REPORT OF THE MARKET DYNAMICS AND COMMODITIES AD-HOC COMMITTEE

PURPOSE:

This report summarizes the deliberations of the Market Dynamics and Commodities Ad-hoc Committee (MDC) at its 5th meeting on 6-7 October 2011. The report provides updates on the implementation of, and future directions in, market-shaping interventions for antiretrovirals, the extension of the market shaping strategy to additional major product areas such as diagnostics and long-lasting insecticide-treated nets (LLINs), and updates on other critical market-related activities within the Global Fund, including the reform of the voluntary pooled procurement mechanism.
PART 1: INTRODUCTION

1.1 The Market Dynamics and Commodities Ad-hoc Committee (MDC) met in Geneva on 6th – 7th October 2011 for its 5th meeting. The Chair was Mr. Oliver Sabot (Private Foundations constituency), the Vice-Chair was Ms. Shanelle Hall (UNAIDS constituency).

1.2 Items for information included in this report are as follows:

   i. Part 2: Market dynamics progress update and applying the market shaping strategy to additional product areas
   ii. Part 3: Health product prices
   iii. Part 4: Quality assurance of essential medicines
   iv. Part 5: Organizational reform matters

PART 2: MARKET DYNAMICS PROGRESS UPDATE AND APPLYING THE MARKET SHAPING STRATEGY TO ADDITIONAL PRODUCT AREAS

Securing the pediatric ARV market

2.1 Current pediatric ARV treatment coverage is approximately 25 percent globally. The UNITAID/CHAI pediatric ARV project has been providing ARVs for approximately two thirds of pediatric patients in need, and as much as 80 percent of these patients may be absorbed by Global Fund funding as this project is phased out during 2011 and 2012. Other funders include PEPFAR and national governments, notably South Africa.

2.2 As requested by the Board at its Twenty-Third Meeting the Global Fund Secretariat has prioritized maintaining the gains achieved in the pediatric ARV market. The main stakeholders (UNITAID, CHAI, WHO, and Global Fund) and their procurement agents (including UNICEF and SCMS procuring both for U.S. PEPFAR and the Global Fund) met in September 2011 and formed a working group with the aim to coordinate pediatric ARV procurement in line with the Board decision, while also addressing related issues such as optimization of formulations procured so as to promote market sustainability. The consortium of procurement agents was established with coordination from The Global Fund. UNITAID/CHAI will continue to provide support with national and global forecasting. Possibilities of warehousing specific low-volume WHO-recommended pediatric ARVs, and associated costs, are being explored.

2.3 Under the UNITAID/CHAI project, over 45 pediatric formulations are currently procured as product availability and guidelines have evolved over the years. To streamline product selection around the most efficacious and necessary unique products, a WHO-co-chaired working group is developing a proposed pediatric and PMTCT ARV formulary, currently containing 15 optimal formulations and six limited use formulations. The formulary is yet to be harmonized with the WHO Model Essential Medicines List, but can already inform national guidelines and treatment decisions in the interim. This formulary will be used as the basis for the application of the Global Fund’s new product selection optimization policy to pediatric ARV products.

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1 GF/B23/DP21: “Global Fund Market-Shaping strategy and Market-Shaping Interventions for ARVs”
2.4 Next steps are as follows:

i. Bridge funding will be needed as countries transition to alternative funding, including applying for Global Fund Round 11 funding, which may only become available towards the end of 2013. A common agreement and work plan, and a proposal for continued funding during 2012 will be presented to the UNITAID Board in December 2011 for approval, and the probable need for continuation of funding for a small subset of countries through 2013 will be signaled.

ii. A meeting will be held in January 2012 with country representatives responsible for funding, programmatic and procurement aspects. The meeting aims to share lessons learnt, introduce the coordinated procurement approach, including for countries which have already started using their own procurement channels, to collate information on grant funding for pediatric ARVs and to discuss the way forward to implementation of this coordinated approach as per Board request.

iii. Coordinated procurement mechanism will be operationalized during 2012 and will be fully implemented in 2013. As per the market-shaping strategy, countries that wish to procure pediatric ARVs outside the procurement consortium will be requested to satisfy the Global Fund Secretariat that they are able to obtain a sustained supply of the high risk products as determined by the Secretariat.

