Nineteenth Board Meeting
Geneva, Switzerland, 5 – 6 May 2009

GF/B19/7
Decision

REPORT OF AFFORDABLE MEDICINES FACILITY – MALARIA AD HOC COMMITTEE

OUTLINE:

1. This paper presents a summary of progress in preparing for the launch of AMFm Phase 1, presents a revised implementation timeline, and proposes a decision point for Board consideration.

PART 1: INTRODUCTION

1.1 At its Eighteenth meeting the Global Fund Board approved the Policy Framework and Implementation Plan set out in the AMFm Ad Hoc Committee Report to the Board (GF/B18/7 – the "AMFm Report") and reaffirmed its decision to host and manage the AMFm for an initial phase ("Phase 1") in a limited number of countries. The Board requested the Secretariat to begin operation of Phase 1 of the AMFm and requested the AMFm Ad Hoc Committee to continue to oversee the pre-launch preparations. This paper presents an update to the Board from the AMFm Ad Hoc Committee on pre-launch preparations for Phase 1 of the AMFm and a revised timeline for AMFm implementation and the independent evaluation.

PART 2: OVERVIEW OF PROGRESS

2.1 Since the Eighteenth Board Meeting, the Secretariat has established a distinct AMFm Unit and appointed a Director to lead the AMFm effort. There has been excellent progress in the three major work streams which underpin the launch of Phase 1 of the AMFm, namely country access and applications, copayment strategy and manufacturer negotiations, and monitoring and evaluation. The progress with the first of these has included the development of an application form and accompanying guidelines. In designing this form the Secretariat consulted with partners and eligible Phase 1 countries. A multi-country consultation in Nairobi in mid-February 2009, organized by the Harmonization Working Group (HWG) of Roll Back Malaria (RBM), was an important opportunity for countries to discuss the AMFm and be sufficiently informed to make a decision on whether to apply. The call for applications was issued on 20 March 2009 with a revised deadline of 1 July 2009, to allow countries adequate time to develop their applications.

2.2 In the second key area, manufacturer negotiations, the Secretariat has developed its approach to manufacturer negotiations. This includes contracting a negotiation agent (the Clinton Foundation) and convening a Copayment Technical Advisory Group to make recommendations to the Secretariat on setting the copayment and related policy issues. This group has reported and the Secretariat has finalized its copayment strategy accordingly.

2.3 In the third area, namely monitoring and evaluation, a draft Technical Framework for the approach to monitoring, operational research and independent evaluation has been developed and shared with the AMFm Ad Hoc Committee as well as key technical partners for their review and input, notably the Monitoring and Evaluation Reference Group of RBM. A monitoring and evaluation (M&E) workshop will be used to inform countries and provide guidance on the M&E arrangements for Phase 1, to receive their inputs into the Technical Framework, and map in detail additional needs for technical support. The committee determined that it will consult and coordinate with the TERG regarding oversight of the independent evaluation. The Secretariat informed the committee that it intends to constitute an independent expert group to advise the Secretariat on the structure and methods of the independent evaluation of AMFm Phase 1, which the Secretariat will commission.

PART 3: RESOURCE MOBILIZATION

Copayment Fund

3.1 Resources required for ACT copayments were originally estimated at US$212 million (GF/B18/7 – the "AMFm Report"). An updated forecast estimated the resources required as US$225-233 million. The UNITAID Board at its late January 2009 meeting pledged up to US$130 million for the AMFm Copayment Fund. The Secretariat is working with the UNITAID Secretariat on the contribution agreement to the Global Fund Copayment account. The UK DFID has pledged GBP £40 million to the Copayment Fund. In addition to these two pledges, the Secretariat is in contact with other donors that have expressed an interest in contributing towards Phase 1 of AMFm. It is expected that, through these additional resource mobilization efforts, adequate funds needed for launch of the AMFm will be pledged before the Global Fund Board's decision on approval of AMFm applications in October and November 2009.

Funding of Supporting Interventions

3.2 Supporting interventions will be financed through savings from ACT budgets under existing Global Fund grants in the relevant country. If these savings are insufficient to fund the supporting interventions in the country (or there are no Global Fund grants with ACT budgets in the country), countries should request additional funding. The committee has asked for, and is awaiting, a revised estimate from the Secretariat on the amount of funds available from existing grants for reprogramming; the committee also affirmed that only unspent funds previously budgeted for the purchase of ACTs should be reprogrammed.

