

**REPORT OF THE AFFORDABLE MEDICINES FACILITY - MALARIA (AMFM)**  
**AD HOC COMMITTEE**

**PURPOSE:**

This report summarizes the deliberations of the Affordable Medicines Facility - malaria Ad Hoc Committee (AHC) at its meeting on 13-14 October 2011, in subsequent email communications, and its resultant recommendations to the Twenty-Fifth Board Meeting.

## **PART 1: INTRODUCTION**

The Affordable Medicines Facility - malaria Ad Hoc Committee (AHC) met in Geneva on 13-14 October 2011 for its 10<sup>th</sup> meeting. The Chair, Minister Leslie Ramsammy (Latin America and Caribbean), was absent; the Vice-Chair, Kirsten Myhr (UNITAID), chaired the meeting in his absence. The meeting was attended in part by a Technical Evaluation Reference Group (TERG) representative and by the principal investigators from the consortium for the independent evaluation of AMFm Phase 1.

1.1 This paper consists of the following sections:

- i. Part 1: Introduction
- ii. Part 2: AHC Discussion and Recommendations

## **PART 2: AHC DISCUSSION AND RECOMMENDATIONS**

**Input**

### **Status of Implementation**

2.1 The AHC welcomed the update on progress provided by the Secretariat in its quarterly report and commented that major improvements had taken place in terms of availability and affordability of co-paid artemisinin-based combination therapies (ACTs) in AMFm Phase 1 countries. As of end August 2011, the AMFm had approved co-payment for 176.9 million treatments, of which 106.1 million had been delivered in the pilot countries that have started implementation. Independent surveys by Health Action International (HAI), conducted in June 2011 and August 2011, showed evidence of increased availability and reduced prices of AMFm co-paid ACTs compared to originator-brand ACTs and lowest-priced generics in Ghana, Kenya, Madagascar, Nigeria, Tanzania (mainland) and Uganda (i.e. every AMFm pilot where HAI has conducted surveys).<sup>1</sup> By combining price negotiations with an average co-payment of about US \$1.05 per treatment, the AMFm has reduced the median retail prices of quality-assured ACTs from US\$ 4.66-12.55 to US\$ 0.44-1.31 for an adult treatment pack.<sup>2</sup> All direct costs of in-country distribution and storage are borne by the private sector, not by the taxpayer. The AHC discussed the slow implementation of supporting interventions, expressing concern, and concluding that this was due to both slow disbursement of funds through regular Global Fund channels, and slow in-country public sector processes. The lessons drawn from this experience should be applied to any future phase of the AMFm.

2.2 Cambodia is still not able to participate in Phase 1 of the AMFm due to the non-availability of a quality-assured artemisinin-based combination therapy (ACT) to be used in Cambodia (Dihydroartemisinin-Piperaquine). The Secretariat briefed on the regulatory and quality issues that need to be resolved before a product would be available to Cambodia, at the earliest in Q2-3 2012.

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<sup>1</sup> Health Action International. Retail Prices of ACTs co-paid by the AMFm and other antimalarial medicines: report of price-tracking surveys. August 2011

<sup>2</sup> *Ibid.*

2.3 The AHC discussed diagnostics in the context of AMFm and expressed optimism that current and ongoing Implementation Research studies in a number of countries would increase knowledge on how to scale up access to diagnostics, particularly in the private sector. Together with the findings from the Independent Evaluation, these would provide valuable input into the Board's decision in late 2012 on the future of AMFm beyond Phase 1.

2.4 The AHC notes that 35 percent of all co-payments across all AMFm Phase 1 countries are for public sector first-line buyers. The AHC further notes that within some countries, the public sector is procuring ACTs from the private sector. This helps the public sector to avoid stock-outs and suggests that the private sector is a faster channel for assuring the availability of ACTs. The AHC has requested more information about quantities of ACTs involved.