2.5 The MDC commended the Secretariat for work done since May 2011 and encouraged the Secretariat to continue to take the steps necessary to ensure the targeted interventions are implemented in 2012.

Optimizing ARV product selection

2.6 In meetings with WHO Essential Medicines Programme and the HIV/AIDS Department, WHO expressed its support for the proposed optimization of ARV product selection, which will promote the implementation of optimized treatment in grant-funded countries.

2.7 A draft concept note has been circulated to WHO and the MDC for comment, describing the two elements of optimizing product selection. The Secretariat aims to finalize policy design for product optimization in line with the Board-approved market shaping strategy by December 2012 by:

i. Publishing a Request for Proposals in Q1 2012 for an appropriate body to lead the necessary pharmaco-economic analysis to identify the most cost-effective ARV products among WHO-recommended treatment options globally, and

ii. Nominating potential members of an “Expert Working Group,” to develop guidance on the criteria for assessment of countries’ requests for exceptions to the default products identified by the comparative cost-effectiveness analysis. A separate Request for Proposals may be issued for this scope of activities.

2.8 The MDC provided input on the process for creating a credible, robust, transparent, and efficient process for designing and implementing the product selection policy. The MDC expressed that steps should be taken to accelerate the execution of the policy and emphasized a number of additional considerations for the design and selection of the expert work, including:

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2 GF/B23/9 Revision 1 : Report of the Market Dynamics and Commodities Ad-hoc Committee
2.9 The MDC noted that, while streamlining the selection of pediatric ARVs (see 2.1-2.5) will provide a good operational entry point, the committee stressed the importance of focusing product optimization work in 2012 on other products (i.e., adult 1st and 2nd-line ARVs) that will maximize value for money.

2.10 In response to the Board’s request, the Secretariat has analyzed the use and markets of ARV FDCs, with a view to identify opportunities to expedite transition to FDCs. It was found that:

i. FDCs accounted for 70 percent of treatments reported to the Global Fund’s Price and Quality reporting system (PQR) in 2009-2010, although in four countries which had among the highest expenditures for ARVs, less than 50 percent of reported treatments were FDCs;

ii. Finished products which comply with the Global Fund Quality Assurance Policy for Pharmaceutical Products (QA Policy) are available or being developed for treatment of adults; and

iii. Patent issues can be a driver of price differentials and may influence the development of needed FDCs and the uptake of certain FDCs in developing countries

2.11 Given this situation, the MDC supported a shift to ARV FDCs in principle. However, given the continued need for single-ingredient formulations to address issues of patents, pricing, product availability and continuation of treatment, at this time the MDC does not recommend the introduction of a specific policy to expedite transition to fixed-dose combination ARVs.

2.12 In response to potential intellectual property obstacles to ARV FDCs, most MDC members (one constituency abstained) endorsed the principles of encouraging originator companies to expand equitable voluntary licensing practices with broad geographical scope, encouraging countries to obtain technical assistance for full use of mechanisms to overcome patent barriers to the uptake of FDCs, and encouraging originator companies to voluntarily disclose full patent status information in all countries, as well as proactively seeking licensing partnerships with generic suppliers.

**Voluntary Pooled Procurement (VPP) adaptation of policies and procedures**

2.13 In response to the Board’s request to prioritize policy and procedural changes to enable the VPP to strategically manage demand, the Secretariat commissioned a consultancy to evaluate approaches to make the VPP procurement process more efficient. The following four elements were proposed:

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3 GF/B22/DP11: “Expediting transition to fixed-dose combinations of ACTs”

4 GF/B23/DP21: “Global Fund Market-Shaping strategy and Market-Shaping Interventions for ARVs”
A. Creation of a specific account for funds to be utilized by the VPP on behalf of countries to enable the mechanism to pool volumes and improve outcomes;
B. Using conservative annual volume guarantees to achieve better prices and other market outcomes;
C. Regularized ordering and delivery schedules
D. Applying a confirmed ordering process, subject to evidence that the commodities can be reliably and safely delivered

