Table 1: Summary of proposed Global Fund interventions to shape ARV markets to maximize patient outcomes and increase value for money

	PROPOSED INTERVENTIONS	CURRENT STATUS
<p>General</p> <p>Impact and resource implications</p>	<p>Investments:</p> <ul style="list-style-type: none"> • Coordinate and drive implementation and documentation of market-shaping interventions • Apply strategy to additional products, including for tuberculosis and malaria, to achieve further increases in value for money <p>1 FTE starting in October 2011¹¹, to be continued in 2012 and 2013 (To coordinate market dynamics strategic intervention activities)</p> <p>Project/data management software: Business case to be channeled through the Global Fund IT Advisory Board (ITAB) - 2012: USD 200,000; 2013: 100,000</p>	<p>No investments: → Insufficient capacity to strategically shape markets, including through use of VPP and by encouraging additional supplier entry where relevant</p> <p>Lower value for money through missed opportunities to shape markets</p>
<p>High risk products: Secure pediatric ARV marketplace</p> <p>Impact and resource implications</p>	<p>Investments:</p> <ul style="list-style-type: none"> • Ensure continued pediatric ARV treatment by coordinating procurement through a consortium of a limited number of procurement agents in countries formerly supported by the UNITAID pediatric program¹² • Work with partners to ensure necessary country activities (e.g. robust forecasting) <p>1 FTE starting in October 2011¹¹, to be continued in 2012 and 2013. (To coordinate procurement, facilitate participation in the pediatric consortium of Procurement Agents, communicate with partners for in-country support)</p> <p>Operational costs, 2011: USD 50,000, continuing in 2012-13 at an annual amount of USD 125,000 (Provision of technical support to participating countries - forecasting, procurement planning - in collaboration with partners)</p>	<p>No investments: → Insufficient actions to meet minimum market conditions after phase-out of UNITAID pediatric program¹², resulting in excessive supply delays for pediatric ARVs and potential treatment disruption</p> <p>Significant negative health outcomes through disruption of treatment for HIV-positive children</p>

¹¹ Should the Board approve the resource implications of this strategy in the third Quarter of 2011, recruitment would conclude by the end the third quarter and budgetary implications would start on or about October 2011 (Quarter 4).

¹² The UNITAID pediatric program has coordinated procurement of pediatric ARVs in 34 countries for 70 percent of global demand; 46 percent of the UNITAID demand is expected to be assumed by Global Fund (see Resource Document 1)

	PROPOSED INTERVENTIONS	CURRENT STATUS
<p>High opportunity products: Accelerate product introduction</p> <p>Impact</p>	<p>Investments:</p> <ul style="list-style-type: none"> Strategically manage demand of targeted new products, including through required use of the VPP (except in cases of country rationale for alternatives) to consolidate volume as appropriate Develop joint program with UNITAID for new product introduction, including policies for smoother transition, to create value for money benefits for both organizations. <p>No budgetary implications for 2011 foreseen¹³</p>	<p>No investments: → No strategic planning for new product introduction, resulting in slow uptake and higher prices of new, superior products (see Attachment 1)</p> <p>Lower health impact and value for money through slower uptake of market optimization (e.g., slower price reductions) for superior products</p>
<p>All products:</p> <p>a. Optimize product selection</p> <p>Impact and resource Implications</p>	<p>Investments (coordinated with partners):</p> <ul style="list-style-type: none"> Commission rigorous comparative cost-effectiveness analysis of relevant products to identify significant differences in value for money Establish policy to require countries to use products found to be significantly more cost-effective unless an appropriate justification is provided, with defined criteria for approving country requests for alternative products (with support from expert group), appropriate periods for transition, and other policy measures. <p>1 FTE from October 2011¹¹, to be continued in 2012 and 2013 (Contract management, technical advice on opt-out mechanism)</p> <p>Commissioned cost-effectiveness analysis - 2011: USD 50,000; 2012: USD 200,000; 2013: USD 150,000</p> <p>Expert working group on opt-out mechanism - 2011: USD 50,000; 2012: USD 125,000; 2013: USD 75,000</p>	<p>No investments: → Suboptimal selection of WHO-recommended first- and second-line ARV regimens</p> <p>Suboptimal health impact, Missed opportunity for Global Fund savings of up to USD 170 million over five years</p>

¹³ Budgetary implications for 2012 and 2013, if any, cannot be anticipated yet. These will depend on whether a new ARV product will receive regulatory approval and will be recommended by WHO and will be targeted by market dynamics interventions in that timeframe.

	PROPOSED INTERVENTIONS	CURRENT STATUS
<p>b. Reduce funding volatility and stock-outs</p> <p>Impact and resource Implications</p>	<p>Investments:</p> <ul style="list-style-type: none"> Operational and financial policy changes to enable VPP to pool volumes and strategically shape markets, including enabling commitment and representation of volumes on behalf of PRs Implementation of additional VPP strategies such as volume guarantees and split tenders Revolving fund to bridge disbursement delays which can cause stock-outs <p>No budgetary implications at present</p>	<p>No investments:</p> <ul style="list-style-type: none"> →VPP not equipped with strategies and policies to shape markets →Disbursement delays result in frequent emergency orders and higher costs →Current policies do not allow effective pooling according to Board decisions due to inability to make advance commitments <p>Higher risk of stock-outs Inability to achieve best prices and other market outcomes such as sustainable supply</p>
<p>c. Strengthen country strategic procurement</p> <p>Impact and resource Implications</p>	<p>Investments:</p> <ul style="list-style-type: none"> Support country capacity in strategic procurement practices by providing resources directly to relevant country institutions and not third party organizations. <p>1 FTE starting in December 2012 , to be continued in 2013 <i>(To develop proposal for additional incentives for countries, improve capacity building services and provide direct support to country institutions)</i></p> <p>Operational costs - 2011: USD 50,000 continuing in 2012-13 at an annual amount of USD 125,000</p>	<p>No investments:</p> <ul style="list-style-type: none"> →Insufficient resources to improve procurement and supply management in countries → Resources channeled to third party organizations for technical assistance rather than appropriate country institutions <p>Lack of in-country capacity prevents improvements in value for money by shaping markets and affects grant performance</p>
<p>Total Annual resource implications (estimated)</p>	<p>2011: 4 FTEs starting on or about October, and USD 200,000 2012: 4 FTEs (cont'd from 2011), and USD 775,000 2013: 4 FTEs (cont'd from 2011) and USD 575,000</p>	
<p>Estimated Total Resources to launch Strategy (estimated)</p>	<p>4 FTE's and USD\$ 1,550,000 from 2011-2013</p>	

2.26 The MDC recommends the following decision point to the Board:

Decision Point 1: Global Fund Market-Shaping Strategy and Market-Shaping Interventions for ARVs

Part 1 - Key principles of Market-Shaping Strategy

- 1) *The Board acknowledges the critical role of the Global Fund in shaping markets to maximize global access to health products in accordance with the applicable Global Fund quality assurance requirements at affordable and sustainable prices and further emphasizes its desire for the Global Fund to more actively shape the markets for health products to optimize price, quality, design, and sustainable supply.*

Part 2 - Market-Shaping Strategy

- 2) *The Board approves the market-shaping strategy of the Global Fund set out in Annex 1 to the Report of the Market Dynamics and Commodities Ad-hoc Committee (“MDC”) to the Board (GF/B23/9 Revision 1) (“Market-Shaping Strategy”). The Board requests the MDC to oversee the refinement and implementation of the Market-Shaping Strategy.*

Part 3 -Market-shaping interventions for Anti-Retroviral medicines (“ARVs”)

- 3) *The Board approves the strategic interventions for ARVs in accordance with the Market-Shaping Strategy (“Strategic Interventions”) as recommended by the MDC and described in Annex 1 to the MDC Report to the Board (GF/B23/9 Revision 1).*
- 4) *The Board requests the Secretariat to implement the Market-Shaping Strategy and relevant Strategic Interventions under the oversight of the MDC. The Board requests that an implementation framework and appropriate policies and procedures be developed to effectively implement the Strategic Interventions with appropriate consultation. The Board requests the MDC to report back on progress at the Twenty-Fourth Board Meeting.*
- 5) *Recognizing the risk of supply disruption to pediatric ARVs for certain Global Fund grant programs due to the phase-out of the UNITAID pediatric ARV program, as identified by the MDC and outlined in Table 1 of the MDC Report to the Board (GF/B23/9 Revision 1), the Board requests the Secretariat to prioritize the implementation of the Strategic Interventions set out in Section 5.2.2 of the Market-Shaping Strategy. Further, the Board requests the Secretariat, in consultation with UNITAID and other relevant partners, to facilitate the provision of support to principal recipients to sustain pediatric ARV treatment. The Board further requests the Secretariat to prioritize the execution of the appropriate policy and procedural changes to enable the Secretariat to use the VPP to strategically manage demand for pediatric ARVs to ensure the consistent and timely availability of these products purchased through the VPP.*
- 6) *The Board requests the Secretariat and MDC to provide an update on progress in refining and implementing the Market-Shaping Strategy and the Strategic Intervention for ARVs at the Twenty-Fourth Board Meeting. The Board also requests the MDC to oversee an independent evaluation of the strategy after an appropriate period of implementation.*