3.3 In accordance with the Board-approved principles for the AMFm, resource mobilization for supporting interventions is part of ongoing resource mobilization for Global Fund grant making and should be integrated into the Global Fund resource mobilization strategy. Accordingly, any additional funding for supporting interventions will be sourced from the Global Fund's general pool of funds.

PART 4: REVISED TIMELINE

4.1 At its Eighteenth meeting in November 2008, the Global Fund Board approved the launch of AMFm Phase 1 in 2009 with the following provisions: an application deadline of mid-March 2009, decisions on TRP recommendations taken by the Board at its Nineteenth Board meeting in May 2009 and launch of the AMFm in August 2009. It was advised, however, that this schedule would likely change. Indeed, because of significant work by the Secretariat to develop the application form and guidelines, and by countries to prepare their applications, it was not feasible to launch with this time-line. The committee, under its authority provided by the Board to make minor modifications to the framework and implementation plan, has approved the following changes to the implementation timeline:

AMFm proposal submission deadline and review

4.2 The application deadline has been extended to 1 July 2009 to allow adequate time for countries to develop their applications for AMFm Phase 1. The Secretariat will screen applications in July 2009. The Technical Review Panel (TRP) will review AMFm applications in late August or early September 2009 and report its recommendations to the Board in October 2009.

Board review and approval

4.3 Under this revised timeline, Board approval of proposals for supporting interventions under the AMFm proposals is now expected to be made at the Board's Twentieth meeting in November 2009.

Independent Evaluation

4.4 At its Eighteenth meeting the Board requested the Secretariat commission an independent technical evaluation of the roll-out of the AMFm in the AMFm Phase 1 countries. The Board requested the committee with oversight of AMFm Phase 1 to review the findings of this evaluation and to make a recommendation to the Board on its completion (originally estimated for the second half of 2010), at which time the Board would determine whether to expand, accelerate, terminate or suspend the AMFm business line. The revised timeline for applications has an effect on the timing of the independent evaluation and consequent decision of the Board on the AMFm business line. The independent evaluation is now foreseen to be completed in mid 2011, with its findings reported to the Board no later than at its last meeting in 2011.

PART 5: UPDATE BY WORK STREAM

5.1 The following section contains an update of progress by work stream.

(5a) Country Access and Applications

Introduction

5.2 This section covers the ongoing consultation process with eligible Phase 1 countries, the application and approval process and the process and timing for funding for Phase 1.

Individual country consultations and Technical Support

5.3 Country stakeholder consultations in conjunction with partners have been beneficial in clarifying implementation design and time-lines of the AMFm. Secretariat staff have responded to questions and discussed concerns raised by national level stakeholders. The Harmonization Working Group (HWG) of RBM is coordinating technical support to countries in formulating their AMFm applications. The Clinton Foundation has lead within that process and is providing technical support and brokering technical support by others.

AMFm Consultative Workshop – Nairobi, 12-14 February 2009

5.4 In line with its role of coordinating technical support for countries, the HWG convened a conference from 12-14 February 2009 in Nairobi, Kenya to discuss the AMFm in detail with eligible countries and partner organizations. High-level delegations from 10 of the 11 eligible countries participated in this 3-day event. Overall goals were:

- To enable all eligible countries to make an informed, evidence-based country decision on whether or not to apply to the AMFm
- To identify a pathway for decision making on an AMFm application submission, and if appropriate, application development

5.5 Discussions focused on key areas of the AMFm, including private-public sector coordination, safety and the regulatory status of ACTs, and the scope of supporting interventions. In addition, potential roles and economic viability of ACT manufacturers in AMFm eligible countries were discussed. The Secretariat provided responses to country delegations and incorporated many of their comments into the application form and guidelines.

Application Form and guidelines

5.6 The Secretariat developed a separate, short AMFm Phase 1 Application Form with accompanying guidelines. This was released to eligible Phase 1 countries on Friday 20 March 2009. The form was developed through a broad consultative process that incorporated comments from eligible countries, technical partners, the Ad Hoc Committee and relevant teams from within the Global Fund Secretariat.

Grant Agreements for Supporting Interventions

5.7 As presented in the committee's report to the Eighteenth Board Meeting ((GF/B18/7), funding for supporting interventions will be sourced from the reprogramming of savings under ACT budgets of existing Global Fund grants or, if such funding is insufficient, through additional funding from Global Fund grants and other donors. Regardless of whether funding is from ACT cost savings under existing Global Fund grants or from additional grant financing, funding for supporting interventions for AMFm Phase 1 will be managed and disbursed through an existing Global Fund malaria grant (a "host grant") identified by countries in their AMFm application). Channeling supporting interventions through an existing grant, rather than negotiating a new grant for AMFm Phase 1, streamlines grant negotiations and management for participating countries and accelerates disbursement of funds for supporting interventions.

