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# The Global Fund

To Fight AIDS, Tuberculosis and Malaria

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GF/B21/07  
Board Input

## REPORT OF THE AFFORDABLE MEDICINES FACILITY - MALARIA (AMFm) AD HOC COMMITTEE (AHC)

### OUTLINE

1. This paper presents a summary of progress in preparing for the launch of the Affordable Medicines Facility - malaria (AMFm) Phase 1.

## PART 1: INTRODUCTION

1. This paper provides an update on preparations for the operational launch of the Affordable Medicines Facility-malaria (AMFm) Phase 1. This report also outlines deliberations of the AMFm Ad Hoc Committee regarding several issues related to the implementation of AMFm Phase 1. This paper contains seven parts and two annexes:

- PART 1: Introduction
- PART 2: Overview of Progress
- PART 3: Update on Progress by Work Stream
- PART 4: Review of Parameters and Costs of the Independent Evaluation
- PART 5: Product Eligibility and Regulatory Status
- PART 6: Parasitological Confirmation of Malaria Using Microscopy or Rapid Tests
- PART 7: Publicizing Achievements of AMFm Phase 1
- Annex 1: Co-payment Amounts
- Annex 2: Guidance on Location of Further Information

## PART 2: OVERVIEW OF PROGRESS

2.1 Since the last Board meeting, considerable progress has been made in the five major work streams for implementation of Phase 1 of the AMFm, namely: Country Access; Manufacturer Negotiations and Contracting; Monitoring, Evaluation and Implementation Science; Supply Chain Management; and Market Dynamics.

2.2 Relating to Country Access, four out of five countries successfully completed the Technical Review Panel (TRP) clarifications process.<sup>1</sup> Adding these to the five countries whose applications required no TRP clarifications, a total of nine applicant countries received final approval to participate in AMFm Phase 1. They are: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (mainland), Uganda and Zanzibar. Negotiations for 'host' grant amendments for AMFm are progressing. All grant amendments are on track for signature by the end of April 2010. The Secretariat is working with the Roll Back Malaria (RBM) Partnership on mobilizing the private sector in each AMFm Phase 1 country to support uptake of AMFm co-paid Artemisinin-based Combination Therapies (ACTs).

2.3 Master Supply Agreements with eligible manufacturers are being finalized. The agreements are expected to be signed by the end of April. Options for a universal logo for all co-paid ACTs have been developed and field-tested, and a logo design has been pre-selected. The Secretariat is proceeding to fulfil in-country logo trademark registration requirements. The First-Line Buyer Undertaking has been finalized and is ready for signature by Principal Recipients (PRs). The necessary adaptation of the Undertaking for use by other first-line buyers is in progress. A co-payment system has been established within the Secretariat to process and facilitate co-payment transactions.

2.4 On Monitoring, Evaluation and Implementation Science, for the Independent Evaluation of Phase 1, the two Requests for Proposals that were issued have concluded in accordance with standard Global Fund procedures. These included an Independent Evaluator (i.e., a consortium led by Macro International Inc. (ICF Macro) with the London School of Hygiene and Tropical Medicine) as well as three Data Collection Contractors (i.e., Drugs for Neglected Diseases *initiative*, Centre de Recherche pour le Développement Humain and Population Services International). Time was required in order to ensure due diligence for, and cost minimization of, the work to be contracted for the Independent Evaluation. Based on market

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<sup>1</sup> Rwanda withdrew its application to participate in AMFm Phase 1 (see Section 3.1).

research and cost proposals received from suppliers, the design, scope and costs of the Independent Evaluation were re-examined in line with technical guidance from the Technical Evaluation Reference Group (TERG). The Committee has articulated guiding principles for the evaluation, and the Secretariat will work with the Committee to define appropriate parameters for the evaluation. The Finance and Audit Committee (FAC) is making a recommendation to the Board to carry-over US\$ 2.85 million of unspent 2009 budget to 2010 in order to fund the increased cost of the Independent Evaluation for 2010.

2.5 All AMFm Phase 1 applicants, with the exception of Rwanda, participated in an implementation science workshop co-convened by the World Health Organization's Special Programme for Research and Training in Tropical Diseases (WHO/TDR) and its Regional Office for Africa (WHO/AFRO) in December 2009 in Accra, Ghana. Plans are advancing to ensure the provision of technical support for AMFm-related research funded through AMFm Phase 1 grants. Implementation science work, commissioned by the Clinton Foundation (CHAI) and funded by the Bill & Melinda Gates Foundation, is being defined with input from the Global Fund to ensure that the topics addressed will have direct relevance for the Global Fund Board decision to be made on the future of AMFm upon completion of Phase 1.

2.6 The Secretariat is developing a working paper on supply chain supporting interventions for AMFm and has shared it with partners for comments and input. This paper will help guide support to countries on overcoming potential bottlenecks to AMFm during implementation. The Secretariat has worked with RBM and UNITAID to develop a Request for Proposals (RFP) for ACT forecasting services. This is expected to be issued by UNITAID by end of April 2010 and the costs of such forecasting services will be borne by UNITAID. The results of the forecasting will be shared by UNITAID with the Secretariat and the Committee in line with the Committee's request to have revised forecasts available six months into implementation.

### **PART 3: UPDATE ON PROGRESS BY WORKSTREAM**

#### **TRP Clarifications**

3.1 At its Twentieth Meeting, the Board approved TRP funding recommendations for AMFm Phase 1. According to the recommendations, five out of ten applicants were approved as category 1: *recommended for funding with no or some issues identified for the Secretariat to take into account during the process of negotiating the amendment to the 'host' grant agreement*. The five applicants were Cambodia, Madagascar, Niger, Tanzania and Zanzibar. A further five approved applicants were classified as category 2: *recommended for funding, pending TRP satisfaction with further technical information provided by the applicant relating to components of the AMFm application*. Of these five countries, Rwanda decided not to pursue the TRP process after submitting its first clarifications response and withdrew its application to participate in AMFm Phase 1. The letter from the Rwandan Country Coordinating Mechanism (CCM), which specified its reason for withdrawal, is attached to this report (Attachment 1). The four remaining countries in category 2 responded to the TRP and were approved by the TRP by the Board deadline of 31 January.

