



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Twentieth Board Meeting
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GF/B20/8
Information

REPORT OF THE MARKET DYNAMICS AND COMMODITIES AD HOC COMMITTEE

OUTLINE:

1. This report summarizes the deliberations of the Market Dynamics and Commodities Ad Hoc Committee (MDC) at its meeting on 3 October 2009.

PART 1: INTRODUCTION

1.1 The Market Dynamics and Commodities Ad Hoc Committee (MDC) met in Geneva on 3 October 2009 for its 1st meeting. The Chair was Mr. Dai Ellis; the Vice-Chair was Ms. Shanelle Hall.

1.2 This report contains the following topics:

i. Items for information (Part 2):

- Review of MDC Terms of Reference;
- Quality Assurance Policies;
- Voluntary Pooled Procurement;
- Price and Quality Reporting; and
- Prioritization of areas for further study and action.

1.3 Guidance on the location of further information is provided at the end of this report.

PART 2: ITEMS FOR INFORMATION

Information

Review of MDC Terms of Reference

2.1 The MDC reviewed in detail the terms of reference for the committee set out by the Board in GF/B19/4. In line with its guiding principles the Global Fund has thus far not worked to actively influence market dynamics for essential AIDS, TB, and malaria products. Although large scale financial investments in countries by the Global Fund has led to noticeable improvements in market outcomes for many products, the Board has recognized the Global Fund's potential to significantly influence and improve market dynamics to further enhance access by affected populations to health products. In particular, given the size of its investment in such products, the Global Fund can more effectively address issues relating to affordability, quality, predictable uptake and supply of such products. As a result, the Board has gradually steered the Global Fund towards a more active role in market dynamics and set a clear goal for its actions in this area: "Core strategic objective of market dynamics: For the Global Fund to take on a deliberate, strategic and appropriate role in enabling recipients to gain access to improved market conditions (supply, price, quality, sustainability) for the procurement of essential health products with Global Fund resources" (GF/B14/DP15).

2.2 The MDC has accordingly agreed that it has an important role to play in exploring and pursuing opportunities for the Global Fund to better leverage its purchasing power to improve market dynamics of relevant products and therefore outcomes for countries and patients. The MDC's actions in this area will take into account the Global Fund's core operating principles, including its emphasis on country ownership and its role as a financing institution. As a result, the MDC will consider the market-related activities of other relevant global health actors and the Global Fund's relationship and coordination with these organizations in its explorations.

2.3 Given its broad mandate, the MDC noted the importance of adopting a focused agenda of work on topics with the greatest urgency and potential impact in transforming the market dynamics of relevant products so that it is able make timely and high-quality progress towards the market dynamics goal set by the Board.

2.4 With the MDC only constituted in September 2009, the MDC agreed that the agenda for the first meeting should center on briefings on the current status of market-related initiatives within the Global Fund and prioritizing its work on these and other topics for the coming year.

2.5 The MDC has and will continue to work with the PIC on the transition of relevant items from the PIC to the MDC. Coordination discussions have been held between the PIC and MDC Chairs and Vice Chairs, and further planning will be discussed with the new PIC leadership, once announced. MDC Members noted that while the Board decision temporarily removes responsibility from the PIC for the areas covered in the MDC terms of reference (GF/B19/4: "This committee will temporarily remove the Portfolio Committee's responsibilities in this area."), the MDC should continue to provide updates to and seek the PIC's input on relevant items.

2.6 Given the context required for effectively discussing ongoing initiatives and potential future interventions, the MDC agreed that consideration should be given to potentially holding an additional committee meeting for further in-depth briefings of members on market dynamics and related activities of the Global Fund ahead of the next MDC meeting. These briefings will also help the MDC to refine its priorities for the next two years. These refined priorities will be shared with the Board leadership.

2.7 The MDC stressed the importance of increasing participation by the implementing constituencies represented on the committee. Early notification of meetings and distribution of background documents were noted as steps that should improve attendance and efficiency of discussions for all members.

2.8 The Secretariat provided a brief summary of recent Board decisions that pertain to the MDC. The briefing highlighted the 19th Board's decisions on minimizing stock-out risks and preventing treatment disruptions (GF/B19/DP1), accelerating access to cost-effective new technologies and optimized HIV treatment regimens (GF/B19/DP2), and supporting countries in expediting the transition to fixed-dosed co-formulations (GF/B19/DP27). The approvals of the Quality Assurance Policy for Pharmaceutical Products (GF/B18/DP3), as well as the establishment of the Voluntary Pooled Procurement Service and strengthening of the Price Reporting Mechanism (GF/B15/DP4), were also noted. Decision Points on scaling up responses to tuberculosis and malaria were also noted for the market dynamics and health products implications (GF/B18/DP5, GF/B17/DP6).

Quality Assurance Policies

2.9 In order to transition the oversight of quality assurance (QA) policies to the MDC, the MDC was briefed by the Secretariat on the revised QA policy for pharmaceutical products (the QA Policy) and the implementation challenges encountered to date. MDC Members emphasized that further information and time is needed for the committee to fully understand the context of the QA policy as a whole to enable it to effectively fulfill its oversight role.

