



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Twenty-Second Board Meeting
Sofia, Bulgaria, 13-15 December 2010

GF/B22/10
Board Decision

REPORT OF THE AMFM AD HOC COMMITTEE

PURPOSE:

1. This report summarizes the deliberations of the Affordable Medicines Facility-malaria Ad Hoc Committee (AHC) at its 7th and 8th Meetings in June and October 2010. It includes an overview of progress in implementing AMFm Phase 1 and the AHC's recommendations to the Twenty-Second Board Meeting.

PART 1: INTRODUCTION

1.1 The Affordable Medicines Facility-malaria Ad Hoc Committee (AHC) met in London on 22-23 June 2010 for its 7th Meeting and in Geneva on 18-20 October 2010 for its 8th Meeting. The acting Chair for the 7th Meeting was Kirsten Myhr (UNITAID). The Chair for the 8th Meeting was Minster Leslie Ramsammy (Latin America and Caribbean); the Vice-Chair was Kirsten Myhr (UNITAID).

1.2 This report includes the following sections. Part 5, Appropriate Duration of AMFm Phase 1, contains an item for Board Decision.

- i. PART 2: Update On Progress in the Implementation of AMFm Phase 1
- ii. PART 3: Defining and Judging the Success of AMFm Phase 1
- iii. PART 4: Comparative Effectiveness and Cost Effectiveness
- iv. PART 5: Appropriate Duration of AMFm Phase 1
- v. PART 6: The Interface Between AMFm and Diagnostics for Malaria
- vi. PART 7: The MDC's Proposed Decision Point on FDCs
- vii. PART 8: Considerations and Implications post-Phase 1

PART 2: UPDATE ON PROGRESS IN THE IMPLEMENTATION OF AMFm PHASE 1 Information

2.1. For the first time, antimalarial medicines co-paid by the AMFm are available to buyers and patients at the country level, starting in Ghana and Kenya. The Committee appreciates that these are early stages and that much remains to be done and learned. Nevertheless, the Committee notes that the key innovation in AMFm is working in practice: the combination of negotiations with manufacturers, a factory-gate co-payment that reduces costs to first-line buyers, together with channeling through all sectors, is starting to get quality-assured artemisinin-based combination treatments (ACTs) to those who need them at country-level. The Committee commends the work of the Secretariat, implementing countries and technical partners, as well as the cooperation of eligible manufacturers of quality-assured ACTs, whose joint work made this progress possible less than 10 months after the Board approved AMFm Phase 1 applications in November 2009. The Committee is concerned that some countries have indicated that, given the uncertainty over whether the AMFm would continue beyond Phase 1, and potential consequences of reverting to pre-AMFm scenarios if there were no Phase 2, they were reluctant to make the maximum effort to implement activities and changes needed to ensure the success of AMFm Phase 1. The Committee wishes to encourage implementing countries and partners to work together to make AMFm Phase 1 a success.

Country Access

2.2 As of mid-November 2010, amendments to grant agreements had been completed for the following AMFm Phase 1 pilots: Cambodia, Ghana, Kenya, Madagascar (new grant agreement), Niger, Nigeria, Tanzania and Zanzibar. A grant amendment is still outstanding for Uganda. Disbursements under the amended or new grants for AMFm activities have been made to the following countries: Ghana, Kenya, Madagascar, Niger and Tanzania. Supporting interventions have started to be implemented in those countries. The Committee notes that amendments to grant agreements in most countries took longer than anticipated. This meant that placement of orders for ACTs and initiation of disbursements started later than anticipated. These amounted to a delayed start to implementation for all Phase 1 countries.

2.3 AMFm marketing and trade sensitization (provider training) are immediate priorities in countries following grant signature. Kenya has undertaken a media launch to formally initiate AMFm implementation in the country. Ghana and Nigeria have organized workshops with stakeholders to establish timelines for soft launch (radio, TV interviews, newspaper advertisements, and media kits) and national launch events. Similar workshops are planned in Kenya and Tanzania. Kenya, Madagascar, Niger and Tanzania have identified Sub Recipients (SRs) to implement AMFm marketing activities. Roadmaps for marketing are available for Ghana and Nigeria. Trade sensitization has started in Ghana.