#### **Grant Amendment and Timelines**

3.2 As outlined in the AMFm business plan and updated implementation plan,<sup>2</sup> AMFm supporting interventions and related activities will be managed where possible through existing malaria grants: the 'host' grants. Principal Recipients of host grants are responsible for implementation of AMFm related activities, including, but not limited to: policy and regulatory reform; pharmacovigilance; provider training and supervision; Information, Education and

<sup>2</sup> GF-PSC9-03 Business Plan; GF-AMFmAC05-02 Implementation Plan

Communication (IEC) campaigns; and measures to increase access for vulnerable populations of interest, such as poor people, and those in remote locations. Several implementing countries will also introduce or expand provision of Rapid Diagnostic Tests (RDTs) to support ACT scale-up, including undertaking operational research where needed to inform scale-up in the private sector. This requires negotiation of grant terms with PRs. The grant negotiation process includes a Local Fund Agent (LFA) assessment of the PR, a negotiation and document preparation phase and finally an implementation letter or other document amending the host grant agreement. A new grant agreement is expected to be required for Madagascar as the Country Coordinating Mechanism (CCM) proposed a new PR for the management of AMFm activities. In addition, for those cases where there are expected savings resulting from lower cost co-paid ACTs under other grants, those savings are to be transferred to the host grant. The negotiation process also includes the signature of implementation letters or other documentation to effect such transfers. The target deadline for grant amendment is the end of April 2010. The Secretariat is working with Principal Recipients to incorporate AMFm activities into 'host' grants. This work has progressed well, and most grants are expected to be amended by mid-April 2010, although the exact timeframe will be determined by the individual circumstances of each implementing country.

### **Next Steps Following Grant Amendment Signature**

3.3 Following grant amendment for a participating country, the PRs and other first-line buyers in that country will be in a position to order co-paid ACTs and start the process of implementing AMFm supporting interventions. In accordance with the current time-line, it is expected that first-line buyers will be able to order co-paid ACTs from May 2010, and the first co-paid ACTs will be delivered in-country from August 2010.

### **Partner Support to AMFm Phase 1 Implementing Countries**

3.4 The RBM partner network supports implementation of AMFm Phase 1 at country and global levels. The RBM Harmonization Working Group (HWG) AMFm workstream leaders - WHO and CHAI - have been active in providing and brokering support to CCMs and PRs during the grant amendment process and in preparing for implementation. The openness of RBM's AMFm workstream to all partners provides an opportunity for all willing and able stakeholders to share information and contribute to the development and implementation of AMFm. Members of the partner network develop strategies, frameworks and tools to improve in-country support, implementation and impact. Currently, a framework for engaging the private sector, and a tool to monitor progress in implementation, are being discussed and crafted within the partner network.

3.5 The RBM Partner network facilitates links to implementing partners. In addition, the Committee agreed that it will invite the co-chairs of the AMFm workstream of the HWG to relevant sessions of Committee meetings in order to provide updates to the Committee on progress in implementation.

### **Manufacturer Agreements**

3.6 In early 2009, the Secretariat convened a Co-payment Technical Advisory Group (CTAG) to provide the technical basis for the approach to co-payments. The CTAG's recommendations and inputs from RBM partners informed the Secretariat's decision on the technical design of co-payments and the resulting negotiation strategy. In mid-2009, the Secretariat initiated negotiations with pharmaceutical manufacturers through the contracted services of CHAI as a negotiation agent. The negotiations were planned in three stages: i) Establishment of Maximum Prices and Co-payment amounts, ii) Signature of Term sheets, and iii) Signature of Master Supply Agreements (MSAs).

- i. The Maximum Prices were established in May 2009 for each ACT formulation, strength and pack size. All manufacturers have agreed to reduce the private sector price of their ACTs to the negotiated public sector price. A revision of these maximum prices was undertaken in March 2010 (to reflect, among other things, exchange rate fluctuations and the cost of the logo). In addition, CHAI provided the Global Fund with analyses on proposed co-payment amounts for each ACT formulation, strength and pack size, which would be equal across all manufacturers. Based on CHAI's analysis, the Secretariat has finalized the co-payment amounts per formulation and pack size. Maximum prices and co-payment amounts will be reviewed regularly, and any shifts in the market that may affect the resulting first-line buyer prices will be taken into consideration during follow-on pricing reviews. The co-payment amounts and maximum prices are attached as Annex 1. These amounts are subject to periodic change (at least once a year) by the Secretariat to reflect changes in manufacturers' sales prices and other relevant developments.
- ii. The Term Sheet is a non-binding commitment from each manufacturer to provide its products at or below the established Maximum Prices, under specified terms and conditions. Negotiations of Term Sheets with all six manufacturers eligible to participate in the AMFm have been concluded.
- iii. The MSAs outline the contractual relationships between the Global Fund and each manufacturer. They incorporate the requirements from the Term Sheet as well as other more detailed terms. MSA templates were sent in early February 2010 to the six eligible manufacturers for their review. Negotiations have progressed well, and four of the eligible manufacturers were ready to sign as of mid-April. Negotiations with the two other manufacturers were at an advanced stage.

3.7 As the Global Fund's contract with CHAI ended on 28 February 2010, a request for proposals has been issued for the selection of a negotiating agent, who would start an 18-month contract in June 2010. This negotiation agent would be employed on a retained basis to provide negotiation services for the Global Fund as and when new manufacturers of ACTs come on the market and to review maximum prices and co-payment amounts.

### **Universal Logo**

3.8 At its Twentieth Meeting in November 2009, the Global Fund Board decided that a universal logo would be applied to the packaging of all ACTs purchased through the AMFm. This logo would be the same across all AMFm Phase 1 countries and across all eligible ACT products. The Secretariat was mandated to commission the development of the logo. Following the Twentieth Board Meeting, a creative brief was developed to define the logo's target audience, key attributes to be conveyed, design elements and a development plan. In November 2009, a request for information was sent to three design firms, who then developed logo samples on a pro bono basis. A shortlist of concepts was submitted to manufacturers in order that they could provide their input on the logo's visual appeal, technical feasibility, cost and regulatory implications. Based on the feedback from manufacturers, several logo samples were selected for field-testing in four countries, primarily to ensure that the logo has no negative connotations in local contexts. The Clinton Foundation paid for the field-testing which was undertaken by Population Services International through its country platforms. The testing was concluded in March, and an appropriate logo design has been pre-selected.

3.9 In parallel, a search was conducted to explore the legal requirements for trademark registration in AMFm-eligible countries and in the countries of the manufacturers. A budget has been defined for the search, submission, publication and registration of the selected logo, and relevant jurisdictions were identified. This search work has been initiated and is expected to be complete by end of April 2010. Branding guidelines for the logo are being developed by

the Secretariat, in close collaboration with partners, and will be issued to PRs and other entities managing marketing campaigns relevant to AMFm once finalized. According to current timelines, the logo will be ready for deployment on co-paid ACTs in time for first-line buyers to place orders in early May 2010. First deliveries are expected by August 2010; however, the date of delivery depends on when orders are placed and how long it takes suppliers to deliver co-paid ACTs once orders are confirmed.