5.8 Accordingly, as soon as an AMFm proposal is approved by the Board, the Secretariat will work with the CCM and Principal Recipient to amend the grant agreement of the designated AMFm 'host' grant, to incorporate the activities, budget and performance framework for AMFm Phase 1 supporting interventions. It is expected that this amendment will be signed within two months of Board approval of AMFm applications.

5.9 If savings from ACT budgets under existing Global Fund grants exceed the amount needed to fund supporting interventions, CCMs may apply to use these excess savings to scale-up ACT access through the public sector.

Date of ordering co-paid ACTs

5.10 Ensuring AMFm participant countries can proceed quickly is a priority. Accordingly, the committee has agreed that eligible first line buyers will be able to initiate (but not finalize) the process for ordering co-paid ACTs as soon as the Board approves the country's AMFm application. This means that, as soon as the grant amendment for supporting interventions has been signed for that country, orders for co-paid ACTs can be immediately confirmed.

(5b) Co-payment Strategy and Negotiations

5.11 In developing its co-payment strategy the Global Fund Secretariat sought advice from an independent Co-payment Technical Advisory Group (CTAG). In addition, the Global Fund Secretariat sought comments and suggestions from the AMFm Ad Hoc Committee and other key stakeholders including members of the former Roll Back Malaria (RBM) Task Force on the AMFm.

5.12 The criterion for choosing the approach for co-payment setting and the co-payment level was driven by three main guiding principles

i. Ensuring that resulting prices of ACTs to end-patients are comparable to prices for CQ and SP
ii. Ensuring that mono-therapies, which increase the probability of resistance by the malaria parasite to artemisinin, are replaced by ACTs as widely as possible\
iii. There is minimal disruption to current business practices and market competition is preserved while maintaining the innovative spirit of the AMFm.

5.13 The Global Fund will negotiate a price of each ACT formulation with respective manufacturers, which may involve different pricing for the same formulation based on the varying cost structures of manufacturers. This approach recognizes differences in cost structures among incumbent manufacturers, and an attempt to encourage more firms to enter the ACT market. The negotiations will cover each formulation, (for example Artemether-Lumefantrine (AL), Artesunate + Amodiaquine (AS+AQ) etc.) and dosage form (infant, child, adult etc). In order to allow for newly pre-qualified manufacturers or large changes in the prices of the active pharmaceutical ingredient (API), the prices will be renegotiated at least once per year, unless the Global Fund decides otherwise.

5.14 The AMFm will use a fixed co-payment for each ACT formulation from a particular manufacturer. The fixed dollar payment will be such that the targeted first-line buyer price is about US$0.04 - 0.06 (weighted-average across the various dosage forms) per treatment. Existing ratios of prices between dosage levels (i.e. adult, child, etc.) will be kept in order to avoid perverse incentives to use child doses for adults or vice-versa.

5.15 The Secretariat will monitor effects of this approach with a view to detecting unintended consequences that may work against the purpose of the AMFm, and take corrective actions. It will also include this topic among those for multi-country operational research. Finally, this topic will be included in the independent evaluation of AMFm Phase 1.

5.16 The full co-payment strategy is attached as *Attachment 1.* It was provided to the committee for information and advice, but not approval.

Product eligibility

5.17 The Board has previously confirmed that its Global Fund Quality Assurance Policy for Pharmaceutical Products (as approved in November 2008 - Decision Point GF/B18/DP11) will be applied when identifying eligible products. For a product combination to be included for co-payment under AMFm it must satisfy the following criteria:

i. It should be in the country's national treatment guidelines
ii. It should be in the WHO Treatment Guidelines (for that country/region)
iii. It should be registered in the country

5.18 In accordance with the Global Fund Board decision of November 2008 (Decision Point GF/B18/DP7), both co-formulated and co-blistered ACTs will be eligible for co-payment under the AMFm, provided that they meet standards set forth in the Global Fund QA Policy for Pharmaceutical Products and that manufacturers are compliant with the AMFm policy to prohibit procurements from companies that market oral monotherapies.