Part 4 - Budgetary Implications

- 7) The Board recognizes that implementation of the proposed Strategic Interventions for ARVs have budgetary implications for the Secretariat's operating expenses budget starting in 2011 as described in Table 1 of the MDC Report to the Board (GF/B23/9 Revision 1). The estimated implications for 2011 amount to USD 350,000 for provision of market-shaping tools and implementation of Strategic Interventions, including 4 Full Time Equivalents ("FTEs") starting on or about October 2011.**
- 8) The Board requests the Finance and Audit Committee ("FAC") to consider and approve the budgetary implications of this Decision Point within the framework of the 2011 administrative budget review, which is scheduled for June 2011**
- 9) The Board further requests the FAC to consider the budgetary implications of market-shaping strategies including the continued cost of the 4 FTEs for 2012 and later years as part of the regular budgeting cycle.**

Part 5 - MDC authority to approve implementation of subsequent Strategic Market Interventions

- 10) Recognizing the MDC's technical competency, the Board authorizes the MDC to approve the implementation of other Strategic Interventions for health products procured using Global Fund financing, without requiring further approval or authorization from the Board, provided that such Strategic Interventions:
 - (a) will not increase the Operating Expenses Budget of the Global Fund beyond the matters referred to in Part 4 above;**
 - (b) will not contravene, or require an amendment to, a Decision Point or policy approved by the Board; and**
 - (c) are consistent with the principles set out in the Market-Shaping Strategy.****
- 11) The MDC shall notify the Board through the relevant MDC Reports to the Board of:
 - (a) any subsequent Strategic Interventions approved by the MDC for implementation in accordance with this Decision Point; and**
 - (b) the progress of the implementation of such Strategic Interventions, including the phase-out of Strategic Interventions in accordance with the Market-Shaping Strategy.****

Part 6 - MDC Authority Extends to Any Successor

The Board agrees that at its Twenty-Fourth Meeting it will request the Policy and Strategy Committee (PSC) to recommend a course of action about the continuation of the MDC. Consequently, the Board determines that the authority and responsibilities conferred on the MDC in this Decision Point as applicable, shall apply with such necessary and consequential changes to any successor body or panel that may be approved by the Board to replace the role and responsibilities of the MDC in respect of this Decision Point.

PART 3: EXPEDITE TRANSITION TO FIXED-DOSE COMBINATION (FDC) ACTS For decision

3.1 Transition to FDC ACTs is consistent with the market-shaping strategy proposed in Part 2 of this paper, as it contributes to value for money in grant-funded programs by optimizing treatment outcomes, and provides added incentives for manufacturers to focus on producing FDC ACTs which meet internationally recognized quality standards.

3.2 At its 3rd meeting, the MDC decided to assess country implications before requiring transition to FDCs of ACTs for which both co-blistered and FDC formulations exist, i.e. artesunate+amodiaquine (ASAQ) and artesunate+mefloquine (ASMQ). The Secretariat has reviewed implications in countries and sources of finished products presented in FDC that comply with the Global Fund Quality Assurance Policy for Pharmaceutical Products (the QA Policy) for these two combinations:

- i. **ASMQ** is recommended as first-line treatment in four Eastern Asian and four Latin American countries, while in Africa there has been limited experience with the use of ASMQ and concerns have been raised about the tolerance in infants. Orders for ASMQ with Global Fund funds are expected to remain limited to few countries and low volumes, and ASMQ is likely to be phased out once other ACTs become available.
- ii. **ASAQ** is recommended as first-line treatment in 21 African countries and in Indonesia. Most have already procured and used FDCs. The number of countries reporting procurement of co-blisters and the volumes procured have steadily decreased since 2008. Few potential barriers remain for transition to FDCs:
 - Of 19 countries with active Global Fund grants for malaria treatment, all except Eritrea have reported completed or planned procurement of ASAQ FDCs exclusively or in addition to co-blisters. Eritrea is moving to FDCs in 2012/13.
 - Of four countries not currently supported with grant funds for malaria treatment but having ASAQ as nationally recommended first-line treatment, only one (Indonesia) is yet to register FDCs; the others have been procuring FDCs, although not exclusively.
 - AMFm has co-paid co-blistered ASAQ treatments in two countries in 2010; orders for ASAQ co-blisters represented a small proportion of the total¹⁴. Contracts with buyers contain a clause reserving the right for the Global Fund to switch to financing only FDCs with 90 days' notice. At its 3rd meeting the AMFm Committee was supportive of the MDC's approach, and has re-affirmed this support in the follow-up to its 4th meeting.

3.3 The MDC agreed that preferential funding for FDCs should be introduced as soon as two finished products complying with the QA Policy exist on the market. This is to encourage a competitive market to reduce the risk of supply disruptions.

¹⁴ As confirmed in the report of the AMFm Committee to the Board at its Twenty-Third Meeting (GF/B22/8)

- i. For ASAQ, one source exists of a FDC finished product (in presentations for all 4 age groups) complying with the QA policy, with sufficient production capacity to cover expected Global Fund demand. Two other FDC finished products are under review by the WHO Prequalification Programme, and it is likely that one or both of them will be prequalified by the end of 2011. Since only few potential barriers remain as mentioned under point 0 above, it can be considered that countries are ready to move to FDCs. To ensure a smooth transition in grant-funded programs, a grace period of up to one year should be envisaged, to be granted at the discretion of the Secretariat.
- ii. For ASMQ, the condition of having two FDCs available is unlikely ever to be met. No qualified FDC finished products are on the market except a locally used product in Brazil; one FDC finished product is currently under WHO prequalification. Currently, some Eastern Asian countries procure co-blisters, and Thailand uses loose tablets to suit its weight band requirements. However, this combination is likely to be phased out as new ACTs become qualified. The MDC did therefore not see a need for additional provisions in the policy to accelerate the transition to FDCs for ASMQ.

3.4 The MDC recommends the following decision point to the Board:

Decision Point 2: Expediting transition to fixed-dose combinations of artemisinin-based combination therapies (ACTs)

1. *In accordance with Board Decision Point GF/B22/DP11, the Board notes that the Market Dynamics and Commodities Ad-hoc Committee (“MDC”), in line with WHO guidance, has presented recommendations to the Board regarding appropriate transition by recipients of Global Fund financing to the use of fixed-dose combinations (FDCs) of artemisinin-based combination therapies (ACTs).*
2. *The Board determines that once the Secretariat has decided in its discretion that there are at least two FDC Finished Pharmaceutical Products of an ACT Formulation (“FDC ACT”) for the treatment of uncomplicated malaria that comply with the Global Fund Quality Assurance Policy for Pharmaceutical Products (as approved by the Board in accordance with Decision Point GF/B22/DP9) (“QA Policy”), and each FDC ACT is considered “available” as defined in Section 8 of the QA Policy,*

then,

- (a) the Global Fund shall notify Principal Recipients in writing and on the Global Fund website that it has made such a decision (the date of such notification being the “Notification Date”); and*
- (b) from 90 days after the Notification Date, Global Fund financing for that ACT formulation can only be used to procure FDCs of that ACT formulation.*
3. *For recipients of Global Fund financing that have not procured FDC ACTs using Global Fund financing prior to the Notification Date, a grace period of up to one year to transition to FDC ACTs can be applied on a case-by-case basis, at the discretion of the Secretariat. The Secretariat, in collaboration with partners, will facilitate the provision of support to recipients of Global Fund financing to conduct an effective and timely transition to FDC ACTs where necessary and appropriate.*

This decision does not have material budgetary implications for the 2011 Operating Expense Budget.

Intellectual property rights and access to treatment

4.1 The MDC discussed the relevance, emphasized in a recent UNDP/UNAIDS/WHO policy brief¹⁵, of TRIPS flexibilities to access to health products in developing countries. The MDC acknowledged the measures that the Global Fund has already taken in this regard, including defining a health product procurement policy that encourages grant recipients to use TRIPS flexibilities to achieve lowest possible prices for products of assured quality through competitive procurement¹⁶, the Global Fund Executive Director's exchange with the EU and the Indian Government in relation to the upcoming free trade agreement, and the ongoing support that the Global Fund Secretariat provides to recipient countries on these issues in collaboration with partners and technical experts. The MDC will further discuss intellectual property issues as part of its work on market dynamics interventions under the proposed market-shaping strategy. The USG delegation did not support the recognition of Global Fund policies in this area or the plan for the MDC to further these issues in subsequent meetings.