### **Pre-shipment Quality Control Testing**

3.10 The AMFm requires that all ACTs to be co-paid by the AMFm be pre-qualified by WHO, approved by a Stringent Drug Regulatory Authority (SDRA), or permitted for use by the Expert Review Panel (ERP). The AMFm also requires that all co-paid ACTs be quality control tested, which is an extension of the current Global Fund Quality Assurance policy. For 'ERP-permitted for use' ACTs, the Global Fund Secretariat currently coordinates the randomized quality control testing of the products prior to their delivery to designated recipients. In the context of the AMFm, quality control testing of co-paid ACTs will be coordinated and funded by the Global Fund Secretariat and conducted by the same testing laboratory contracted by the Global Fund for testing non-AMFm ACTs. In order to implement a comprehensive testing scheme, the Secretariat has decided that all AMFm ACTs, whether pre-qualified by WHO, approved by a Stringent Regulatory Authority (SRA), or ERP-permitted for use, will be tested on a randomized basis before shipment. A new laboratory has been selected by the Global Fund through competitive tender to conduct all quality control testing, including for anti-malaria products.

### **Pharmacovigilance and Drug Resistance Monitoring**

3.11 Within a Global Fund-wide approach, the Secretariat is formulating an AMFm strategy for pharmacovigilance. The Secretariat, in collaboration with WHO, has established an action plan to review baseline data and prepare a report on the efficacy of ACTs in AMFm Phase 1 countries.

3.12 The Committee notes that pharmacovigilance is an issue with implications wider than just the AMFm or malaria treatment: it is a Health Systems Strengthening (HSS) issue. As such, the Committee calls on the Global Fund and partners, under the technical leadership of WHO, to play a role in ensuring that pharmacovigilance is given due priority and importance. The Committee also calls on partners to play a role in supporting countries to assess and track drug efficacy and drug resistance.

### **First-line Buyer Undertaking**

3.13 To be considered eligible to purchase ACTs under the AMFm, each first-line buyer must sign a First-Line Buyer Undertaking. This Undertaking sets out the eligibility criteria for first-line buyers and includes some key commitments by the buyer, including, but not limited to, the obligation of the buyer to have all necessary licenses, waivers, or other governmental approvals for importing, selling and distributing (as applicable) co-paid ACTs in the relevant AMFm-eligible countries. The First-Line Buyer Undertaking has been finalized and shared with relevant Principal Recipients and other potential buyers seeking to participate in AMFm Phase 1. The Secretariat is reaching out to potential first-line buyers to inform them of the AMFm and how to participate in it through the RBM Partnership, through ACT manufacturers and through CCMs and other in-country bodies.

### **Co-payment System**

3.14 The Secretariat has modified the Global Fund System (GFS) to process co-payments for ACT purchases and carriage to AMFm implementing countries. The system will process co-

payment requests from all public and private sector actors, including principal recipients and their procurement agents, private first-line buyers, and wholesalers. The Secretariat will inform suppliers and first-line buyers how to use the co-payment system. A user manual and online training programs are under development.

3.15 Up-to-date reports on co-payments and ACT deliveries will be publically available on the AMFm external web page. The system will automatically update in order to provide interested parties with current information. A more detailed database of co-payments and deliveries will be accessible to the Global Fund Secretariat.

### **Cambodia ACT Situation**

3.16 The Committee expresses concern about the situation regarding Cambodia's selection of ACT formulation for AMFm Phase 1 - Dihydroartemisinin-piperazine (DHA-PPQ). Cambodia's application for participation in AMFm Phase 1 has DHA-PPQ as the first-line treatment choice - covering both public and private sector needs. The Committee noted that Cambodia's ACT formulation selection is in line with WHO's technical recommendations for first line treatment in Cambodia. However, there is no current DHA-PPQ product eligible for procurement under the Global Fund Quality Assurance Policy. While public sector needs are expected to be covered until the beginning of 2011 through sufficient existing in-country stock of Artesunate Mefloquine (AS+MQ), the private sector would likely need to replenish their ACT stocks with DHA-PPQ soon.

3.17 The Committee notes that a contingency plan for Cambodia has been discussed by the Ad Hoc Market Dynamics and Commodities Committee (MDC) and that a proposed decision point will be presented to the Board for decision at its Twenty First Meeting. The Committee understands that the contingency plan has been developed in order to provide Cambodia with options, although these plans are likely to be limited in time until the end of 2010, by which time it is hoped that at least one DHA-PPQ product will either pass the Expert Review Panel (ERP) review or will be authorized by a Stringent Drug Regulatory Authority. The Committee supports the efforts of the MDC to find a temporary solution that will enable first-line buyers in Cambodia to purchase suitable ACTs under AMFm. However, some members of the Committee noted a concern that the Global Fund might be seen as relaxing its Quality Assurance Policy. Some members of the Committee also noted that the implementation of the contingency plan could pose a reputational risk to the AMFm and the Global Fund by making non-quality assured drugs bearing the AMFm logo available.

### **Supply Chain Management**

3.18 Five activities have been planned to support the distribution of co-paid ACTs through both public and private sector channels. These activities include:

- i. Production of communication materials on private sector logistics-related lessons learned on distributing co-paid ACTs;
- ii. Identification and dissemination of effective strategies for tracking co-paid ACTs;
- iii. Identification and dissemination of effective strategies for combating counterfeit antimalarials;
- iv. Identification and documentation of effective incentives for increasing uptake by, and coverage through, the private sector; and
- v. Development of a framework for supply chain performance improvement.

3.19 A draft working paper on supply chain supporting interventions for distributing co-paid ACTs through both private and public sector channels has been prepared and sent out to key country level supply chain actors for comments. Following receipt of comments, a revised version will be produced containing information and guidance on effective supply chain

supporting interventions for distribution of ACTs through public and private channels. This paper will be shared with implementing countries and partners to assist in successful implementation of AMFm Phase 1.

3.20 Some manufacturers in AMFm pilot countries have expressed to the Global Fund and the RBM Partnership their concerns about eligibility of their ACTs for co-payment from the AMFm, as the Global Fund has clear and specific quality and eligibility criteria for products it will fund. Considering that the Global Fund does not have the mandate to provide any direct assistance to manufacturers, the Secretariat has consulted with the RBM Secretariat, which issued a note on the topic. In addition, the Secretariat is in discussion with the office of the United Nations Secretary General's Special Envoy for malaria, with a view to co-convening a forum to facilitate discussions between Africa-based manufacturers and potential investors who might provide capital and/or technical support to facilitate the achievement of product eligibility for their ACTs in line with the requirements of AMFm Phase 1.

3.21 The Secretariat has initiated discussions with technical partners to formulate a plan of action for improving supply chain performance. Key steps in the development process are a framework design, field testing and validation by multiple technical partners.