5.19 AMFm Ad Hoc Committee members had significant discussion on the issue of fix-dosed combinations versus co-blistered combinations. There was consensus among AMFm Ad Hoc committee members (and with the Global Fund Secretariat) that co-formulated products were preferable and that the Global Fund should explore opportunities, within its mandate, to support and accelerate the transition to co-formulated products. The AMFm Ad Hoc Committee notes that there are multiple technical issues involved that also need to be taken into account, including the impact of changed policies on the availability of approved products, the need for training to smoothly implement a shift to co-formulated ACTs, inadvertent biases towards products of lower quality, risks of supply disruption, and the inadvertent creation of monopolies for certain formulations.

Sense of the AMFm Ad Hoc Committee

5.20 The AMFm Ad Hoc Committee was informed that the WHO is in the final stages of updating its policy and guidelines on co-formulated and co-blistered ACTs, and is requesting the Global Fund Board to discuss with WHO to expedite their release.

5.21 The AMFm Ad Hoc Committee notes that these issues are not specific to the AMFm in that they pertain to all Global Fund grants that support malaria treatment. It therefore is requesting review of this important issue by other Board committees with relevant competencies and responsibilities.

(5c) Monitoring and Evaluation

5.22 The M&E framework, which is under development, sets out the approach to monitoring, operational research and independent evaluation of AMFm Phase 1, of the AMFm. An overview of the framework, attached as *Attachment 2*, was provided to and discussed by the committee, but

is neither fully reviewed nor approved. The committee is seeking the advice and counsel of the TERG in this area.

Oversight and commissioning of the Independent Evaluation

5.23 As mandated by the Board, the AMFm Ad Hoc Committee will oversee the Independent Evaluation of Phase 1 and report to the Board its conclusion on the independent evaluation. The AMFm Ad Hoc Committee will consult with TERG in relation to this Independent Evaluation, while respecting the mandate of the Secretariat to manage its implementation.

5.24 The Secretariat will commission an independent evaluation of AMFm Phase 1 as mandated by the Board and has advised the committee of its intent to constitute an independent Expert Advisory Group (EAG) dedicated to assist and advise the Secretariat on the design of this evaluation. The Secretariat will need timely and high-quality advice from a body dedicated to the specific challenges of the AMFm, with a mix of skills customized for the specific purpose of the AMFm, and which has a finite lifespan. It noted that this EAG will have no role in the management or oversight of contractual processes for the independent evaluation which will be the responsibility of the Secretariat. The EAG will not formally advise the AMFm Ad Hoc Committee, but technical advice received from the EAG will be available to both the Secretariat and the AMFm Ad Hoc Committee. The committee has determined that it will rely on the guidance and support of the TERG regarding oversight of this independent evaluation, but it has left to the Secretariat the decision on whether to seek its own counsel as it commissions the independent evaluation.

PART 6: GOVERNANCE OF AMFm

6.1 The AMFm Ad Hoc Committee was established at the Seventeenth Board Meeting as a temporary ad hoc committee with the purpose of overseeing the preparations for the launch of AMFm Phase 1 (GF/B17/DP16). The committee's mandate expires at the Nineteenth Board Meeting at which time the Board will need to consider the future governance structure for AMFm (GF/B18/DP7). This part of the Report sets out the committee's recommendations to the Board on continuing governance of the AMFm during the remainder of Phase 1.

6.2 In developing its recommendations, the committee took into account the following considerations:

i. AMFm is being launched in a limited, phased approach, with a decision on global roll-out expected in 2011;
ii. It is important to ensure a degree of continuity between the preparatory and implementation stages of AMFm and to ensure that the valuable experience and knowledge already gained by the committee is not lost;
iii. Since the committee was only established in May 2008, a decision to extent its mandate for the Phase 1 period would mean that, based on the current timeline, its total mandate (and the terms of its members) would not exceed 2.5 years;
iv. Recognition and continued participation of important stakeholders such as UNITAID and RBM is essential;
v. Committee membership requires a substantial commitment of time and resources, especially at this critical stage in the AMFm;

vi. The establishment by UNITAID of a separate body to oversee its immediate interests in the AMFm, and the need for the Global Fund Secretariat to provide additional reports to UNITAID should be avoided; and
vii. The need for technical expertise as AMFm moves into implementation.

6.3 The committee noted that the UNITAID Board conditioned its $130m contribution to the Global Fund co-payment fund on a role in the Global Fund's governance of AMFm.