This document is part of an internal deliberative process of the Global Fund and as such cannot be made public until after the Board meeting.

¹⁵ UNAIDS/WHO/UNDP. Using TRIPS flexibilities to improve access to HIV treatment. Policy Brief. March 2011. http://www.who.int/entity/phi/phi_trips_policybrief_en.pdf

¹⁶ "The Fund encourages Recipients to apply national laws and applicable international obligations in the field of intellectual property including the flexibilities provided in the TRIPS agreement and interpreted in the Doha declaration in a manner that achieves the lowest possible price for products of assured quality." (Third Board Meeting, 2002. The Global Fund Board Decisions Related to Quality Assurance Policy. Section C. Point 10)

MARKET DYNAMICS STRATEGY

In 2004, the Global Fund actively shaped a market. The result was accelerated access to essential treatment for hundreds of millions of people. Working closely with the World Health Organization (WHO), the Global Fund facilitated countries to rapidly switch funding and policies from suboptimal therapies to the highly effective artemisinin-based combination therapies (ACTs). By the end of the year, 21 additional African countries were using ACTs and all but 2 countries were using the drugs by 2007. Distribution of the drugs also leapt from less than 1 million in 2003, to 190 million from 2004-2007 - one of the largest and fastest scale-ups of a pharmaceutical product ever. Competition in the market increased - from one quality-assured supplier in 2004 to seven in 2010 - and the price of the drug fell more than 50 percent over 5 years, enabling even greater scale-up.

Without the active engagement of the Global Fund, this dramatic change would have taken many more years, if at all, at the cost of many lives and increased risk of drug resistance. Yet, despite the persistence of critical market challenges for other essential products, the Global Fund has not worked to actively shape a market outside of malaria treatment. This market-shaping strategy aims to fill that gap, providing the Global Fund with deliberate and surgical approaches that can benefit millions of patients and save hundreds of millions of dollars while continuing to support and strengthen countries' procurement capacity.

1. RATIONALE AND OBJECTIVES

In 2007, the Board of the Global Fund to Fight AIDS, Tuberculosis, and Malaria determined that the organization should play a greater role in influencing the market dynamics of the health products that it finances and created two new mechanisms to pursue that approach. While the Global Fund has made significant progress in implementing those mechanisms - Voluntary Pooled Procurement (VPP) and Price and Quality Reporting (PQR), as well as the quality assurance policies - it remained, for the first nine years of its operation, a largely passive actor in the market, allowing its investments to intrinsically influence supply dynamics but not strategically using its central role in the market to pursue better outcomes that will further its health impact goals.

This strategy builds on the Global Fund's work to date and its core organizational strategy and principles to make the organization an active 'market shaper.' Under this strategy, the Global Fund will set specific objectives for the characteristics of and outcomes from (i.e., price, quality, availability, and product design) selected product markets and implement relevant interventions that will leverage its grant investments to achieve those objectives.

This more active role in markets is a significant new direction for the Global Fund, which has pursued a largely ‘hands-off’ model to date. Market issues are inherently complex and consistently changing. As a result, the Global Fund will need to develop new interventions, policies, and numbers and skills of staff to be able to implement the necessary nuanced and strategic actions to improving markets over both the short- and long-terms. It will also require the Global Fund to work closely with relevant partner organizations that have expertise and investments in these markets. This strategy reflects those imperatives, providing the MDC and Secretariat with the necessary flexibility to adapt interventions to evolving markets and ensuring that the selection of target products and interventions is closely coordinated with the actions of other partners.

It has often been assumed that more actively shaping markets would require the Global Fund to significantly compromise one of its core principles, that of country ownership. This strategy proves that assumption false, identifying approaches the Global Fund can take to dramatically impact markets while enabling principal recipients and countries to retain the majority of decision-making related to procurement of health products funded by the Global Fund. By focusing on products that will not otherwise be available or affordable and time-limited interventions, this strategy is focused on choices between **access or lack of access to life-saving products** instead of a choice between local ownership and optimal value for money.

Market-shaping objectives

The overall goal of this market-shaping strategy is to dramatically expand the Global Fund’s impact on the three diseases by improving market outcomes of and therefore access to essential health products. To achieve this goal, the Global Fund will actively pursue a set of specific objectives. At present, there are four such objectives that will guide the organization’s market-shaping activities, but these may be refined and/or expanded as product markets and the Global Fund evolve over time. The current objectives include:

1. Accelerate the introduction and maturation of new, more cost-effective products;
2. Ensure recipients procure the most cost-effective, WHO-recommended health products or regimens that meet the Global Fund quality assurance policies;
3. Strengthen countries’ capacity to implement strategic procurement practices;
4. Ensure the continued availability, affordability, and innovation of products, including those for which there are not currently sustainable market conditions.

The MDC, working with the Secretariat and relevant partners, will translate these objectives into specific targets for each market in which the Global Fund intervenes in order to guide implementation and hold the Secretariat and other relevant actors accountable for the intended results. For example, a target may be set of ensuring a new, more effective product is successfully introduced in a specific number of countries within a specific number of years following WHO recommendation. These targets and progress against them will be reported to the Board and its relevant committees.

2. APPLICATION AND IMPACT OF MARKET-SHAPING STRATEGY

2.1 Market classification framework

A critical principle of this strategy is that the Global Fund should only intervene in markets when necessary and tailor its interventions to the specific challenges of the target market. The first step in the strategy is accordingly the thorough analysis of relevant markets and application of a simple but robust market classification framework. Those classifications determine the general objectives the Global Fund should pursue in that market and the interventions it can use to achieve those objectives. The different market classifications and corresponding objectives and interventions are summarized in Figure 1.

Figure 1. Market classification framework

Ensure continued efficient functioning of market; use of highest value for money products; strengthen countries' capacity to improve outcomes without intervention.	Accelerate introduction of and achievement of optimal market outcomes for relevant products and ensure sustainable supply base.	Prevent disruptions in access and deteriorating price and availability, while maintaining incentives for product innovation
1) Medium or large market size AND 2) Balance in supplier and buyer power	1) Low market size and high market growth potential AND/OR 2) High supplier power relative to buyer power	1) Low market size and possible demand fragmentation AND 2) Low market growth potential
Strategic procurement practices e.g. splitting tenders, prompt payments, high quality forecasts, predictable ordering		
Optimizing product selection of highest VFM products		
<ul style="list-style-type: none"> • Strengthen country strategic procurement • Maintain diverse and low-risk purchaser base 	<ul style="list-style-type: none"> • Strategic consolidation and management of demand • Volume-based guarantees • Price negotiations • Streamlined product registration • Expedited SRA approval 	<ul style="list-style-type: none"> • Increase/ coordinate volumes • Consolidate product mix
All countries	High-volume countries	Varies ¹

2.2 Application of classification framework for strategic interventions

Market analysis and classification of products:

The Global Fund, working with partners, will ensure that there is regular and rigorous analysis of the markets for key health products to determine critical factors such as market size and the relative power of suppliers in determining price and supply. Based on those and other relevant factors, the Global Fund will determine markets that are already largely healthy (“**market equilibrium**”) and therefore require minimal, if any, additional intervention and those that face challenges that present significant opportunity for major additional benefits (“**high opportunity**”) or risk of disruption (“**high risk**”). Greater detail on the relevant analytical factors and the definitions that the Global Fund will use in classifying products can be found in the attached Consultant Report (see Attachment 1).

Markets are constantly evolving and will often move between the different classifications in this framework. For example, a product which began as “high opportunity” due to presence of a single supplier and low initial demand, may be reclassified as at equilibrium once more suppliers enter the market and demand increases. It is therefore essential that the Global Fund and its partners consistently monitor and reanalyze markets (e.g., on an annual basis) to determine if existing interventions can be phased out or if new interventions are required.

Intervention design

It is expected that the Global Fund will focus most of its interventions in the limited number of markets that are classified as either ‘high risk’ or ‘high opportunity.’ However, this framework is not an exact science and there may be specific challenges in markets that are otherwise healthy that warrant intervention from the Global Fund. Interventions will be designed for each product market and tailored to the specific challenge(s) in that market. Figure 1 provides guidance on the interventions that are best suited to each market classification, but, given the diversity in markets, the MDC and Secretariat are able to apply any intervention in the “toolkit” if the conditions of the market warrant it. Interventions will be phased out once the relevant challenges are adequately resolved and the absence of the intervention will not lead to a significant deterioration in market conditions.