3.22 During 1-2 March 2010, the Massachusetts Institute of Technology (MIT)-Zaragoza International Logistics Program and the Zaragoza Logistics Center hosted a workshop on 'Covering the last mile for malaria treatment: the private sector and AMFm' jointly with the University of California, San Francisco (UCSF), ExxonMobil and RBM. The Secretariat contributed to the design of the workshop, to ensure that the agenda was highly relevant to the objectives of AMFm Phase 1, and participated in it. The objectives of the meeting were joint learning and identification of strategies to contribute to making best use of the private sector during AMFm Phase 1 and options for identifying and resolving constraints to effective distribution of co-paid ACTs through the private sector. Participants examined the following critical issues:

- i. Existing private sector distribution relations and options for maximizing distribution;
- ii. National Malaria Control Programs (NMCP)/Country Coordinating Mechanisms stewardship of the private sector and oversight of the implementation of AMFm Phase 1;
- iii. End-user target prices and incentives for enhancing coverage, regulation and monitoring;
- iv. Demand generation among providers and consumers; and
- v. Partner responses to challenges related to implementation of AMFm Phase 1.

3.23 Experts on the design and management of malaria treatment programs in the private sector gathered for the meeting to advance planning for practical steps to support the roll-out of AMFm Phase 1. The relevant suggestions from that workshop included:

- i. The Secretariat to prepare and send to countries an information packet for first-line buyers on how to place purchase orders for co-paid ACTs;
- ii. The Secretariat to consider facilitating new market entry for first-line buyers who do not currently have distribution arrangements with AMFm eligible manufacturers;
- iii. The RBM Harmonization Working Group work stream for AMFm to provide support to countries in efforts to engage the private sector and in monitoring the distribution of co-paid ACTs;
- iv. The Secretariat to provide guidance to countries on use of the AMFm logo; and
- v. Partners and NMCPs to collect data on existing distribution chains and prepare comprehensive AMFm launch plans.



## **RFP for the Provision of ACT and Artemisinin Demand Forecasting Services**

3.24 At its 5<sup>th</sup> meeting, the AHC requested that a working group be established under the leadership of RBM, in consultation with UNITAID, to review the ACT demand forecast for AMFm and produce a refined forecast after approximately six months of implementation of AMFm Phase 1. The Secretariat has subsequently worked with RBM and UNITAID to develop and issue an RFP for the provision of ACT and artemisinin demand forecasting services. The purpose of the RFP is to deliver forecasts that can inform policy decisions and planning. The specific activities will include: a demand forecast for countries involved in AMFm Phase 1, a global demand forecast for ACTs and a global artemisinin and artemisinin-based Active Pharmaceutical Ingredient (API) forecast. The preparation of the RFP is in its final stages, and it is expected to be issued before the last week of April. The funding and management of the RFP and contract rest with UNITAID. The results of the forecasting will be shared by UNITAID with the Secretariat and the Committee in line with the Committee's request to have revised forecasts available six months into implementation.

### **Implementation Science**

3.25 In December 2009 in Accra, Ghana, WHO's Special Programme for Research and Training in Tropical Diseases (WHO/TDR) and its Regional Office for Africa (WHO/AFRO) co-convened an operational/implementation research workshop for all countries that submitted AMFm Phase 1 applications. All applicants participated in the workshop with the exception of Rwanda. Technical assistance was provided to help countries advance the transformation of the implementation science plans articulated in their AMFm proposals into more fully developed research proposals. Plans for ensuring the provision of ongoing technical support are being developed with WHO/TDR and WHO/AFRO to help ensure that effective projects are implemented in a timely manner to help make the most of the learning opportunity that AMFm Phase 1 provides.

3.26 The Global Fund is providing input to the Clinton Foundation as it finalizes its plans for implementation science related to AMFm Phase 1. With funding from the Bill & Melinda Gates Foundation, the Clinton Foundation is commissioning implementation science work to address issues of relevance to the Global Fund Board decision regarding the future of the AMFm beyond Phase 1. At present, these topics include: supplier incentives to increase coverage and uptake of subsidized ACTs in remote retail shops; assessing the feasibility of introducing, and the demand for, RDTs and ACTs in private drug shops; and optimizing the impact of ACT packaging on patient adherence and willingness to pay. Findings will be fed into the Independent Evaluation report to be considered by the Board.

### **Commissioning of the Independent Evaluation: Time required for due diligence and cost minimization of the independent evaluation work**

3.27 Following preparation of the AMFm Phase 1 M&E Technical Framework in 2009, the Secretariat issued two Requests for Proposals: one for the Independent Evaluator of AMFm Phase 1, and one for the Data Collection Contractors to conduct baseline survey work. The process and timeline for awarding these contracts were as follows:

<b>Timeline for commissioning an Independent Evaluator</b>	
August 2009	<ul style="list-style-type: none"> <li>○ A Request for Proposals (TGF-09-022) was issued to competitively tender an Independent Evaluator responsible for, among other tasks, completing a meta-analysis of findings, both within and across countries, between baseline and endpoint measures.</li> </ul>
September 2009	<ul style="list-style-type: none"> <li>○ A Technical Evaluation Committee was convened to review bids.</li> </ul>
October 2009	<ul style="list-style-type: none"> <li>○ Procurement Review Committee approval was requested to proceed with negotiations.</li> <li>○ Ad Hoc Committee requests report on risks of conflict of interest among potential consultants to firms bidding for the Independent Evaluation work.</li> </ul>
December 2009	<ul style="list-style-type: none"> <li>○ Secretariat completes due diligence on conflict of interest risks and sends report to the Ad Hoc Committee.</li> <li>○ Corporate Procurement Unit was granted authorization to initiate negotiations with the recommended supplier.</li> </ul>
December 2009 to February 2010	<ul style="list-style-type: none"> <li>○ Iterative process within the Secretariat (and between the Secretariat and the winning bidder) to minimize the increase in the cost of the Independent Evaluation compared to the budget presented in the Ad Hoc Committee's report to the Eighteenth Board Meeting.</li> <li>○ Technical guidance sought from the Technical Evaluation Reference Group at its 14<sup>th</sup> meeting on the parameters of a fit-for-purpose independent evaluation of Phase 1.</li> </ul>
<b>Timeline for commissioning Data Collection Contractors to conduct baseline survey work</b>	
August 2009	<ul style="list-style-type: none"> <li>○ A Request for Proposals (TGF-09-035) was issued to competitively tender up to four contractors to collect baseline household and outlet survey data.</li> </ul>
September 2009	<ul style="list-style-type: none"> <li>○ A Technical Evaluation Committee was convened to review bids.</li> </ul>
October 2009 to February 2010	<ul style="list-style-type: none"> <li>○ As above for the Independent Evaluator.</li> </ul>

3.28 The Secretariat considered it paramount to ensure probity in the use of funds and technical integrity of the work. The time required to ensure due diligence of the contracting process and to address cost concerns (through a re-examination of the scale and scope of the evaluation outlined below) caused delays in awarding contracts to the firm that would conduct the independent evaluation and those that would conduct the baseline data collection. These contracts were awarded in early March 2010. The Independent Evaluator is a consortium led by Macro International Inc. (ICF Macro) with the London School of Hygiene and Tropical Medicine. The three baseline Data Collection Contractors are: Drugs for Neglected Diseases *initiative*, Centre de Recherche pour le Développement Humain and Population Services International.