6.4 The committee also noted that the Policy and Strategy Committee (PSC) is recommending that the Board maintains the current AMFm Ad Hoc Committee as a separate, temporary ad-hoc committee for the duration of AMFm Phase 1 (see GF/B19/4). The committee supports the PSC's recommendation and recommends that the Board adopt the following adaptations to the current structure and scope of the AMFm Ad Hoc Committee:

i. The current Chair of the committee has indicated that he will be resigning from this role at the end of the Nineteenth Board Meeting and together with the Chair of the Board recommends that the Vice Chair assume the role of Chair as has recently been done with another committee of the Board.
ii. The Chair of the Board, in consultation with the leadership of the committee, recommends that the Board of UNITAID be invited to nominate a representative to serve as a Vice-Chair of the committee, based on the criteria for leadership set out in Section I.4 of Committee Rules and Procedures, including strong leadership skills, commitment and subject specific expertise. This special arrangement recognizes the importance of the partnership with UNITAID on the AMFm and increases alignment between the oversight needs of both the Global Fund and UNITAID. The appointment of the representative of the UNITAID Board will be subject to approval of the Board Chair and the committee Chair. This proposal is supported by a majority of (but not all) committee Members, with some expressing concern about the precedent of having non-Board delegates serve in committee leadership positions.
iii. The committee recommends the World Health Organization (WHO) constituency be included as a member of the committee, and that the Private Foundations delegation (which had been serving as Chair) be allowed to continue participation as a regular member.
iv. The committee recommends that the Board adopt the revised terms of reference for the committee set out in **Annex 1** to this Report, though it notes that it did not have time to fully deliberate these and so advises that it may seek modifications to these terms of reference at future meetings of the Board.

PART 7: BOARD DECISION POINT

Decision Point 1: AMFm Phase 1

The Board recalls its decision regarding the Affordable Medicine Facility – malaria ("AMFM") (GF/B18/DP7).

The Board notes that it will vote on the AMFm proposals at its Twentieth meeting. The Board understands that the independent evaluation of AMFm Phase 1 is now estimated to be completed in the second half of 2011.

The Board decides to maintain the AMFm Ad Hoc Committee as a separate committee of the Board for the duration of the AMFm Phase 1 period with the terms of reference set out in Annex 1 to the Report of the AMFm Committee (GF/B19/7). The Board approves the appointment of Professor Eyitayo Lambo as Chair of the AMFm Committee and requests the Board Chair to invite the UNITAID Board to nominate a suitable representative to serve as Vice-Chair of the AMFm Committee. The appointment of the UNITAID Board representative shall be subject to the approval of the Board Chair and the AMFm Committee Chair. The Board also approves the inclusion of the Private Foundations delegation as additional member of the AMFm Committee, and approves the inclusion of representatives of Roll Back Malaria and the World Health Organization as non-voting members of the Committee.

The Board notes pending WHO guidance that fixed-dosed co-formulations (FDCs) are strongly preferable to co-blistered ACTs and may help to delay resistance to artemisinin. The Board also notes that multiple technical issues need to be taken into account to ensure a smooth transition to an exclusive use of FDC ACTs. The Board urges that WHO expedite finalization of this guidance on FDCs and co-blistered ACTs.

The Board requests its Chair to delegate to the relevant committee(s) the task of identifying and considering options for the Global Fund, within its mandate as a financing institution, to support countries in expediting the transition to FDCs, taking into consideration the implications for quality, supply, pricing and appropriate use of ACTs, and to report back to the Board at its Twentieth meeting.

This decision does not have material budgetary implications.

Annex 1

AMFM AD HOC COMMITTEE – TERMS OF REFERENCE

The AMFm Ad Hoc Committee is an ad hoc committee of the Board established for the sole purpose of overseeing and advising the Board on the development, launch, implementation and evaluation of the first phase of the Affordable Medicine Facility for Malaria (AMFm).

Terms of Reference

The committee shall have the following responsibilities:

- Oversee the preparations for launch of the AMFm Phase 1, review reports provided by the Secretariat and provide guidance to the Secretariat
- Advise the Board on critical strategic and policy matters related to AMFm Phase 1
- Provide regular updates to the Board on progress
- Oversee the independent evaluation of AMFm Phase 1 and report the findings to the Board
- Based on the results of the independent evaluation, make recommendations to the Board on whether to expand, accelerate, terminate or suspend the AMFm business line

In fulfilling these responsibilities the committee will have regard to the Principles for AMFm Policy Framework, Implementation and Business Plan set out in the Board's decision at the Seventeenth Board Meeting (GF/B17/DP16).

The committee shall report directly to the Board and shall consult with other committees as appropriate in developing its recommendations and advice to the Board.