This approach will ensure that most Global Fund market-shaping interventions are **targeted** and **time-limited**, thereby minimizing any trade-offs of core Global Fund principles that are required to implement them.

Assessment of interventions

In determining when to intervene in a market and which interventions to employ, the Global Fund will analyze options against a set of criteria, which are consistent with its core principles. Those criteria include:

- 1) **Potential total impact:** The intervention’s impact on patient outcomes, product access, and financial savings;
- 2) **Implications for country capacity:** The intervention’s impact on and alignment with countries’ capacity and systems for procuring and managing health products;

- 3) **Increase in value for money:** The intervention's impact on the value for money achieved with Global Fund health product investments;
- 4) **Fit with existing Global Fund processes and potential additional burden:** The additional transaction costs (e.g., new policies and/or complicated and burdensome processes) created by the intervention; and
- 5) **Complementarity with partners:** The alignment of the intervention with the actions of other partners in the market and potential for unnecessary duplication.

The last criterion is particularly important as, in keeping with the principles of this strategy, the Global Fund should not intervene where other partners are already adequately addressing market challenges. The Global Fund should encourage partners to fulfil their roles in market-shaping activities rather than conducting all necessary actions itself. However, the Global Fund should plan its interventions based on actual actions conducted by partners and not potential actions that may not be implemented at the right time or with the necessary quality.

2.3 Expected impact of strategy

The initial application of the strategy by the MDC and Secretariat to markets for ARVs has revealed that strategic interventions can have a dramatic impact on the Global Fund's core objectives in a number of areas, with potential greater effects as interventions are pursued for other products, including malaria and tuberculosis. The strategy is intended to be durable so that impact will be achieved with future (e.g., a potential malaria vaccine) as well as current health products.

Improved market outcomes are a global public good so the impact of the Global Fund's interventions will benefit not only its direct recipients, but other countries and purchasers as well.

For example, major areas of expected impact of the strategy will include:

Improved health outcomes: Market-shaping interventions can improve health outcomes in a number of ways, including increasing the speed at which a product is introduced and enabling access to more effective, higher quality, and/or better designed products.

Increased value for money: Increasing use of and reducing prices of more effective products can significantly improve the value for money realized with Global Fund investments. For example, initial interventions in ARV markets are estimated to result in estimated potential savings of approximately USD 250 million for the Global Fund (more than USD 500 million globally) over five years with equal or greater health impact.

Accelerated access to effective products: Accelerating introduction of new, cost-effective products can dramatically increase health outcomes and save hundreds of millions of dollars compared to the more gradual uptake that would take place without intervention.

Reduced stock-outs and product disruption: High risk products may not be sufficiently attractive to suppliers given small and potentially fragmented volumes and low market growth potential. Given public health interests, efforts can be taken to improve market functioning and increase appropriate supplier incentives. These efforts can prevent disruptions in access and deteriorating price and availability, while maintaining

incentives for product innovation.

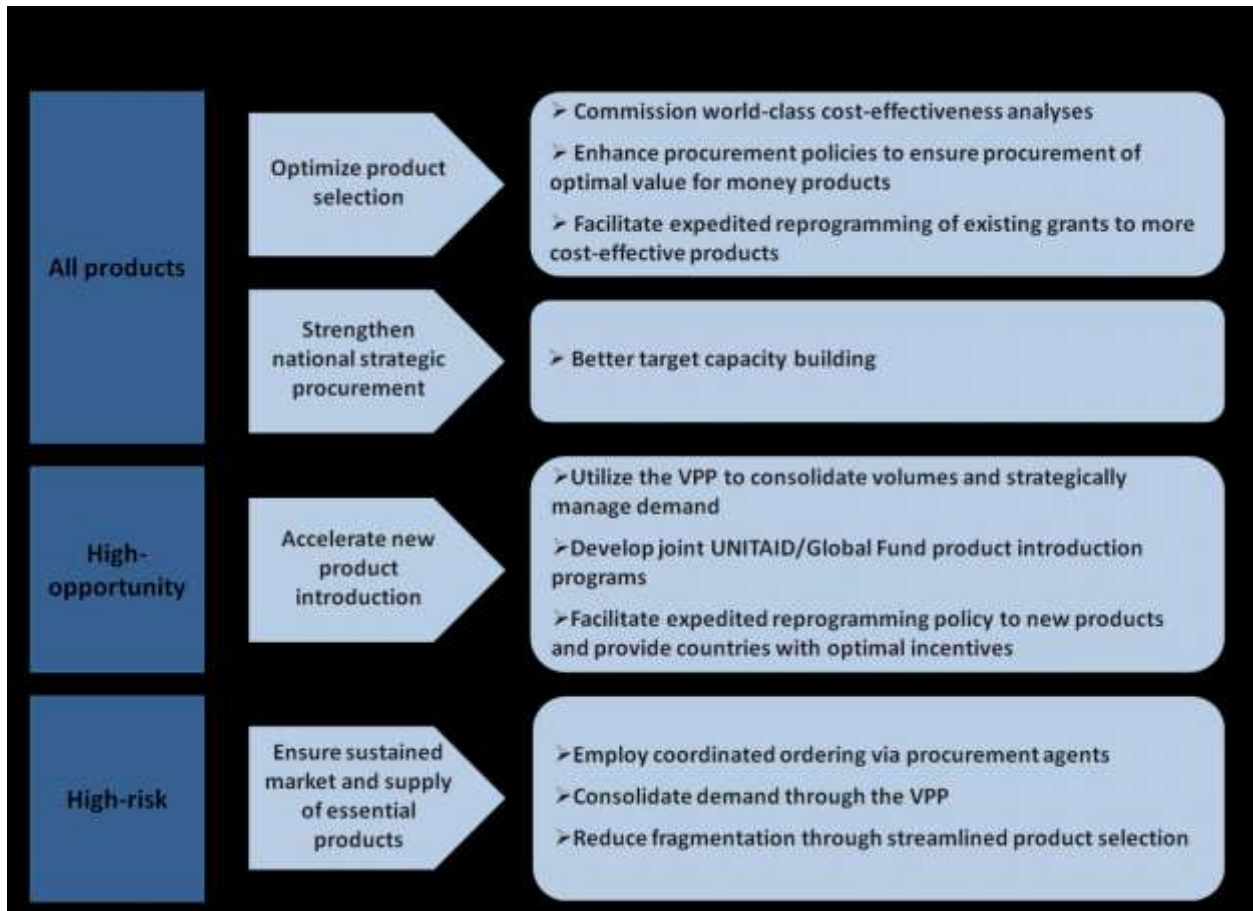
This strategy has the potential to impact market and health outcomes in the medium- and long-term as well as the short-term. By providing more predictable, lower risk markets and clear pathways to ensure rapid scale-up of effective new products, the Global Fund's interventions can encourage new suppliers to enter markets and continued innovation and development of products.

3. STRATEGIC INTERVENTIONS

Given the diverse and changing nature of markets, this strategy provides the Global Fund with a “toolkit” of additional interventions that it can select from to shape specific product markets. This toolkit builds on the core architecture and mechanisms of the Global Fund, including the VPP, quality assurance policies, and PQR, and introduces several additional interventions that will be critical to achieving the organization's market-shaping goals. The specific policies and procedures needed to implement these additional interventions will be developed by the Secretariat in line with this strategy.

The interventions in the toolkit are grouped according to their application to the three major market classifications: high opportunity, high risk, and all product markets, including market equilibrium (see Figure 2).

Figure 2. Overview of strategic interventions



3.1 Strategic interventions for high opportunity products

High opportunity products, which include many newly developed products, are characterized by low market size and high market growth potential. Many high opportunity products face a negative cycle, with low product demand leading to suboptimal production, which in turn leads to higher prices that suppress demand. Given time, these challenges will often naturally resolve themselves, but the long delays lead to significant losses in health impact and value for money.

Objectives

- Accelerate the number and scale of countries accessing products
- Accelerate improvements in market outcomes for the products, including lowered price and increased availability
- In parallel: broaden the supplier and production base to ensure sustainable market gains

Interventions

Given the defining challenges outline above, high opportunity markets will typically require interventions that will provide greater and more predictable demand for the product. If managed strategically, this demand will enable suppliers to overcome the risk that limits supply and keep prices high, which in turn will enable greater country access, thereby breaking the vicious circle.

Since interventions for high opportunity products are largely volume-based, they do not need to be applied in all countries, but can rather be focused in countries that represent a sufficient level of volume to meet the minimum needs of suppliers. As described above, the overarching objective in these markets is to shift the products from a high opportunity to a market equilibrium classification, with interventions being phased-out as soon as that is achieved.