### **Independent Evaluation**

2.5 The AHC discussed the AMFm Phase 1 Multi-Country Baseline Report of the Independent Evaluator (a consortium of ICF Macro and the London School of Hygiene and Tropical Medicine). The AHC concluded that the baseline report was a good snapshot of the situation in each country at the outset of AMFm Phase 1. The AHC noted that there was a higher than expected baseline level of Artemisinin Monotherapies (AMTs) in several of the Phase 1 countries, including in both the public and private sectors. The AHC requested that the endline report put more focus on explaining how and why the results for each country were achieved in order to be a useful report for making a recommendation on the future of the AMFm Phase 1. The original technical framework for the independent evaluation provided for a quasi-experimental design with comparator countries. Based on technical guidance from the TERG in 2010 and feedback from the independent evaluator, the AHC dropped the quasi-experimental design in favor of in-depth country case studies. The AHC now believes that it would be helpful to have some comparators, and requests the Secretariat to explore this option with the Independent Evaluator. The AHC understands that this option is subject to technical feasibility and constraints on the budget for the independent evaluation.

### **Comparative Effectiveness and Cost-Effectiveness of AMFm**

2.6 In response to the Board's decision at its twentieth meeting in November 2010 (GF/B20/DP24) regarding the independent evaluation of AMFm Phase 1, that in addition to measuring progress against four defined objectives, it would “**...consider evidence that the AMFm will achieve these four objectives more cost-effectively than other financing models that aim to achieve similar objectives solely or principally through the expansion of public sector services (i.e. public health facilities and community health workers only)**”, the AHC requested that the Secretariat commission a two part study of the comparative effectiveness and cost-effectiveness of AMFm. The first part of this would assess the feasibility of a full study. The consulting firm evaplan International Health at the University Hospital Heidelberg won the competitive tender and completed the first part of the study.

2.7 The AHC had a full discussion of the study, with input from both the TERG representative and the Independent Evaluator, and concluded that a full study of the cost-effectiveness and comparative effectiveness of AMFm was not feasible and therefore the second part of the study would not go ahead. The reasons for the study not being feasible include, but are not limited to:

- i. The unavailability of relevant data;
- ii. The lack of appropriate comparator financing models;
- iii. The difficulty of measuring with certainty the attributable effects of AMFm; and,
- iv. The difficulty of estimating costs and disentangling impacts of one financing model versus another.

The AHC proposes instead that the Independent Evaluation report should at least attempt to estimate additional impact and costs at country level. The AHC understands that this option is subject to technical feasibility and constraints on the budget for the independent evaluation.

### **ACT Demand Estimates and Projections**

2.8 The UNITAID-funded consortium led by Boston Consulting Group (BCG) briefed the AHC on its updated demand estimates and projections. The AHC noted an increase from the previous level of demand predicted for ACTs in both 2011 and 2012. This was attributed to increased demand for ACTs in the private sector through AMFm. The AHC acknowledged that there was a lot of uncertainty in the figures. The BCG representative emphasized that the supply side was tight for the end of 2011 but would probably improve in 2012. The AHC expressed concern about a mismatch in orders in Zanzibar in relation to perceptions of need. The AHC believes ACT manufacturers need visibility of the future of AMFm, without which there will be increased instability in the market. The AHC encourages better planning and communication among all parties to ensure sufficient supply and to make the best use of manufacturing capacity. The AHC noted that semi-synthetic artemisinin would likely be available in 2013 in a limited quantity.

### **Financing and Managing ACT Demand**

2.9 The AHC notes that approved orders to date for AMFm co-paid ACTs are slightly less than projected on the basis of 2008 forecasts. However, recent ACT forecasts and order trajectory indicates a trend in which approved orders would exceed initial estimates by the end of AMFm Phase 1. In addition, the average co-payment per treatment is higher than envisaged in 2008. The Secretariat has introduced a system of levers to manage demand and to conserve funds for the remainder of Phase 1: promote pediatric packs and fixed dose formulations, prioritize the public sector and allow deliveries to catch up with orders. The AHC notes that this system has been successful in meeting these immediate goals but may have other consequences. For example, if it is too stringent, approved orders will fall short of demand, leading to higher retail prices. The Secretariat also briefed that the co-payment fund, if it continued to be depleted at the current rate, would be fully depleted by January 2012. Accordingly, the Secretariat has applied for additional funding of US\$50 million from UNITAID and US\$74 million from the UK Department for International Development (DFID). The UNITAID decision on further funding will be known by mid-December 2011; the timing for the DFID decision is as yet unknown.