2.10 The MDC was briefed on the PIC's recommendation to the Board to modify the QA policy in order to address challenges encountered with a number of multi-source malaria and TB products. The MDC endorsed the recommendation of the PIC and developed the following amendments to the proposed decision point to further clarify the modification¹. The MDC will present these amendments to the PIC as "friendly" amendments and, if accepted, the PIC will present the final revised text of the Decision Point to the Board at the Twentieth Board Meeting. The MDC noted that it will monitor the implementation and effect of the QA Policy modification and asked the

¹ One constituency reserved its position on the proposed modification of the QA Policy while strongly supporting the renewed commitment to the fundamental quality principles of the QA Policy, as reflected in the proposed friendly amendment.

Secretariat to report at the next MDC meeting on the effectiveness of the QA Policy modification in addressing the challenges identified.

PIC Decision Point 2: Quality Assurance Policy for Pharmaceutical Products

Friendly Amendment proposed by MDC

1. The Board recognizes that, as described in the Portfolio and Implementation Committee's Report to the Board (GF/B20/XX), there are challenges with identifying sources for certain essential and long-established multi-source treatments that meet the requirements of the Global Fund's revised Quality Assurance Policy for Pharmaceutical Products ("QA Policy"). In order to avoid disruption to treatment of patients, but without compromising the fundamental quality assurance principles of the QA Policy, the Board ~~therefore~~ decides to revise the QA Policy to expand the eligibility criteria for a risk/benefit review of products by the Expert Review Panel (ERP) by adding the following provision at the end of paragraph 13 of the QA Policy:

"Provided that the criteria in paragraph (ii) above is met, multi-source [8] FPPs that are not WHO-prequalified or SRA-authorized do not meet the criteria in paragraph (i) above are also eligible for review by the ERP for associated potential risks/benefits in accordance with paragraph 10 of this Policy."

Footnote 8: For these purposes, "multi-source" means a pharmaceutical product for which the monograph of the finished dosage form was published in the International, U.S. or U.K. Pharmacopoeia before 10 October 2002"

2. The Board requests the Market Dynamics and Commodities Ad Hoc Committee to evaluate the impact and effectiveness of this revision to the QA Policy in addressing the implementation challenges identified by the Secretariat and to report to the Board at its last meeting in 2010.

2.3. The Board notes that it will take some time for dossiers for these multi-source FPPs to be prepared and submitted to the next set of ERP reviews and that an interim exception is necessary to avoid disruption in essential treatment. The Board decides that, on an exceptional basis and for the period up to 30 June 2010 only, grant funds may be used to procure multi-source FPPs, provided that:

- (a) there are no other FPPs for that product formulation available (as defined in the QA Policy) that are WHO-prequalified or SRA-authorized or ERP-recommended;*
- (b) the site at which such FPP is being manufactured must, at the time of the procurement, be in compliance with the relevant GMP standards as verified by the WHO Prequalification Program, or an SRA or a regulatory authority participating in PIC/S;*
- (c) the FPP has been selected for procurement by relevant UN procurement agencies; and*
- (d) the notification/confirmation and testing processes described in paragraphs 9 and 31 of the QA Policy will apply to such procurement.*

2.11 The MDC asked the Secretariat to report on the further experience in implementing the QA Policy at its next meeting, taking into account questions raised by members. Members noted that this report should include a discussion of the potential metrics for evaluating the performance of the Expert Review Panel.

2.12 The MDC welcomed briefs from the Secretariat on the progress towards developing QA policies for diagnostics and pharmaceutical products other than antiretroviral, anti-malarial and anti-TB medicines. The MDC briefly discussed the process for the further development of these policies and emphasized that it will have inputs on those processes. The Chair and Vice Chair agreed to collect inputs from MDC members on potential modifications to the processes and discuss them with the Secretariat in the weeks following the meeting.

Voluntary Pooled Procurement

2.13 The Secretariat briefed the MDC on implementation progress of the Voluntary Pooled Procurement (VPP) and Capacity Building Services (CBS) initiative.

2.14 The MDC emphasized its important role in supporting the Secretariat in precisely defining and evolving the strategy of the VPP in order to realize the Board's goal of having an impact on market dynamics of relevant products (GF/B14/DP15) as well facilitating improved performance of grants through more efficient procurement. In addition to the discussion of overall strategy, a number of emerging issues were discussed where the MDC could provide guidance to the Secretariat. These issues included VPP's potential strategy and involvement with emergency orders, buffer stock, and partner procurement.

2.15 In order for the MDC to help define and oversee an effective strategy for the VPP initiative, the MDC stressed the need for a process that would sequentially:

- i. define more detailed objectives and principles for the VPP;
- ii. determine the strategies that will best achieve the detailed objectives; and
- iii. provide the Secretariat with clear guidance on how to implement the optimal strategies in ongoing operational decisions and set metrics for the evaluation of the strategy and its implementation

Building on the Secretariat's plans for an evaluation of the VPP, the MDC suggested an independent study be commissioned that would provide an analytical basis for the MDC's discussion on the above points. It was emphasized that the study should incorporate input from implementing countries where possible.