3.1.1 Utilize the VPP to consolidate volumes and strategically manage demand

If a product market requires consolidated demand, the VPP can be set as the default procurement channel for that product until the specified market conditions have been met. This additional requirement can be applied to a limited set of countries determined during the design of the intervention (e.g., only the expected highest volume purchasers for the product) and those countries that are included will have the option of declining to participate. If a country declines to participate and wishes to purchase the product through an alternative channel using Global Fund financing, it will need to justify its decision based on key criteria. These criteria, which will be elaborated by the Secretariat, will include the ability to obtain similar or greater outcomes such as price and consistent supply for the product and the alignment of the alternative channel with national systems and policies (e.g., not another third-party procurement agent).

The Secretariat and VPP procurement agents will need to strategically use this consolidated demand through approaches such as volume guarantees, split tenders, and volume-based negotiation. The Secretariat will need to develop relevant policies and/or partnerships to enable these strategies (e.g., volume guarantees may require changes to policy or collaboration with an outside partner to provide the guarantee). The VPP will also need to be equipped with the policies and operational capacity to be able to effectively pool and manage volumes (see Section 5 below).

3.1.2 Develop joint UNITAID/Global Fund product introduction programs

As a catalytic financier, UNITAID has the ability and mandate to commit significant additional resources to accelerate introduction and shape the market of a new product, including by encouraging new suppliers to enter target markets to increase sustainability and affordability. Such a program is only possible, however, if UNITAID is able to efficiently transition financing for the product to another donor such as the Global Fund once the market objectives are achieved. Experience to date indicates that transition is difficult without additional planning and policies from both UNITAID and the Global Fund.

While the Global Fund will need to work closely with a range of partners to effectively implement this strategy, there is a particularly strong opportunity and need to collaborate closely with UNITAID. This is because of the need for UNITAID to have a clear transition plan to a major financier such as the Global Fund to optimally use its resources to shape markets and the fact that it is one of very few organizations with a specific mandate and significant resources to shape markets for AIDS, tuberculosis, and malaria products.

A joint program between UNITAID and the Global Fund, working with other partners as relevant, can accordingly reduce the financial burden of both partners while maximizing outcomes for countries. Those programs will require two additional critical actions on the part of the Global Fund:

- 1) Upfront planning and agreement - The relevant decision-makers in the Global Fund and UNITAID will need to agree on the components of a program, including the countries, timeline, financing levels, and transition methods. The Global Fund Secretariat will accordingly seek to engage with their counterparts at UNITAID to develop a specific plan for a joint product introduction program as well as to jointly consult with relevant countries to ensure the program aligns with countries' needs and challenges. This plan will be reported to the MDC and subsequently to the Board as appropriate.
- 2) Efficient transition policies - To prevent disruption in treatment access during the transition between financiers, the Global Fund will need to develop additional policies that will enable recipients to access funding for the product with minimal delays. These policy revisions will be developed by the Secretariat and may include provision of funding outside the normal round-based process and/or expedited application for and approval of product funding (e.g., changing the guidance to the TRP so that the default is the relevant component will be approved unless there are serious technical concerns). The Secretariat will present these proposed policy revisions to the MDC at the same time as the broader plan for a joint program with UNITAID for discussion and recommendation to the Board as necessary.

3.1.3 Facilitate expedited reprogramming policy to new products and provide countries with optimal incentives

Global Fund recipients have indicated that lack of clarity and efficiency in reprogramming processes have reduced their incentive to switch to more cost-effective products during a grant. The Secretariat will accordingly adjust reprogramming policies, including through providing countries with clearer "first right of use" on savings (i.e., the recipients will have the opportunity to reinvest the freed resources to achieve the goals of the grant before they are returned to the general Global Fund resource pool), and effectively communicating them to countries and partners.

Responsible reprogramming requires recipients to complete a range of technical and operational actions, which may lead to delays regardless of the efficiency of Global Fund processes. As a result, it will be important that countries receive appropriate technical assistance. If necessary, the Secretariat can play a more active role in facilitating reprogramming to accelerate introduction of specific high opportunity products. The Global Fund did this in 2004 when it worked with WHO to help countries rapidly transition grant funding to artemisinin-based combination therapies (ACTs). Facilitation approaches will be determined by the Secretariat but could include conducting regional meetings to support countries to efficiently complete reprogramming processes and better coordinating with partners to provide in-country support.

3.2 Strategic interventions for high-risk products

High risk products are typically supplied from unattractive marketplaces for suppliers given limited market size and growth potential, potentially coupled with high product fragmentation. As a result, without intervention, suppliers may not consistently provide the products or may exit the market altogether, jeopardizing access for countries and patients.

Objectives

- Ensure sustained and affordable supply of products to prevent disruptions in patient access
- Prevent deterioration in price and inconsistent availability
- Maintain adequate incentives for suppliers to continue to innovate in the product area

Interventions

Interventions will focus on consolidating volumes to present suppliers with sufficient properly planned demand to warrant continued, consistent production. This can be done by consolidating orders at either the buyer or supplier (e.g., by coordinating order timing among different purchasers) and/or by limiting the number of product variations.

Similar to high opportunity products, interventions for these products can be geographically targeted to those countries that will provide sufficient volume to meet the minimal conditions necessary for suppliers to continue production. However, such targeting should only be pursued following careful analysis in order to ensure that other countries do not face challenges in accessing the products as a result of targeting specific countries.

3.2.1 *Employ coordinated ordering via procurement agents*

In some cases, sufficient and predictable demand can be generated by coordinating order timing (e.g., on a quarterly basis) between countries receiving Global Fund financing for a high-risk product. Given the challenges of coordinating orders between many different purchasers, this will require the Global Fund to limit the number of channels through which countries can procure the products.

The Secretariat will establish a 'procurement consortium' of a sufficiently limited number of procurement agents, including the VPP, and require countries to purchase the relevant products through one of them. If the Secretariat determines reduced country participation can still meet the minimum conditions to ensure product availability, it can allow countries to decline to participate in the consortium. In order to procure the product through a mechanism outside the consortium, the country must provide a strong justification that both it and other countries will be able to obtain consistent supply of and equivalent prices of the product and other relevant criteria, as determined by the Secretariat.

Both this and the next intervention (consolidated demand through the VPP) will require support to be provided to principal recipients and countries to ensure that they are able to produce accurate forecasts and place timely orders for the relevant products. In addition, there will typically need to be ongoing active engagement with suppliers to ensure they have the necessary insight into market development and are planning and investing appropriately to sustain supply. The Secretariat will therefore need to work with partners to ensure such support is appropriately provided. Given its hands-off model, the Secretariat should not provide this support directly, but rather should work with partners to ensure relevant organizations with capacity to provide such support are identified, funded, and held accountable for relevant performance targets. In some cases, the Secretariat may need to contribute resources and/or contract a partner directly, but this should only be pursued if other partners are unable to mobilize and manage the necessary resources.

3.2.2 Consolidate demand through the VPP

If coordinated ordering will not provide sufficiently significant and predictable demand and/or there are opportunities to better shape the relevant market through active management of demand by a single purchaser, the MDC can set the VPP as the default procurement channel for the high risk product. This intervention will require a country to procure the product through the VPP unless it demonstrates that it and other countries are able to obtain equivalent or better market outcomes. Given the risk of supply disruption of these products, it will be particularly important that the VPP is able to efficiently manage country orders as described in Section 4.

3.2.3 Reduce fragmentation through streamlined product selection

In some cases, the risk of supply disruption is increased by the large number of variations in the products and regimens recommended in WHO guidelines, which reduces the demand for each variation, and therefore the incentives for suppliers to produce them. Consolidating products to those that are optimal can therefore increase predictable supply without reducing patient outcomes. To enable this consolidation, the Global Fund can require its recipients to procure only those versions of the product that are identified as preferable in international guidance (e.g., in WHO guidelines or other relevant technically robust international formulary lists) and/or are deemed to provide significantly greater value for money compared to alternatives though rigorous analysis (see under Section 3.3.1 below). Countries will then be able to request to procure alternative products by providing a strong technical rationale, which will be reviewed by a relevant technical body on the basis of criteria developed by the Secretariat such as the impact on product availability and patient health outcomes.

3.3 Strategic interventions for all products, including market equilibrium products

Although products that are determined to be at equilibrium do not present significant risks or opportunities, there are still often inefficiencies that limit health impact and value for money. The overall aim in these markets - as well as some high risk and high opportunity markets that face similar challenges - is to further increase the efficiency and predictability of procurement and ensure the use of products that provide maximum value for money. In addition, country procurement capacity impacts all products and market-shaping efforts and should therefore be strategically strengthened as part of this strategy.