3.29 Under the oversight of the Independent Evaluator, the Data Collection Contractors will implement national level outlet survey work to assess ACT availability, affordability and market share at baseline in all AMFm Phase 1 countries and in one comparator country. To assess ACT use at baseline, data made available from household survey work completed with

funding from non-Global Fund sources will be analyzed by the Independent Evaluator. The Independent Evaluator has the responsibility of supporting a harmonized approach to methods and procedures across all contractors and countries for the baseline outlet survey work as well as of assessing the extent to which this is achieved. In this regard, the Independent Evaluator will convene a harmonization workshop with all Data Collection Contractors to achieve consensus on survey instruments and sampling approaches, among other factors. The Technical Evaluation Reference Group (TERG) and up to three representatives of the AMFm Ad Hoc Committee have been invited to participate in this workshop which is scheduled to last four days in April 2010.

## **PART 4: REVIEW OF PARAMETERS AND COSTS OF THE INDEPENDENT EVALUATION**

### **Description of review process**

4.1 The requirements and parameters of the independent evaluation have evolved over the past two years. The changes have implications for the evaluation's feasibility, fitness for purpose, relevance, scope and costs.

4.2 At its Seventeenth Meeting, the Board decided that an independent evaluation of the roll-out of the AMFm would be commissioned by the Global Fund Secretariat, under the guidance of the appropriate committee.<sup>3</sup> The Board decided that: "Expansion from the initial phase to a full roll out in all eligible countries will occur within a year of launch unless clear failures ("red flags") in the AMFm design are observed." At its Eighteenth Meeting, the Board confirmed this decision,<sup>4</sup> with budgetary requirements for the Independent Evaluation and multi-centric operational research set at US\$ 6.0 million for the entirety of Phase 1. At its Nineteenth and Twentieth Meetings, the Board further specified the parameters of the Independent Evaluation.<sup>5</sup> The AMFm Ad Hoc Committee's report to the Twentieth Board Meeting (November 2009) included the following text (paragraph 4.4. of the report):

"The AHC is aware that a 12 month implementation timeline presents issues regarding the parameters of the evaluation given the difficulty of measuring success in 12 months. In particular, since the Seventeenth Board meeting, some constituencies have stated that AMFm Phase 1 must provide definitive proof of attributable increases in ACT use among the poorest and most remote populations. The majority of AHC members acknowledge that this is not a realistic expectation within 12 months in the context of many implementing countries. AMFm is a new business model without direct precedent in global health. ACTs are no longer new technologies, but co-paid ACTs will be new. In the Final Report of the Global Fund Five-Year Evaluation: Study Area 3, it was noted that *"The findings related to ACTs are the most perplexing and worrisome of the four primary malaria interventions because they show the least improvement."* A key lesson from the Five-year Evaluation relates to the timeline for measurable changes that can be attributed to a new intervention or business model: *"Most importantly, five years is an extraordinarily limited amount of time over which to measure global level outcomes and impact, especially in a new program with a new model. Investments of both new resources and new approaches require time to take root and bear fruit."*

The AHC will work to define reasonable parameters for success or otherwise of AMFm Phase 1, based on the Monitoring and Evaluation Technical Framework and the timeline for implementation. The Developed Country NGOs constituency expressed a

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<sup>3</sup> Annex 1 to Decision Point GF/B17/DP8

<sup>4</sup> Decision Point GF/B18/DP7

<sup>5</sup> Decision Point GF/B19/7 Attachment 2; Decision Point GF/B20/DP24

concern that, in measuring the use of ACTs, the Monitoring and Evaluation Technical Framework would measure not only malaria specific fevers but fevers due to other causes. The Developed Country NGOs constituency also wished to have it noted that in their opinion, impact of AMFm on use of co-paid ACTs among the poorest and remote populations must form the basis for a “red flag” regardless of the evaluation period, and they would not compromise on this.”

4.3 The Board made the following decision at its Twentieth Meeting:

*“The Board refers to its earlier decisions regarding the Affordable Medicine Facility - malaria (“AMFm”) and clarifies its intent that the Global Fund will only expand from Phase 1 (the pilot phase) of AMFm to a global scale-up on the basis of evidence gathered during the pilot phase that the initiative is likely to achieve its four stated objectives: (i) increased ACT affordability, (ii) increased ACT availability, (iii) increased ACT use, including among vulnerable groups, and (iv) “crowding out” oral artemisinin monotherapies, chloroquine and sulfadoxine-pyrimethamine by gaining market share. The Board further clarifies that it will 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).”*

4.4 The Decision Point (GF/B20/DP24) cited in paragraph 4.3 stated that *“This decision does not have material budgetary implications.”* However, based on market research for the evaluation parameters specified at the Nineteenth and Twentieth Board Meetings, the projected cost of the Independent Evaluation and Implementation Science increased from US\$ 6.0 million to US\$ 21.5 million (for all twelve eligible applicants plus two comparator countries). The sum of US\$ 21.5 million was an increase of US\$ 15.5 million (258 percent) over the US\$ 6.0 million that the Committee submitted to the Eighteenth Board Meeting. The Secretariat considered this increase of 258 percent to be excessive.

4.5 The Secretariat sought technical guidance from the Technical Evaluation Reference Group (TERG), in line with the mandate set forth by the Board at its Nineteenth Meeting (*“...The Board confirms that the Technical Evaluation Reference Group (TERG) will provide guidance with regard to the technical parameters of the design of the independent evaluation of the AMFm, under the oversight of the AMFm Ad Hoc Committee...”*).<sup>6</sup> At its 14<sup>th</sup> meeting on 8 February 2010, the TERG examined the rationale, technical appropriateness, methods, scope, timeline and feasibility of the independent evaluation, as well as potential approaches to judging the success of AMFm Phase 1. Ms. Kirsten Myhr, Vice-Chair of the Ad Hoc Committee, participated in the TERG meeting. Based on the discussion that took place during its meeting, the TERG produced a position paper for the Policy and Strategy Committee (PSC) on the AMFm Independent Evaluation which articulated the technical parameters of a fit-for-purpose evaluation over the implementation timeline of Phase 1. The position paper was considered by the Policy and Strategy Committee at its 13<sup>th</sup> meeting.<sup>7</sup> The TERG position paper on the AMFm Independent Evaluation was shared with the AMFm Ad Hoc Committee, and the Chair of the TERG attended relevant sessions of the Ad Hoc Committee’s 6<sup>th</sup> meeting and presented the TERG’s findings. The TERG position paper is attached to this report (Attachment 2).