2.14 The MDC re-emphasized the Board decision that policies and procedures of the VPP should be urgently and appropriately improved to enable market shaping interventions since much of the impact of the new market shaping strategy relies on an effectively functioning VPP. The committee noted that it is the responsibility of Secretariat management, not a Board committee, to design and implement appropriate operational corrections and encouraged management to ensure rapid implementation of relevant improvements such as those presented. The MDC recommended that the Secretariat bring further issues to a committee or the full Board only when the necessary improvements would go beyond existing Board decisions, including the approval of the market shaping strategy (GF/B23/9).

Capacity-building

2.15 The Secretariat described the ongoing holistic approach to capacity-building in health product supply management in collaboration with partners. An information note was included in funding Rounds 10 and 11, strongly encouraging applicants to identify challenges within their pharmaceutical systems and include activities for pharmaceutical systems strengthening, including pharmaco-vigilance, in grant proposals.

2.16 The MDC noted the Secretariat’s progress in implementing the changes to capacity building included in the Market Shaping Strategy, including ensuring that support was provided directly to local institutions rather than through third-party providers (GF/B23/9 Revision1).

Resourcing the Secretariat for implementation of market-shaping strategy

2.17 The MDC was briefed that, since the approval of the Board Decision on market-shaping in May 2011, the Secretariat has relied on existing staff to implement the additional ambitious market dynamics interventions for ARVs. Due to the ongoing reform, the four additional positions requested in the Board Decision for market-shaping activities were converted to consultant positions; and recruitment is currently on hold.

2.18 The MDC expresses serious concern about the lack of staff capacity for market dynamics interventions and strongly recommended that the Secretariat obtain additional capacity as soon as possible. The MDC also noted that partners should provide the Secretariat with support in implementing the strategy where possible to ensure continued progress while capacity is increased.

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Information Note: http://www.theglobalfund.org/WorkArea/DownloadAsset.aspx?id=23081

GF/B23/DP21: “Global Fund Market-Shaping strategy and Market-Shaping Interventions for ARVs”
Applying the market shaping strategy to additional products: Long-lasting insecticide nets (LLINs)

2.19 In its report to the 23rd Board, the MDC noted LLINs were a product niche that would be explored for further application of the Market Shaping Strategy (GF/B23/9 Revision 1). At this meeting, the MDC was briefed on the preliminary findings of a Gates Foundation-funded study on LLIN markets. It was noted that LLINs comprise a significant portion of the Global Fund’s financing for malaria programs and that, despite some data showing a downward pricing trend and increased competition in the market, there were likely opportunities to increase value for money through targeted interventions.

2.20 Several key challenges were identified to maximizing value for money in the Global Fund’s current support for LLIN procurement, including:

- Selection of products based on price alone rather than cost-effectiveness, which is prevented by current lack of measures of LLIN effectiveness (e.g., durability);
- High levels of product fragmentation due to minor differences in specifications, some of which increase costs and lead times;

2.21 The report identified several approaches that the Global Fund could take to address these challenges and maximize value for money. These included: 1) applying the product selection policies adopted in the market shaping strategy to ensure recipients procure the most cost-effective products; and 2) rationalize net specifications in areas where these incur significant financial or program costs with little evidence of commensurate user benefit. In addition, the report noted that steps to strengthen country procurement practices were important to improving market outcomes.

2.22 The MDC noted that the LLIN market appeared to meet the conditions for a classification of “equilibrium” in the market shaping framework, with some areas of fragility given high supplier concentration, fragmented specifications and fluctuating demand. It discussed that the primary intervention for equilibrium markets in the strategy was the product selection optimization policy and, as such, the application of that policy as recommended by the report was appropriate and merited further development. The MDC accordingly highlighted the following issues and next steps:

i. Definition and collection of data of LLIN durability is critical and urgent since these data are required to effectively measure LLIN cost-effectiveness. The MDC noted that it WHO was essential to this effort. It also discussed that experience and expertise from the textile industry could be harnessed to assess durability of nets and that a group with experience developing and measuring standards in that industry (including for the WHO and other public bodies) could be engaged to support the comparative cost-effectiveness analysis.