2.10 On 31 October 2011, the AHC sent to the leadership of the Global Fund Board and the UNITAID Board a communication on the need for additional funds to cover co-payments during the remainder of AMFm Phase 1. The AHC discussed whether it would be possible that unused funds from AMFm supporting interventions could be reprogrammed for co-payments, and asked the Secretariat to investigate the feasibility of this and how much could be available. Should there be no additional monies for co-payment by January 2012, the AHC recommends that the Secretariat, Board Leadership, AHC and donors should meet to discuss how to respond. A response could include stopping co-payments, which the AHC recognizes will have important ramifications at the country-level for Phase 1 pilots.

## **Scenario Planning**

2.11 The AHC discussed the scenario planning exercise conducted by the Secretariat. Through this exercise, AMFm Phase 1 countries have been consulted on the progress and challenges of the AMFm and their perspectives on the future of AMFm beyond Phase 1, within the parameters of the different decisions the Board could take at the end of 2012. The main messages from implementing countries were that implementation has gone well so far and that they would like to continue with AMFm in order to increase access to quality-assured ACTs through the private sector. The countries also suggested some modifications to the mechanism, including speedier disbursement of funds for critical supporting interventions and access to RDTs. In addition, countries indicated that they would like advance notice of the future of AMFm beyond Phase 1 in order to plan adequately.

2.12 The AHC has requested the Secretariat to continue work to prepare during 2012 more detailed and costed Secretariat-level scenario plans for after phase 1 of AMFm. This should include working with the Roll Back Malaria (RBM) partnership to elaborate country-specific scenarios with cost implications and details of what each scenario would look like in each country. This work will feed into the AHC's recommendation to the Board on the future of the AMFm in late 2012. The AHC stresses the need for an appropriate transition period of 6-12 months post-Phase 1 to allow time for implementation of the Board Decision on the future of AMFm and to provide more predictability to ACT manufacturers and implementing countries. The AHC notes that additional Funds will be needed to cover co-payments and supporting interventions during the transition period in 2013.

## **Governance Reform**

2.13 The AHC was briefed by the Advisor to the Board Chair on the proposed changes to governance arrangements for the Board and its committees. The AHC was requested to provide input regarding the planned transition from the current arrangement whereby there are two Ad Hoc Committees (AMFm and Market Dynamics and Commodities) to having a Market Dynamics Advisory Group to advise the soon to be created Investment, Strategy and Impact Committee. The AHC acknowledged that there may be benefits to the new structure including more attention for the AMFm at Board meetings and new expertise from the Market Dynamics Advisory Group. The AHC though, does have the following concerns:

- i. Whether it is sensible to make this change now, given that the AMFm AHC only has two more scheduled meetings before the end of AMFm Phase 1.

- ii. That the newly formed Market Dynamics Advisory Group may not have sufficient time to focus properly on AMFm in addition to its other responsibilities and competing interests.
- iii. That the newly formed Market Dynamics Advisory Group may not have the country level market, and/or malaria-specific experience to provide guidance on AMFm.
- iv. AMFm is hosted by the Global Fund on behalf of many partners. These partners should be consulted on the reform of the governance arrangements for AMFm.

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.

### 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>

<b>Item:</b>	<b>Further information available:</b>
1. Status of Implementation	GF/AMFm10/03: “Quarterly Update, September 2011” GF/AMFm10/06: “HAI Price Tracking Report, August 2011” - <b>available on Governance Extranet</b>
2. Independent Evaluation	GF/AMFm10/07: “Independent Evaluation Phase 1 Multi-country Baseline Report” GF/AMFm10/08: “Independent Evaluation Phase 1 Multi-country Baseline Report Presentation” - <b>available on Governance Extranet</b>
3. Comparative Effectiveness and Cost-Effectiveness	GF/AMFm10/04: “Comparative Effectiveness and Cost-Effectiveness Study, Evaplan” - <b>available on Governance Extranet</b>
4. Scenario Planning	GF/AMFm10/05: “Scenario Planning Secretariat Update” GF/AMFm10/09: “Scenario Planning Report for the Institutional Arrangements of the AMFm” GF/AMFm10/10: “Multi-country Stakeholder Consultation Report” - <b>available on Governance Extranet</b>
5. Governance Reform	GF/AMFm10/02: “Governance Presentation” - <b>available on Governance Extranet</b>