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<sup>6</sup> Decision Point GF/B19/DP27

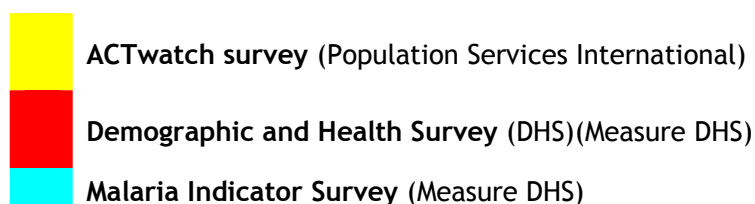
<sup>7</sup> GF/PSC/13/06

## Outcomes of Review Process

4.6 Based on the technical guidance from the TERG, the Secretariat has sought to reduce the cost of the independent evaluation while remaining as close as possible to the parameters and scope of work required by the Board. Accordingly, the Secretariat has reduced the number of comparator countries where surveys would be directly commissioned by the Global Fund. Furthermore, the Secretariat has eliminated all plans for the Global Fund to pay for data collection through national level household surveys uniquely for the purpose of the AMFm, which were the principal drivers of the 258% cost increase over the estimate presented by the Committee to the Eighteenth Board Meeting in November 2008. Instead, existing household survey data made available from relevant data collection activities completed no sooner than the third quarter of 2008, and paid for by other sources, will be made available to the Independent Evaluator for the purposes of conducting analyses. The table below displays completed survey work and the period data collection took place. Each of the surveys below included malaria modules standardized through the work of the RBM Monitoring and Evaluation Reference Group (MERG)<sup>8</sup> permitting the possibility of making appropriate comparisons across countries and time and by subgroups of interest (e.g., categories of income, rural/urban residence, etc.).

**Table Indicating Period of Data Collection for National Level Household Surveys (Completed within the past 2 years and including a Malaria Module, by quarter)**

Data Collection Period for National level Household Surveys	2008		2009				2010			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cambodia				ACTwatch survey						
Ghana	Demographic and Health Survey (DHS)									
Kenya		Demographic and Health Survey (DHS)								
Madagascar		ACTwatch survey	Demographic and Health Survey (DHS)							
Niger*										
Nigeria	Demographic and Health Survey (DHS)				ACTwatch survey					
Tanzania						Demographic and Health Survey (DHS)	Demographic and Health Survey (DHS)			
Uganda				ACTwatch survey			Malaria Indicator Survey (Measure DHS)			
Zanzibar						Demographic and Health Survey (DHS)	Demographic and Health Survey (DHS)			



\* *The most recent national level household survey conducted in Niger was a DHS in 2006.*

4.7 The Committee recalls earlier Committee Reports and Board Decisions on the Independent Evaluation. The Committee also notes the budget implications of the scale and

<sup>8</sup> To ensure consistency and accuracy in national and regional reporting, RBM MERG guidance has included guidelines, questionnaires, recommended tabulations, and relevant manuals to assist those conducting household-level malaria surveys, representing the combined experience of RBM MERG Household Survey Task Force agencies (e.g., World Health Organization, UNICEF, MEASURE DHS, MEASURE Evaluation and U.S. Centers for Disease Control and Prevention).

scope of the evaluation as outlined in the AMFm Phase 1 Monitoring and Evaluation Technical Framework and specified in the two Requests for Proposals that were issued.

4.8 The Committee welcomes and endorses the technical findings of the TERG and acknowledges that the TERG's findings provide broad technical guidelines for measuring and defining the success of AMFm Phase 1. The Committee welcomes continuous engagement with the TERG in defining the way forward. The Committee also welcomes ongoing engagement with the Expert Advisory Group (EAG) established by the Secretariat in defining the way forward.

4.9 The Committee adopts as the basis for further work the TERG's recommendations to: establish, ex-ante, realistic success metrics for AMFm Phase 1; apply methods that will obtain valid evidence for decision-making; use the evaluation to learn, not to identify "Red Flags"; study the intended and unintended effects of the universal AMFm logo; update guidelines for the TERG's work on the evaluation of AMFm Phase 1 and consult with the Expert Advisory Group that was convened by the Secretariat. This work will be done in two parts: (i) translation of the TERG's guidance into specific methods for defining and judging the success of AMFm Phase 1 within the current constraints of time and resources committed to AMFm Phase 1; and, if the Board so requires, (ii) defining the financing, operational and institutional requirements for a time extension of AMFm Phase 1 to provide a basis for an evaluation that emphasizes assessment of attributable effects of AMFm on increased use of ACTs among the poorest and most remote populations.

**Next Step 1: Translation of the TERG's guidance into specific methods for defining and judging the success of AMFm Phase 1 within the current constraints of time and resources committed to AMFm Phase 1**

4.10 The Committee will convene and lead the development of specific methods for defining and judging the success of AMFm Phase 1 within the current constraints of time and resources committed to AMFm Phase 1, with technical guidance from the TERG. The core parameters for evaluating the business model will be the upstream parameters of price, availability, and market share of co-paid ACTs compared to those of less desirable antimalarials. Each of these parameters will be represented by a set of measurable indicators. The Committee agreed to convene a meeting by teleconference prior to the Twenty First Board Meeting to discuss principles for how to define and judge success of AMFm Phase 1 and to advance work to specify details after the Twenty First Board Meeting. The Committee will define multiple criteria for judging success; this approach is expected to be more robust than using single measures as "Red Flags" for judgment. For example, the Committee will consider (i) progress in establishment of the business model; (ii) country engagement; (iii) achievements of the business model in terms of the parameters of price reduction, increased availability and increased market share of co-paid ACTs; (iv) demonstration effect and learning; and (v) unintended consequences of the business model, such as effects of the AMFm logo on quality-assured ACTs that do not bear the AMFm logo.

4.11 The Committee endorses the TERG's finding that there is value in comparing and contrasting how alternative financing models perform, rather than comparing the AMFm (a financing model) against specific approaches to service delivery. The Committee will establish a basis for benchmarking and making comparisons with other financing models. Such comparators will include the Global Fund's grant-based mechanism, which is the channel through which the Global Fund would normally channel any additional funds to expand access to ACTs. Any comparisons would be with reference to similar periods of implementation.

4.12 The Committee agrees with the TERG's observation that participating countries are likely to move at varying paces, and the opportunities for learning are greatest in fast-moving countries. The Committee agrees with the TERG's suggestion that the design of the

evaluation prioritize in-depth country case studies, blending qualitative and quantitative methods, rather than a primary focus on inter-country comparisons. This will provide opportunities to assess and learn, in addition to quantitative measures of what has changed, how and why the new model unfolds in a variety of contexts, while drawing lessons that can help future operations.