ii. The MDC emphasized that it was important to ensure that there were continued incentives for manufacturers to produce innovations in LLINs (i.e. to improve durability, resistance management, etc.) as the product selection policy and other interventions are applied. It noted that steps could be taken to maintain those incentives such as a target product list released by WHO.
Acceptability and ultimate usage of LLINs are important. Efforts to study and analyze usage should be encouraged and supported to support, for example, optimal rationalization of LLIN specifications.

iii. Supplier diversity must be preserved to ensure market sustainability and competition. Specific attention should be given to encourage smaller suppliers given the risks inherent in a highly concentrated supplier landscape.

2.23 The committee requests that the consultant continue the study, including engaging with the Secretariat and WHO and relevant partners to further analyze and develop potential interventions related to product selection, rationalization, and innovation.

2.24 The MDC asks the Secretariat, with active support of the MDC/MDAG and relevant partners such as WHO to actively pursue the following key steps to applying the product selection policy to LLINs:

- Use existing data to develop approaches to arrive at a more rationalized list of net specifications to guide recipient procurement;

- Develop clear timelines and processes to develop durability guidance and rapidly collect and analyze relevant data to enable comparative cost-effectiveness analysis. Identify a relevant institution to conduct cost-effectiveness analysis with all relevant data to feed into product selection decisions. Such analysis should take into account competitive dynamics in the market.

2.25 The committee encourages the new Market Dynamics Advisory Group (MDAG) to follow up these issues as a high priority.

**Applying the market shaping strategy to additional products: Diagnostic product landscapes**

2.26 The committee thanks UNITAID for its strong analysis of diagnostic product markets for the three diseases presented at the meeting. The committee discussed and recognized the opportunities for market shaping interventions to improve access to some of the new potentially high-impact diagnostic products that are expected to be available in the coming years.

2.27 The MDC discussed that diagnostics offered strong opportunities for The Global Fund and UNITAID to develop a joint program, as called for in the market shaping strategy approved by the Board in May 2011\(^7\). Such a joint program could include UNITAID providing initial catalytic financing to ensure rapid introduction of a new diagnostic tool, with the Global Fund providing commitments to ensure smooth transition of funding to ensure that impact on the markets for the introduced products and sustained and further improved. Potential opportunities that were raised in the UNITAID report included accelerating access to new point-of-care diagnostics for HIV, creating a private sector market for malaria rapid diagnostic tests, and further improving access to optimized TB diagnostic products.

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\(^7\) GF/B23/9 Revision 1: Report of the Market Dynamics and Commodities Ad-hoc Committee
2.28 The MDC encouraged the new Market Dynamics Advisory Group to promptly take up the development of opportunities in the diagnostics market. Specifically, the committee requested the Global Fund and UNITAID Secretariats, along with committee members who sit on the governance bodies of both organizations, to meet and develop a concrete joint program on shaping the market of a diagnostic product that could be brought to the Boards of both organizations. This would be the first specific partnership between the organizations under the new market shaping strategy and could maximize the investments of both funders. The MDC suggested that a proposal for a joint program be presented to the first Board meetings of both organizations in 2012.

Applying the market shaping strategy to additional products: anti-TB products

2.29 According to 2008-2011 data reported in the PQR, procurement has been generally in line with WHO recommendations. 77 percent of financing for first-line treatment in adults was for FDCs, 20 percent was for anti-TB kits used in India as per national treatment guidelines, and 2 percent was for single-ingredient medicines in other countries.

i. For adult treatment, there are at least two finished products meeting the Global Fund Quality Assurance Policy for Pharmaceutical Products (QA Policy) for all except two combinations; transition to fixed-dose combinations for treatment of adult patients is not expected to present major challenges.

ii. For treatment of children, a single manufacturer currently supplies pediatric fixed-dose combination anti-TB products meeting the requirements of the QA Policy. This situation has resulted in substantial price increases. Interim WHO recommendations are currently in force, dis-incentivizing investments in quality products as the guidelines are likely to change in the coming years. New formulations complying with updated recommendations for adjusted dosages are only expected to come into use in approximately 2017. In the interim, single ingredient formulations are still needed in addition to FDCs.