Price and Quality Reporting

2.16 The Secretariat briefed the MDC on implementation progress of the Price and Quality Reporting (PQR) system launched in February 2009. As the system has been operational for a short period of time and a new version would be launched shortly after the meeting, the MDC agreed that it should engage in a more robust discussion of the performance of the system and the role of the MDC at its next meeting. In the interim, MDC Members will test a new version of the system being launched at the end of October and will provide suggestions for improvement or requests for additional information prior to the next meeting to the Secretariat.

2.17 The MDC asked the Secretariat to provide a detailed report at the next MDC Meeting on progress with the PQR. The MDC requested that the paper include background on the selection of product categories reported in the PQR and a discussion on opportunities for reporting on diagnostic products other than rapid diagnostic tests (RDTs). The MDC further emphasized the

importance of considering harmonization with other databases related to pharmaceutical product procurement managed by partners.

Prioritization of Areas for Further Study and Action

2.18 The MDC agreed that accelerating the uptake of new technologies is a high priority that the committee should examine in the coming year. It was emphasized that the MDC should consider the full range of issues, including technologies not currently available, those that are available but not being accessed, and the supplier base for new technologies. The MDC requested that the Secretariat prepare a paper for the next meeting on an analytical framework for accelerating uptake of new technologies and the potential options for the Global Fund. Members emphasized that it will be important for the Global Fund's potential actions in this area to not duplicate those undertaken by partner organizations, notably UNITAID, and requested that this be taken into consideration in relevant papers and future discussions. The paper will also include focuses on specific product areas of interest, including antimalarial artemisinin-based fixed-dose co-formulation (FDCs) and HIV technologies. This paper will serve as the foundation for the MDC discussing and responding to the Board's specific requests (GF/B19/DP27, GF/B19/DP34) in these areas at the next MDC meeting.

2.19 The MDC noted that there are challenges in specific health product categories that may require or benefit from the MDC's involvement. The Secretariat briefed the MDC on challenges encountered to date with the procurement of long-lasting insecticide-treated nets (LLINs). The MDC asked the Secretariat to prepare a short paper on the challenges experienced with LLINs to facilitate a discussion on potential appropriate action by the MDC. In close collaboration with the AMFm Committee, the MDC also agreed to monitor issues in the Artemisinin-based Combination Therapies (ACT) market. The MDC asked the Secretariat to coordinate with the Roll Back Malaria Partnership (RBM) to provide a summary of current issues in the ACT market and ongoing actions by other institutions to enable identification of potential gaps.

2.20 MDC Members stressed the importance of developing a common definition of market dynamics and the Global Fund's role in interacting with and influencing these dynamics. It was agreed that an external expert will be commissioned by the Secretariat with MDC input to build on existing work in preparing a paper that will enable the MDC to adopt a clear definition of and approach to market dynamics. The MDC also agreed that it will be important for it to regularly monitor the status of markets for major health products relevant to the Global Fund to enable a systematic approach to appropriate intervention. The MDC and the Secretariat will discuss effective approaches to conduct such monitoring, including through collaboration with partner organizations and the establishment of metrics to be regularly reported on.

2.21 The MDC noted the need for background information from the Secretariat on the mechanisms used for evaluating health product selection and budgets in Global Fund grants. The MDC requested the Secretariat to report on the existing approaches employed by Global Fund mechanisms (i.e., Secretariat, Technical Review Panel, etc.) to evaluate health product budgets and potential options for additional actions.

2.22 The MDC noted the important role that UNITAID plays in improving the market dynamics of AIDS, TB, and malaria products and its partnership with the Global Fund that is codified in the Board-approved "Road Map." To further strengthen the coordination between the two institutions on market dynamics issues, the MDC requested UNITAID to provide an update to the MDC on its strategy process and suggest possibilities for an updated vision and road map with the Global Fund,

including as relates to potential coordinated action to expedite the uptake of effective new technologies.

2.23 The MDC agreed the Chair and Vice Chair will work with the Secretariat to develop a detailed MDC work plan for the coming period and then seek the input of Members. The MDC's priority areas and workplan will be shared with the Board leadership.

This document is part of an internal deliberative process of the Fund and as such cannot be made public. Please refer to the Global Fund's documents policy for further guidance.

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 MDC password-protected website:

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

Item:	Further information available:
1. Items for information:	
<ul style="list-style-type: none"> • Review of MDC Terms of Reference 	"Introduction Presentation for 1st MDC Meeting.ppt" [*]
<ul style="list-style-type: none"> • Quality Assurance Policies 	Presentation slides from 1 st MDC Meeting "Quality Assurance Policy Update" [*] "Procurement and Quality Assurance Matters" (GF/PIC01/09) [*]
<ul style="list-style-type: none"> • Voluntary Pooled Procurement 	Presentation slides from 1 st MDC Meeting "Voluntary Pooled Procurement" [*]
<ul style="list-style-type: none"> • Price and Quality Reporting 	Presentation slides from 1 st MDC Meeting "Price & Quality Reporting (PQR)" [*]