4.13 The Committee agrees with the TERG that, given the implementation timeline, the downstream aspects of service delivery and use should not form the core of the independent evaluation of AMFm Phase 1. Nevertheless, the Committee will require the independent evaluation to explore this issue on a limited scale in a subset of implementing countries. The Committee strongly encourages technical partners undertaking implementation science or operational research to seize opportunities to study alternative approaches for speedier coverage of the poorest and most distant populations. These may be limited to sub-national settings where implementation is sufficiently rapid to enable deeper examination of service delivery and use of ACTs within the implementation period. The Committee notes that such convenience sampling on a small scale will contribute to knowledge of promising options at the service delivery level, but will neither form a basis for definitive judgment nor for generalization of findings.

**Next Step 2: Potential extension of the timeline to allow for evaluation of the downstream aspects, including service delivery and use of ACTs among the poorest and most distant populations.**

4.14 The Committee notes the ultimate importance of expanding use of ACTs among the poorest and most distant populations. The Committee further notes that the AMFm is not a service delivery vehicle but a financing mechanism, and the approved duration of AMFm Phase 1, which allows for a period of about one year between the baseline and endpoint assessments, does not provide a realistic basis for an evaluation of attributable changes in use among the poorest and most distant populations. If requested by the Board to pursue this option, the Committee would consult with global health experts, including practitioners and analysts, to define a minimum program duration required for such attributable changes among the specified populations in the countries of interest. The Committee would also work with the TERG to develop the technical parameters of an evaluation of service delivery and use.

4.15 The Committee anticipates that the incremental resource requirements for an extension of AMFm Phase 1 would include the following: (i) funds for co-payments for the additional period; (ii) funds for supporting interventions for the additional period; (iii) additional funds for the expanded scope of the evaluation to include direct commissioning of household surveys by the Global Fund; (iv) funds for management of the AMFm by the Secretariat; and (v) resources for partnership support outside the Secretariat, such as technical assistance and operational research. The Committee notes that if the AMFm business model were deemed successful on the basis of parameters defined with guidance from the TERG, the Board might wish to consider not only a time extension but also a geographic extension of the AMFm while seeking definitive proof of attributable changes in use among the poorest and most distant populations. This would further increase the resource requirements for the expanded phase.

4.16 The Committee understands that an extension of the AMFm Phase 1 timeline, and the commitment of any additional resources, would need to be approved by the Board. The Committee is not proposing an extension at this stage.

## **Current Budget Requirements for the Independent Evaluation and Implementation Science Taking Into Account the TERG's Guidance**

4.17 Based on market research and actual cost proposals received from suppliers, the current budget requirements for a fit-for-purpose Independent Evaluation and Implementation Science for Phase 1 are estimated at approximately US\$ 11.35 million. The following table presents a breakdown of the estimated costs.



**Estimated Costs of the Independent Evaluation and Implementation  
Science for AMFm: Total for Phase 1 and Sub-total for 2010**

	Total Estimate Required for Phase 1* (US\$, millions)	Subtotal Estimate Required for 2010 (US\$, millions)
<b>Baseline Data Collection Contractors</b> <i>Source: Bid submissions of recommended suppliers</i>	<b>3.90</b>	<b>3.90</b>
<b>Independent Evaluator</b> <i>Source: Bid submission of recommended supplier and expert option</i>	<b>2.80</b>	<b>1.20</b>
<b>Endpoint Data Collection Contractors**</b> <i>Source: Estimate based on baseline costs</i>	<b>3.90</b>	<b>0.00</b>
<b>Independent Evaluation Subtotal</b>	<b>10.60</b>	<b>5.10</b>
<b>Implementation Science</b>	<b>0.75</b>	<b>0.25</b>
<b>Grand Total</b>	<b>11.35</b>	<b>5.35</b>

\* Any material increase in the scope or parameters of the evaluation may result in increased costs.

\*\*This estimate may need to be adjusted; it will be subject to cost proposals to be received from bidders in 2011. It may increase (due to inflation or unforeseen circumstances) or decrease (if, for example, a country drops out of AMFm Phase 1). Therefore, it should be treated as indicative, not definitive.

4.18 The current budget requirements are US\$ 10.15 million less than the US\$ 21.5 million estimate in paragraph 4.4. This reduction is the consequence of two factors. First, instead of twelve AMFm applicants plus two comparators, the revised estimate now includes the nine AMFm applicants participating in Phase 1 plus one comparator.<sup>9</sup> Second, the estimate excludes costs of national level household survey data collection activities for which the Global Fund will not pay. Included in the US\$ 11.35 million estimate are costs for conducting analyses of secondary data from national level household surveys completed with funding from other sources [e.g., Demographic and Health Surveys (implemented by Measure DHS), Malaria Indicator Surveys (implemented by Measure DHS) and ACTwatch Surveys (implemented by Population Services International)] to be made available to the Independent Evaluator for the purposes of AMFm Phase 1 analyses. These current estimates do not include costs to address the baseline household survey data needs in Niger. The Committee notes this gap and will explore the possibility of a household survey in Niger, including funding options from non-Global Fund sources.

4.19 At the 14<sup>th</sup> Finance and Audit Committee Meeting held during 8-10 March, an Update to the Budget 2010 was presented for consideration and recommendation to the Board for decision.<sup>10</sup> Reasons for the AMFm Unit 2009 professional fees under-spend were further detailed in the FAC paper. The specific budget request was to reallocate US\$ 2.85 million of the AMFm professional fees budget from 2009 (which was under-spent) to the 2010 Budget. This reallocation of the 2009 under-spend, plus the approved 2010 AMFm budget, is expected to cover the revised cost estimates for the Independent Evaluation and Implementation Science for AMFm for 2010. The FAC discussed the request at their 14<sup>th</sup> meeting and decided to recommend to the Board the approval of the re-allocation of US\$ 2.85 million of the AMFm professional fees budget from 2009 to be carried over to 2010.

<sup>9</sup> Benin, Rwanda and Senegal are not participating in AMFm Phase 1.

<sup>10</sup> GF/FAC14/11

## **PART 5: PRODUCT ELIGIBILITY AND REGULATORY STATUS**

### **Fixed Dose Combinations (FDCs) and Co-Blistered Formulations**

5.1 The Board has previously confirmed that the Global Fund's procurement policies, including the Global Fund Quality Assurance Policy for Pharmaceutical Products,<sup>11</sup> will be applied when identifying eligible products for AMFm Phase 1.

5.2 In accordance with the Global Fund's existing policies, both co-formulated and co-blistered ACTs are eligible for purchase, although co-formulated ACTs are preferred. Accordingly, both co-formulated and co-blistered ACTs will be eligible for co-payment under the AMFm, provided that they meet the standards set forth in the Global Fund Quality Assurance Policy for Pharmaceutical Products and that manufacturers are compliant with the AMFm policy to prohibit procurements from companies that market oral monotherapies.