2.30 The MDC notes its concerns about the limited availability of some anti-TB medicines, especially for children, and the possible health impact in poorly regulated markets. The committee recognizes the need to send strong signals to the market to incentivize the development of better pediatric formulations.

2.31 The committee encourages the Secretariat and the Market Dynamics Advisory Group to explore interventions for anti-TB medicines under the market-shaping strategy, drawing on ongoing analysis and experience of the Global Drug Facility and UNITAID. Specifically, the MDC recommends that in optimizing product selection, the decision to fund ACT FDCs in preference to single products (if sufficient products meeting the QA Policy are available on the market) should be extended to adult first-line anti-TB products.
PART 3: HEALTH PRODUCT PRICES

Health product prices

3.1 At its Twenty-Third Meeting the Board has requested the Secretariat to “work with the MDC to determine reference prices to establish maximum levels of Global Fund payments for appropriate products. Reference prices should be set at the lowest accessible competitive price consistent with well-functioning and sustainable markets, recognizing differences according to country income and disease burden.”8 Subsequently, the Board approved the High Level Panel recommendation to “Limit the allowable payment for the purchase of drugs or bed nets to a reference price.”

3.2 The MDC reviewed the Global Fund’s current practices on pricing in detail. Currently the Secretariat mandates that Principal Recipients procure pharmaceutical and health products at prices that are consistent with the lowest possible price achievable on the market. The Secretariat calculates a range of acceptable prices using a number of international reference sources. If a Principal Recipient forecasts or achieves prices above the designated range, they are expected to provide sufficient justification for the higher prices prior to the next disbursement of funds for pharmaceutical and health products.

3.3 At Phase 2 or periodic review the Secretariat benchmarks prices achieved against international references and requires PRs to justify outliers; the results are considered on the grant scorecard and inform subsequent disbursements. Additionally, the Secretariat is building an automated system to more systematically review Round 11 proposals and PSM plan budgets to flag proposed price outliers.

3.4 As a result of these efforts, the Secretariat demonstrated that the vast majority of antiretrovirals procured in 2010 were at prices at or below international reference ranges. Income classification and disease burden did not have any impact on the prices of 96% of the 890 million USD worth of key health products reported in the PQR as having been delivered in 2010.

3.5 Based on the evidence that current Global Fund practices already ensure recipient procurements are in line with international reference prices, the MDC voiced concern that the language of the Board’s May decision point may disrupt, rather than support, these existing efforts. The committee therefore asked the MDC Chair and Vice-Chair to speak with Board leadership regarding this decision point.

PART 4: QUALITY ASSURANCE OF ESSENTIAL MEDICINES

4.1 The Secretariat updated the MDC on its work with partners to introduce joint, harmonized, risk-based requirements for quality assurance of essential medicines. Key partners met in August 2011 under the co-chairmanship of WHO and the Global Fund and agreed that harmonized, risk-based systems are needed to use scarce, technical resources efficiently, to impact markets for these products, and to support recipient countries in strengthening their medicines regulatory and quality assurance systems. Partners agreed on next steps as follows:

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i. WHO will finalize its risk categorization of essential medicines, taking into account risks to patient health due to factors linked to manufacture, distribution and use of products;

ii. Based on risk categorization, donors and procurement agencies will meet in June 2012 to define a common, risk-based framework for quality assurance of all essential medicines. Proposed mechanisms include stringent regulatory review, WHO prequalification and/or an adapted Expert Review Panel process, and independent qualification of procurement agencies;

iii. Partners will develop a common tool, to be formalized by WHO for independent qualification of procurement agencies (by Q3 2012) - based on the WHO Model Quality Assurance System for Procurement Agencies® this tool will serve to assess and rate procurement agencies’ functions (selection of quality-assured products, purchasing, receipt, storage and distribution of products) in a standardized manner; and

iv. WHO will host a website to share information on completed and planned manufacturing site inspections, allowing partners to collaborate and avoid duplication.