Objectives :

- Significantly increase value for money by facilitating use of clinically similar products that provide significantly greater value for money
- Strengthen countries' capacity to implement strategic procurement practices

3.3.1 Interventions to optimize product selection

At times, some principal recipients and countries procure products or regimens that provide significantly lower value for money than available alternatives. Recipients indicate that this is due to lack of guidance on the cost-effectiveness differences between products and insufficient incentives to select the more cost-effective options. As reported by these recipients,¹⁷ as long as the Global Fund will finance any product option regardless of its comparative cost-effectiveness, countries will not consider value for money in many product selection decisions.

In this strategy, the Global Fund will accordingly take steps to ensure its recipients receive relevant comparative cost-effectiveness analysis, and will create appropriate requirements and incentives for recipients to procure products that are significantly more cost-effective than direct alternatives.

► Commission rigorous comparative cost-effectiveness analyses

The Secretariat will commission, in coordination with WHO, an appropriate expert organization (e.g., the National Institute of Clinical Excellence in the United Kingdom) to conduct timely and high-quality comparative cost-effectiveness analyses between selected WHO-recommended health products or regimens. These products should be direct alternatives used to achieve the same health objectives (e.g., two NRTI first-line ARVs). The prioritization of products that are selected for comparative analysis should be determined by the total level of Global Fund spending and the magnitude of difference in price and effectiveness between alternatives.

¹⁷ In-country experts expressed strong concern that comparative cost-effectiveness is often not factored into product selection decisions, in part because the Global Fund would finance either set of regimen choices: “clear global guidance and incentives on choosing VFM options from the Global Fund would have changed the debate. In the absence of this, local clinicians felt free to choose the product they were most familiar and comfortable with.” (Attachment 1)

The commissioned expert organization will also be required to develop robust, easily accessible tools that will enable countries to conduct similar comparative analyses using local data. The Secretariat will select the expert organization in consultation with WHO and on the basis of clearly defined criteria, including demonstrated skill and experience in pharmacoeconomic analysis, experience in translating pharmacoeconomic analysis into clear and robust policy conclusions, and ability to produce those conclusions in rapid but reasonable timelines. The conclusions of these comparative cost-effectiveness analyses will be communicated to relevant principal recipients and partners to serve as a global resource as well as to inform Global Fund policy and decision-making (see next sub-section).

The Secretariat, in consultation with relevant partners, will work with the selected expert organization to define the parameters of effectiveness (e.g., the outcome factors that will be included) in a manner that will ensure the analysis is both rigorous, feasible, and in line with the intent of the MDC (see key principles on page 32).

► **Enhance procurement policies to ensure procurement of optimal value for money products:**

The Global Fund will establish policies and procedures that will require countries to provide a strong justification to procure products that are significantly less cost-effective than available direct alternatives. This will include products that:

- Have been found to be significantly less cost-effective in relevant rigorous comparative analysis (see above); and/or
- Are not identified as recommended and/or preferred in WHO guidelines; and/or
- Are not included in other relevant international guidance (e.g., a pediatric ARV formulary list developed by relevant technical partners);

The Secretariat will need to develop means of robustly and efficiently assessing country justifications for procuring an alternative product, including through use of an appropriate technical advisory group. Countries that do not provide a sufficiently strong rationale will not be able to procure the product in question with Global Fund resources.

Several critical elements of this policy will need to be developed further by the Secretariat in consultation with the WHO and other partners. These include:

- The threshold of cost-effectiveness differences that would require the use of the preferred product (i.e., the definition of ‘significant’ in the policy above);
- The criteria that will be employed to assess country justifications for procuring less cost-effective products. These should include, at a minimum, different conclusions from rigorous local cost-effectiveness analysis;
- The period allowed for a country to responsibly transition, or “grace period,” if it needs to change products as a result of this policy.
- The use of funds that are saved from existing grants through transition to more cost-effective products. This component of the policy should be in line with the intervention in this strategy to clarify reprogramming policies to provide countries with incentives to adopt more cost-effective products, including through “first right of use” of savings.

- The approach to countries with active grants that transition to more cost-effective but higher priced products as a result of this policy and face a budget shortfall as a result.
- The specific implementation of this policy within the architecture of the Global Fund, including the points in the grant cycle at which the Secretariat will ensure compliance with the policy and steps to align decisions and processes of the Technical Review Panel with this policy.

In further developing this policy, the Secretariat should follow several **key principles**, including: 1) ensure there is no disruption in country and patient access to effective products; 2) minimize delays in transition and access to more cost-effective products; 3) minimize transaction costs on the Secretariat and countries; 4) ensure conclusions are reached on product value for money differences once evidence is sufficiently robust. The fourth principle is in recognition of the fact that there will be areas of uncertainty in every comparative cost-effectiveness analysis due to gaps in data, methodological challenges, and other factors. It is the intent of the MDC that modest uncertainty should not impede clear recommendation on a product if there is considerable evidence indicating a significant difference in cost-effectiveness compared to an alternative (i.e., the Global Fund should act if the evidence is sufficient yet incomplete). At the same time, an analysis for which there is high uncertainty should not result in a conclusion that is used in this policy.

The Secretariat will report its conclusions on all of these issues to the MDC and clearly and effectively communicate the final policy to country recipients. As part of the market analysis and intervention design process, the MDC and Secretariat will determine the specific product choices that will be targeted for rigorous comparative analysis under this policy on the basis of significant differences in effectiveness and/or price between product alternatives.

► **Facilitate expedited reprogramming of existing grants to more cost-effective products**

As described in Section 3.1.3 for high opportunity products, the Secretariat should actively work with countries and partners to facilitate reprogramming of grant resources to more cost-effective existing products where relevant. This approach should focus on cases where countries' product selection results in substantially lower value for money. Reprogramming policies should also be refined and clarified to provide countries with optimal incentives to switch to more cost-effective products, including through "first right of use" on savings.

3.3.2 Interventions to strengthen country strategic procurement capacity

In its 2007 decision creating the VPP¹⁸, the Board determined that countries should receive enhanced support to improve local procurement capacity. This strategy expands on that decision to ensure that resources available for capacity building have the desired impact and that, over the medium-term, countries are able to shape markets and ensure consistent availability of key products with limited intervention by the Global Fund and partners. This Strategy contains only one intervention to achieve this objective, but other interventions

¹⁸ GF/B15/DP15: Market Dynamics and Voluntary Pooled Procurement

should be explored, including the creation of specific incentives for countries to improve procurement practices related to market-shaping.

► **Better target capacity building**

The impact of the current Capacity Building Services (CBS) mechanism has been impeded by channelling resources through third-party agents rather than directly to the country institutions that require additional capacity. As a result, the CBS will be changed to provide resources directly to applicable country institutions (e.g., drug regulatory authority) in a manner that is technically rigorous and performance-based. The specific use of these resources will be determined by the recipient institution in line with the Global Fund's standard policies and principles and will be managed in a performance-based manner. The institution may, as with other grant funds, decide to use these resources to purchase technical assistance. It is expected, however, that these resources will be used for direct capacity investments (e.g., physical or human capacity) and will be complemented by technical assistance provided by other partners.

► **Develop incentives for improved strategic procurement**

Certain country procurement practices, such as application for product registration, forecasting, and tendering, have a major impact on market outcomes. The MDC discussed that the Global Fund could create additional incentives for countries to invest the necessary attention and resources to improve these practices. For example, countries could receive financial or non-financial bonuses if they achieve specified targets on a strategic procurement "scorecard." Such incentive approaches have been successfully used in other areas of global health and other social sectors (see Attachment 1). However, given the complexity of developing appropriate and feasible incentive approaches, this concept will be analyzed further by the Secretariat and discussed by the MDC prior to any specific action.

4. STRENGTHEN EXISTING GLOBAL FUND MECHANISMS

The Secretariat has been severely restricted in the strategic actions it could take to shape markets and ensure timely availability of key products through VPP. As a result, an estimated 60 percent of all orders processed by the mechanism have been emergency orders, and the VPP has not pooled any volumes between countries despite its mandate. Many of the key interventions described above will not be possible unless the Secretariat makes important relevant operational and financial policy revisions that will enable the VPP to resolve these challenges and fulfil its intended role.

4.1 Establish the necessary operational and financial policies to enable the VPP to consolidate volumes and implement strategic interventions

Initial policies and procedures have significantly hindered - and in some cases completely prevented - the VPP from efficiently processing orders for countries and strategically managing the volumes that are channelled through it. Specific challenges included:

- Inability to represent and/or commit volumes prior to approval of specific order details by Principal Recipients, preventing pooling volumes across countries;
- Slow confirmation and placement of orders due to delays in funding disbursements to countries and time-consuming VPP direct payment review process;

- Inability to make advanced financial commitments to suppliers, even within orders;
- Inconsistent duration of country participation in the VPP, which has hindered ability to accurately forecast and represent volumes.