5.3 The Committee recalls the earlier Board decision (GF/B19/DP27) noting that, pending WHO guidance, fixed-dose co-formulations are strongly preferable to co-blistered ACTs and may help to delay resistance to artemisinin. The Board also noted that multiple technical issues need to be taken into account to ensure a smooth transition to an exclusive use of FDC ACTs. The Board urged WHO to expedite finalization of this guidance on FDCs and co-blistered ACTs.

5.4 The Committee recognizes that this is an issue that is not specific to the AMFm and that it pertains to all Global Fund grants that support malaria treatment. WHO has reiterated its guidance which is that co-formulated ACTs are strongly preferred and recommended over co-blistered ACTs. It is understood that the MDC has responsibility for considering this issue as a general policy matter for the Global Fund. However, the AMFm Ad Hoc Committee will give further consideration to the use of financial incentives through co-payments to favor the use of FDCs over co-blistered ACTs, such as increasing the co-payment amount for FDCs so that they are financially more attractive to buyers than co-blistered ACTs.

### **In-Country Regulatory Status of ACTs**

5.5 The Committee discussed the regulatory status of ACTs in AMFm Phase 1 countries and noted that ACTs have Prescription Only status in some countries participating in AMFm Phase 1 and Over the Counter (OTC) status in others. The Committee notes that in countries where ACTs are Prescription Only, there will be a limited number of authorized ACT providers. This should be borne in mind in evaluating the changes between baseline and endpoint for the parameters of (i) Availability and (ii) Market Share of quality-assured ACTs. The Committee acknowledges that the regulatory status of ACTs is a matter for the in-country responsible authority.

## **PART 6: PARASITOLOGICAL CONFIRMATION OF MALARIA USING MICROSCOPY OR RAPID DIAGNOSTIC TESTS (RDTs)**

6.1 The Committee notes the importance of correct diagnosis in malaria treatment. In the 'Guidelines for the Treatment of Malaria 2010',<sup>12</sup> WHO recommends prompt parasitological confirmation by microscopy or with rapid diagnostic tests (RDTs) for all patients with suspected malaria, before treatment is started; treatment solely on the basis of clinical

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<sup>11</sup> The Quality Assurance Policy was revised in November 2008 (Decision Point GF/B18/DP11) and came into effect on 1 July 2009.

<sup>12</sup> [http://whqlibdoc.who.int/publications/2010/9789241547925\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf)

suspicion should be considered only when a parasitological diagnosis is not accessible. The Committee noted that countries were encouraged to include expanding access to malaria diagnostics as a supporting intervention in their AMFm applications. The Committee recalls that several applicants proposed the introduction or expansion of RDTs to support ACT scale-up, including undertaking operational research where needed to inform scale-up in the private sector. In its review of AMFm applications, the Technical Review Panel (TRP) welcomed this as a sound approach to malaria case management.<sup>13</sup>

6.2 The Committee further notes the realities at country level and the multiple challenges of moving from the current situation to the ideal of universal access to parasitological confirmation of malaria. The Committee notes that while the objective of universal access to diagnostics is clear, determining how to achieve it requires further exploration and learning. In order to facilitate the expansion of access to diagnostics for malaria, the Committee calls on the Secretariat and all partners, including manufacturers, to explore options to lower the price of RDTs.

## **PART 7: PUBLICIZING ACHIEVEMENTS OF AMFm PHASE 1**

7.1 With regard to providing accurate AMFm information for implementers, the Committee requests the Secretariat and all implementing partners to ensure collective clarity in communications around the AMFm. In particular, there should be a clear message that co-paid ACTs under the AMFm Phase 1 are available for purchase by buyers in all sectors: public, private-for-profit and not-for-profit.

7.2 The Committee recognizes the work of the Secretariat in reaching agreement with manufacturers to lower the sales price of ACTs under the AMFm to private sector buyers to the same level as the sales price to public sector buyers. The Committee notes the contribution of manufacturers to this development and calls on the Secretariat to publicize this significant achievement. Other similar achievements made during the course of AMFm Phase 1 launch and implementation should also be publicized.

7.3 The Committee also requests ACT manufacturers to extend the availability of the lowered sales price to all first-line buyers of ACTs (public, private-for-profit, not-for-profit) in non-AMFm Phase 1 countries, and not just to AMFm Phase 1 countries.

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<sup>13</sup> See page 7 of GF/B20/10: Report of the Technical Review Panel and the Secretariat on Applications to the First Phase of the Affordable Medicines Facility-malaria (AMFm Phase 1).

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.

## AMFm Maximum Prices and co-payment amounts

Eligible ACT Product	Maximum Acceptable Supplier Sales Price <sup>1</sup> (per Course of Treatment in US\$)		Co-Payment Amount <sup>2</sup> (per Course of Treatment in US\$)	
	Hospital Pack	Individual Pack	Hospital Pack	Individual Pack
<b>Artemether Lumefantrine (20/120mg)</b>				
6x4	1.40	1.43	1.21	1.21
6x3	1.11	1.14	1.00	1.00
6x2	0.74	0.77	0.67	0.67
6x1	0.37	0.40	0.33	0.33
<b>Artemether Lumefantrine (40/240mg)</b>				
3x4	1.40	1.43	1.21	1.21
3x3	1.11	1.14	1.00	1.00
3x2	0.74	0.77	0.67	0.67
3x1	0.37	0.40	0.33	0.33
<b>Artemether Lumefantrine (20/120mg) dispersible</b>				
6x2	0.74	0.77	0.68	0.68
6x1	0.37	0.40	0.34	0.34
<b>Artesunate Amodiaquine Co-blister (50/153mg or 50/150mg)</b>				
12+12	0.78	0.81	0.59	0.62
6+6	0.42	0.45	0.32	0.35
3+3	0.24	0.27	0.18	0.21
<b>Artesunate Amodiaquine Fixed-dose Combination (2.7 AQ:AS ratio)</b>				
100/270mg 3x2	1.00	1.09	0.92	1.01
100/270mg 3x1	0.59	0.68	0.55	0.64
50/135mg 3x1	0.39	0.47	0.37	0.45
25/67.5mg 3x1	0.30	0.38	0.29	0.37
<p><sup>(1)</sup> Manufacturers may quote lower prices.</p> <p><sup>(2)</sup> The co-payment will always be less than the MSP for a product. If the quoted MSP is equal to or less than the listed co-payment amount, the Global Fund reserves the right to adjust the co-payment.</p>				

### 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 Board Member Extranet site (BME) with your usual username and password-protected website:

<http://extranet.theglobalfund.org/board>

Item:	Further information available:
1. Part 3 - Update on Progress  2. Committee Recommendations Regarding AMFm Phase 1	GF/AMFm/AC06/02 - Update  GF/B20/7 - Report of the AMFm Ad Hoc Committee to the Twentieth Board Meeting.  GF/B19/7 - Report of the AMFm Ad Hoc Committee to the Nineteenth Board Meeting  GF/B18/7 - Report of the AMFm Ad Hoc Committee to the Eighteenth Board Meeting