4.2 MDC members noted and commended the Secretariat’s work with key donors and procurement agencies towards harmonized quality standards for essential medicines used in treatment of HIV, malaria and tuberculosis and encouraged it to continue this work.

PART 5 ORGANIZATIONAL REFORM MATTERS

Governance reform

5.1 The MDC was presented with an update on governance reform, including the proposed new structure, with a permanent Market Dynamics Advisory Group, composed of 4 Board nominations and 4-6 qualified individuals from lead partners in the field, and reporting to the Strategy, Investment & Impact Committee (SIIC). The MDC was invited to provide input on the role and key functions of the proposed Market Dynamics Advisory Group, its proposed composition, and the roles of key strategic partners (e.g. UNITAID).

5.2 MDC members supported the proposed reform and emphasized the importance for the proposed Market Dynamics Advisory Group to have similar stature as other technical groups, notably the TRP, to ensure that its recommendations are seriously considered and, given their complex technical nature, considered as whole.

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http://apps.who.int/medicinedocs/documents/s14866e/s14866e.pdf
5.3 With regard to the proposed membership, the MDC suggested that Terms of Reference should be clear and specific to ensure selection of competent members, and that conflict of interest must be managed carefully. There was disagreement among members about the balance of membership between Board nominations versus independent experts. The importance of representation of technical partners, implementers and the generics industry was highlighted. The MDC hopes that the new group will continue to provide a forum for joint work of all relevant partners to impact health product markets, including the important coordination and partnership between the Global Fund and UNITAID, among others.

5.4 In the interim period while the new group is formed, MDC members will continue to work together and will support the Secretariat in implementing the market-shaping strategy approved by the Board at its Twenty-Third meeting.

High level panel report recommendations on procurement

5.5 The High Level Panel identified procurement, storage, distribution and delivery of pharmaceuticals and health commodities as the single biggest category of vulnerability. The Panel recommended to pool health product procurement and to outsource storage and delivery as the norm, except where the Fund certifies a local institution according to Fund standards. The Board did not approve these recommendations at its Twenty-Fourth Meeting.

5.6 The MDC reviewed the Panel’s recommendations and an analysis on the procurement and procurement mechanisms for pharmaceuticals and health products by country categories of risk as identified by the High Level Panel Report.

i. The 87 extreme and high risk countries accounted for 98 percent of the cumulative value of Global Fund health product procurement up to December 2010 (32 extreme risk countries = 43 percent of procurement and 55 high risk countries = 55 percent of procurement).

ii. 18 of the 32 extreme risk countries had used VPP at least once (21 of 55 high risk).

5.7 In extreme risk countries, external procurement mechanisms accounted for 1/3 of all ARV and ACT procurements; 57 percent for LLINs; and 91 percent TB medicines (VPP = 30 percent of these for ARVs and ACTs; and 83 percent LLINs).

5.8 The committee noted that financial risk mitigation in procurement of health products was outside the MDC’s market-shaping mandate. However, the MDC suggests that the High Level Panel report’s recommendations on the mandatory use of pooled procurement is not in line with the objective of the current market-shaping strategy; some members noted that such a mandate could in fact undermine that strategy.

10 “Given this enormous scope, the Panel believes the procurement and management of pharmaceuticals and medical products poses larger risks to the Global Fund’s finances, operations and reputation than any other activity in its business model”
11 “Insist on pooled procurement as the norm, except where the Fund certifies a local institution”
12 “Mandate the outsourcing of drug storage and delivery as the norm, except where the Fund certifies a local institution”
13 Please note that this does not necessarily translate to all PRs within the country or all products in the various grant portfolios were procured through the VPP. This only confirms that VPP was used for at least one procurement transaction
5.9 The MDC also recommended that the Global Fund should do more to build awareness of the Global Fund's past achievements in shaping markets through its rapid and dramatic generation of demand for products, including its effort with WHO to accelerate scale-up and price reductions of artemisinin-based combination therapies for malaria beginning in 2004.
### Annex 1

**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](http://extranet.theglobalfund.org/cme/default.aspx)

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