As part of this strategy, the Secretariat will revise relevant policies and procedures to resolve these challenges. As an effective and strategic VPP is central to a number of the interventions in this strategy, those policy revisions will need to be prioritized. The specific revisions should be determined by the Secretariat, in consultation with relevant Board committees as necessary, but must enable the VPP to pool volumes across countries, commit volumes prior to the approval of a specific quotation, and provide consistent, predictable volumes (for example, by requiring a minimum period for country participation in the VPP, though not changing countries' decisions about whether to join the VPP). Achieving these goals may require the Secretariat to revise existing financial, operational, and legal policies and/or create exceptions to those policies for the purposes of products procured through the VPP.

In general, these revisions will likely require the Global Fund to assume a different role in the relevant portion of grants that are channelled through the VPP, taking modest additional responsibility that has historically been fully deferred to its recipients. While it is important that the greater role that the Secretariat may need to play due to these revisions does not significantly alter the Global Fund's core model or principles, that role is imperative to achieve not only the objectives of this market-shaping strategy, but also the Board's original intent in creating the VPP in 2007 - the VPP cannot pool volumes unless this shift is made. There may already be precedent for this alternative role within the Global Fund: the policies and structures of the Affordable Medicines Facility-malaria provides the Secretariat with greater flexibility to manage and represent relevant product financing on behalf of recipients.

4.2 Employ strategic procurement interventions through VPP

Pooling volumes is not sufficient to shape markets. Those volumes must be strategically managed and allocated to suppliers to prompt the necessary actions and outcomes. To strategically manage volumes, the Secretariat will need to employ a range of procurement techniques through VPP that are often used by other global health organizations. These include: 1) guaranteeing volumes; 2) splitting tenders among suppliers; 3) awarding volumes based on factors other than price (e.g., breadth of registration in recipient countries and/or past track record on meeting supply commitments); and 4) directly negotiating prices and other terms on the basis of volumes and/or costs.

The specific technique(s) used should be determined based on conditions in the market and the objectives of the Global Fund. For example, volume guarantees may be used in markets where suppliers face significant risk to secure lower prices and ensure sustainable supply, while splitting tenders may be used in a market with limited competition to facilitate entry or maintain presence of suppliers and achieve eventual better prices and other market outcomes.

As described above, the Secretariat will revise relevant operational and financial policies to enable the Secretariat to implement these techniques through VPP. The Secretariat will also require staff with relevant skills and experience to conduct these often complex and nuanced techniques.

4.3 Pursue the creation of a revolving fund for the VPP to ensure timely and predictable product supply

In order to mitigate the effect of funding delays on the availability of essential products, the Secretariat will explore and pursue, as appropriate, the creation of a revolving fund¹⁹ that the Secretariat and/or the VPP procurement agents can employ to bridge financing gaps by drawing needed funds and reimbursing them subsequently. Formal linkages with groups who provide such bridge funding will be explored to ensure that this process is viable. This effort will be coordinated with other ongoing efforts within the Global Fund to prevent product stock-outs and build on the best practices of other donor and procurement agents that successfully use similar funds. In developing this approach, the Global Fund should also explore lessons from and linkages to relevant existing mechanisms (i.e. the Pledge Guarantee mechanism). The Secretariat will report its conclusions on the development of such a revolving fund, including the relevant financial and operational implications, to the MDC for discussion and recommendation to the Board if necessary.

5. APPLICATION OF GLOBAL FUND MARKET-SHAPING STRATEGY TO ANTIRETROVIRALS

5.1 Analysis and classification of ARV markets

The ARV market continues to experience significant growth as the number of people living with HIV/AIDS rises and as more patients are put on treatment. Of the 14.6 million people eligible for Antiretroviral Therapy (ART) in low and middle-income countries, 5.25 million were receiving treatment in December 2009. First-line regimens dominate the market, with 91 percent of total patients on adult first-line treatment. Only 2 percent of patients are adults receiving second-line therapy. Pediatric patients make up the remaining 7 percent of patients, with 356,000 children receiving ART.

In 2009, the global ARV market size in generic-accessible countries was USD 790 million. By 2014, this market is expected to reach USD 1.4 - 2.0 billion. The major donors in the market are the Global Fund, PEPFAR and UNITAID. The ten countries with the highest ARV spend from 2009 through June 2010 represent 53 percent of all Global Fund ARV expenditures. Approximately 34 percent of Global Fund-financed ARVs were procured through procurement agents, with UNICEF, the VPP, and IDA responsible for the majority of these volumes. In the ten countries with the highest number of Global Fund-financed patients on ART, 38 percent of Global Fund ARVs by value were procured through procurement agents.

India-based generic manufacturers currently supply over 80 percent of the donor-funded ARV market. Four of the generic suppliers with the largest market share are vertically integrated and can exert greater control over the market for active pharmaceutical ingredients.

Challenges and potential interventions in the ARV market can be best understood by dividing the market into three primary categories: First-line ARVs, second-line ARVs, and pediatric ARVs as shown below:

¹⁹ The Portfolio and Implementation Committee (PIC) is overseeing a feasibility study on a similar fund.

First-line ARVs With generic supplier entry, significant progress has been made over the past ten years to reduce first-line ARV prices and promote competition. Therefore, the market for existing products is at **market equilibrium**, with prices at or near the lowest possible, sustainable levels for many products. There are, however, a range of new ARVs currently in development (e.g., TMC278, GSK 572, etc.) that might provide significant clinical and cost-effectiveness benefits if approved and recommended by the WHO. If and when these emerging ARVs enter the market, they will begin as **high opportunity products**, with access and market optimization likely to be slow unless additional intervention is taken.

Second-line ARVs Over the past five years, significant gains have been achieved in the second-line ARV market. Prices have fallen on average ~50 percent, the supplier base has increased, and volumes have also increased. The main determinant of higher second-line prices is typically the higher cost to manufacture active ingredients. By the end of 2009, approximately 120,000 adults—or 2 percent of the total ART population—were enrolled in second-line therapy. With a relatively robust supplier market, expectations for significant near-term gains on market dynamics are limited. The second-line market is therefore considered at **market equilibrium**.

Pediatric ARVs In 2005, the pediatric ARV market was virtually nonexistent, with fewer than 70,000 patients on treatment globally. While remarkable progress has been made over the past six years in both patient access, including 356,000 patients on treatment at the end of 2009, and in the overall marketplace, this progress is threatened by significant risks in the market. Volumes are still low with very high demand fragmentation, making the market relatively unattractive to suppliers. Given significant downside potential as the current pooled procurement through the UNITAID program is phased out, pediatric ARVs are **high risk products**.

Most ARVs While most first- and second-line ARVs are at market equilibrium, there continue to be significant inefficiencies that affect most ARV products. These include unpredictable funding for and ordering of products and inadequate country capacity to effectively implement key procurement practices such as forecasting and ordering.

In addition, many countries continue to procure ARV regimens that provide lower value for money than clinically comparable alternatives, which country representatives attribute to insufficient information and incentives for them to select the more cost-effective products.

5.2 Global Fund interventions to shape the ARV market

The Global Fund's potential interventions in the ARV market under this proposed strategy have been designed to align with and complement existing efforts by other partners. Among these efforts is the "Treatment 2.0" agenda developed by WHO and UNAIDS²⁰ to shape the future of ARV treatment to most efficiently maximize patient outcomes and coverage. The agenda includes strategies that will achieve impact over the short- (2012), medium- (2015), and long-term (2020) through five priority areas, including reducing costs, optimizing drug regimens, and pursuing more decentralized models of treatment and diagnosis delivery. Global Fund market-shaping interventions, including accelerating the introduction of new, more cost-effective drugs and financing optimal ARV regimens, will be critical to the achievement of several of the objectives articulated in this agenda in both the short- and long-terms.

Other important activities that these interventions will be coordinated with include those of the major current and future financiers of ARV treatment, notably PEPFAR and UNITAID, and procurement partners such as UNICEF.

5.1.2 All ARVs

While the markets for many first- and second-line markets are currently healthy and do not require additional procurement interventions, there are still market-related challenges that significantly impede access to and value for money for these products. The Global Fund can thus have substantial impact by pursuing a number of interventions that will apply to all ARVs but will not affect country choices on procurement channels. These interventions include:

► **OPTIMIZE PRODUCT SELECTION.** Optimize both clinical and financial outcomes by ensuring that countries procure ARV regimens that generate the highest value for money. At present, it is estimated that USD 265-320 million could be saved globally over 5 years without significantly impacting clinical outcomes. To achieve this impact, the Global Fund will apply relevant interventions in Section 3.1 to key ARV regimens. Specific interventions will include:

- **Commission targeted comparative cost-effectiveness analyses:** The Global Fund will commission comparative cost-effectiveness analysis on WHO-recommended ARV products/regimen choices where significant potential VFM opportunities have been identified. Product choices that have been identified to date for such analysis include 3TC vs. FTC, ATV/r vs. LPV/r, and TDF+3TC/FTC vs. ABC+ddl, although more may be revealed through further analysis and consultation. The expert organization that will conduct this analysis will be selected on the basis of the criteria specified in Section 4.3.

²⁰ Treatment 2.0: catalysing the next phase of scale-up. [Comment]. The Lancet, published online February 25, 2011. http://www.who.int/hiv/pub/arv/treatment2_lancet_20110303.pdf

- **Enhance policies to ensure procurement of higher value for money ARV regimens:** The Global Fund will apply the policies detailed in Section 3.1 that require countries to strongly justify the procurement of ARV regimens that provide significantly lower value for money or are not recommended and preferred in relevant international guidance. The ARV regimens that will require justification will include those that: 1) are found to be significantly less cost-effective in the analyses above; or 2) are not preferred in WHO global ARV treatment guidelines; or 3) are not included in an internationally agreed formulary for pediatric ARVs.²¹

Two further interventions will be implemented that apply across all markets and products, but will be particularly important to ensure healthy market conditions for ARVs given the impact of volatile product availability on patient health:

► **REDUCE FUNDING VOLATILITY TO ENSURE PRODUCT AVAILABILITY.** Facilitate supply availability to patients by minimizing funding volatility. This helps secure efficient marketplace functioning while preventing treatment disruptions due to stock-outs and costly emergency orders. To achieve this, the Global Fund will pursue relevant changes to financial models related to procurement, including the creation of a revolving fund and expedited disbursements for essential health commodities.

► **STRENGTHEN NATIONAL STRATEGIC PROCUREMENT.** Enhance national stakeholders' ability to employ strategic procurement practices such as application for registration, forecasting, and tendering, by directly investing in relevant country institutions rather than third-party organizations.

5.2.2 High Risk Products

With the UNITAID pediatric ARV program concluding in 2011/2012, the Global Fund will become one of the largest international funders of pediatric treatment. As a result, it has a central role to play in ensuring that the significant risks in the market are addressed and that countries are able to access uninterrupted supply of high-quality pediatric ARVs. The interventions that the Global Fund will implement to fulfill this role will include:

► **Ensure sustained supply through pediatric procurement consortium:** The Global Fund will employ the intervention detailed in Section 3.2.1 above to establish a consortium of a limited number of procurement agents that recipients that were members of the original UNITAID pediatric program will be required to use to purchase pediatric ARVs with Global Fund resources. This option was selected over the option of consolidating all pediatric ARVs through the VPP due to the substantial volumes that are already being supported by other procurement agents and the limited added benefit of negotiating on the basis of pooled demand. The members of the procurement consortium will commit to following key predetermined procurement practices, notably coordinated ordering on a quarterly basis. As described in Section 3.2.1, countries will have the ability to decline participation in the consortium if they can prove the ability to do without threatening consistent supply of pediatric ARVs for themselves and other countries.

This approach will be dependent on smooth, predictable financial flows to the recipients purchasing pediatric ARVs. As a result, the strategic interventions to reduce financial volatility described above will be critical to the successful prevention of disruption in pediatric treatment. The Secretariat will accordingly need to prioritize those financial solutions for pediatric ARVs at a minimum.

²¹ Such a pediatric formulary list is currently being developed by the Interagency Task Team, with leadership by WHO.

► **Collaborate with partners to support country pediatric procurement practices and supply management:** Ensuring consistent supply of ARVs will require additional activities at both the country and global levels beyond the work of the pediatric procurement consortium, including ensuring robust country forecasting and insight into product availability issues and engagement with suppliers on global forecasts, market trends and opportunity and need for new product introductions. The Global Fund will work with partners, especially UNITAID, to ensure that these functions are effectively conducted, including jointly identifying lead partner(s) that will be responsible for the relevant functions.

► **Reduce fragmentation through streamlined product selection:** The large number of formulations contributes to the high degree of risk for manufacturers by fragmenting the modest demand. As a result, the Global Fund will work with partners to consolidate demand around the most effective and important products by requiring recipients to purchase products from an internationally agreed formulary list unless they provide a strong rationale to use an alternative as described above.

5.2.3 High Opportunity Products

Most newly developed ARVs will be high opportunity products given the significant power the innovator supplier will have on the market and the expected initial slow growth in demand - experience with existing ARVs and other global health products demonstrates that there will typically be long delays in country purchasing of newly released products without intervention. Since some new ARVs will provide significant value for money and/or clinical benefits over current alternatives, the Global Fund will actively work to accelerate their introduction.

A scenario of the launch of TMC278, an ARV currently in clinical development, was analyzed to determine the potential benefits of and optimal interventions for accelerating new ARV introduction. However, the Global Fund will not develop specific interventions to introduce a product until it has received regulatory approval and is recommended by WHO. This analysis is therefore purely indicative and should be considered the basis of actual interventions to be pursued by the Global Fund on that product.

► **ACCELERATE NEW PRODUCT INTRODUCTION.** Global Fund interventions to accelerate access to more rapidly reach a healthy marketplace, including lower sustainable prices, for new ARVs include:

- **Consolidate new ARV volumes through the VPP and strategically manage demand:** As discussed in Section 3.1.1, the Global Fund can require high-volume countries to procure the identified high opportunity ARVs through the VPP until specified market conditions have been met. Countries will have the option of declining participation in this approach, but must provide a strong justification demonstrating their ability to obtain equivalent or superior pricing and other outcomes in order to procure the product through other mechanisms.

- **Develop joint UNITAID/Global Fund new ARV introduction program:** The Global Fund will work with UNITAID to establish a joint program to introduce an appropriate, more cost-effective new ARVs in a manner that maximizes the resources, comparative advantages, and mandates of each organization. This could include UNITAID financing volumes of the new ARV in high-volume countries for a specified number of years to ensure rapid market impact, with a pre-determined and efficiently managed transition of relevant funding needs to the Global Fund at the end of that period. This approach will save both organizations resources compared to individual interventions in the market (e.g., the Global Fund will only begin paying for the ARV once lower prices have been secured while UNITAID will not face risk of extending financing beyond the intended transition date). As noted in Section 4.1, such a program will require the Global Fund to establish policies that will enable more efficient transition than is possible within the current funding architecture.

GUIDANCE ON LOCATION OF FURTHER INFORMATION

The below table indicates where further information on items dealt with in this report can be found:

Where indicated documents are available on the Governance Extranet:

<http://extranet.theglobalfund.org/cme/default.aspx>

Item:	Further information available:
1. Introduction	No paper
2. Market-shaping strategy	<p>GF/MDC04/04 - Voluntary Pooled Procurement http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/MDC04_04_VPP.pptx</p> <p>GF/MDC04/02 - Price and Quality Reporting (PQR) http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/MDC04_02_PQR.pdf</p> <p>Results for Development Institute: Market Dynamics Study: Phase II Report for the Global Fund Market Dynamics Committee (MDC) (Attachment 1 to this report) http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/GF_B23_9_Attachment1.pdf</p> <p>Report of a Technical Consultation of the Market Dynamics Committee. Held in Copenhagen, Denmark, on 22-23 February 2011 (Attachment 2 to this report) http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/GF_B23_9_Attachment2.pdf</p>
3. Expediting transition to ACT FDCs	<p>GF/MDC04/04 - Expediting transition to fixed dose combinations for malaria treatment http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/MDC04_03_ACT_FDCs.pdf</p> <p>Resource document 1 to GF/MDC04/03 - Feasibility study on expediting transition to fixed-dose combinations for malaria treatment in Global Fund-funded programmes http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/GF_MDC04_03_ResourceDocument_1.pdf</p>



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Twenty-Third Board Meeting
Geneva, Switzerland, 9-11 May 2011

GF/B23/9 Revision 1
Attachment 1

Results for Development Institute (R4D)

Market Dynamics Study: Phase II Report for the Global Fund Market Dynamics Committee (MDC)

Posted on MDC Extranet at

http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/GF_B23_9_Attachment1.pdf



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GF/B23/9 Revision 1
Attachment 2

Report of a Technical Consultation of the Market Dynamics Committee
Held in Copenhagen, Denmark, on 22-23 February 2011

Posted on MDC Extranet at

http://extranet.theglobalfund.org/cme/MDC/Docs/MDC04_April11%20Mtg/GF_B23_9_Attachment2.pdf