2.4 The Secretariat is co-organizing with the Roll Back Malaria (RBM) partnership a meeting for AMFm Phase 1 countries to discuss early lessons learned in the implementation of AMFm. The meeting which will be hosted by Ghana will take place 17-18 December 2010. The overall objective of the meeting is for implementers of AMFm Phase 1 activities to share experiences that may be applied to implementation strategies before the end of AMFm Phase 1. The Committee would like to acknowledge the role of partners, in particular the Clinton Health Access Initiative (CHAI), the World Health Organization (WHO), Medicines for Malaria Venture (MMV), Program for Accessible Health, Communication and Education (PACE), Population Services International (PSI), and Malaria No More (MNM), amongst others, who have been engaged under the leadership of RBM, in contributing marketing material and providing support to marketing activities. The Committee welcomed the participation of the co-chairs of the RBM Harmonization Working Group's AMFm workstream in the Committee's 8th Meeting and the briefing given on in-country progress. The Committee expressed concern about the slow pace of implementation of AMFm supporting activities and encouraged partners to assist in implementation.

Manufacturer Negotiations and Procurement

2.5 Master Supply Agreements that outline the contractual relationship between the Global Fund and ACT manufacturers have been concluded with all eligible AMFm Phase 1 manufacturers: Ajanta Pharma, Cipla, Guilin, Ipca, Novartis and Sanofi-Aventis. The agreements are valid until the end of June 2012. Under these agreements, manufacturers will sell ACTs at the same price to both public and private sector buyers. This is the first major achievement of the AMFm and a remarkable example of public-private partnership. Private importers will now pay up to 80 percent less than they did in 2008-2009. The Global Fund pays most of this reduced price (a 'buyer co-payment') directly to manufacturers to further lower the cost to eligible first-line buyers of ACTs. This means that first-line buyers only pay the remainder of the sales price for the ACTs.

2.6 AMFm Phase 1 is open to buyers from all sectors. As of 8 November 2010, a total of 110 First Line Buyers from all AMFm Phase 1 countries (with the exception of Cambodia, for reasons of drug eligibility) have signed a First Line Buyer Undertaking. The majority of buyers (104) and orders are from the private sector and NGOs. The Committee notes that the relative lack of public sector procurement so far is due to a combination of the necessary public sector tender processes and normal, often lengthy, country procurement schedules.

2.7 As of 8 November 2010, the Secretariat has received 51 requests for co-payment totaling 20.7 million treatments and US\$ 21.5 million dollars for co-payment of which US\$ 1.5 million is for freight and insurance. Orders have been delivered to Ghana, Kenya, Madagascar and Tanzania, and ACTs are available for purchase in Ghana and Kenya. The majority of

orders (93 percent) are for Fixed Dose Combinations (FDCs). An AMFm Co-Payment Summary Report has been developed and is available in the public domain.¹ The Co-Payment Summary report provides access to information regarding orders for which co-payment requests have been confirmed, including the country that will receive the order, the first-line buyer who will receive the shipment, the quantity of the specific ACT product (by dose) and the manufacturer. The report also includes the delivery date of each order to the first-point-of-entry and the quantity of the shipment. The information in the database is updated automatically on a daily basis.

2.8 The Secretariat has completed the process of selecting a new negotiation agent for AMFm Phase 1. The outcome of a competitive tender process is the award of an 18-month contract to the consortium AEDES/OTECI. AEDES/OTECI is employed on a retainer basis to: provide negotiation services as and when new manufacturers of ACTs come on the market; review maximum prices and co-payment amounts; and, advise the Secretariat on negotiation strategy with ACT manufacturers. The first revision of maximum prices and co-payment amounts is expected before the end of 2010.

2.9 The trademark registration of the universal logo in all AMFm Phase 1 countries, Switzerland, China, and India and with the African Intellectual Property Organization (OAPI)² is being processed with the support of Keltie, Patent and Trademark Attorneys, based in the United Kingdom (UK). A logo license agreement that defines the conditions of use of the logo and the obligations of the licensee has been shared with implementing partners. Signature of the agreement will be processed when each local entity in charge of the marketing campaign has been identified. All manufacturers have implemented the logo on their product packaging (primary and secondary) following the Global Fund's approval of their artwork. In addition, all manufacturers have developed their own tracking mark that will appear on both the primary and secondary packaging of AMFm co-paid ACTs.

2.10 Contracts with the selected laboratories for Quality Control (QC) testing (NIDQC in Vietnam and SGS Belgium) and the selected agent for sampling (SGS Netherlands) have been signed. Since July 2010, SGS Netherlands has been serving as the backup laboratory until NIDQC is fully operational. SGS Netherlands has already conducted inspection and testing on 12 AMFm orders and have not identified any compliance issues.

AMFm Phase 1 Independent Evaluation

2.11 In advance of the 7th AHC Meeting, the Independent Evaluator submitted to the Committee for its review and approval an Inception Report for the Independent Evaluation of AMFm Phase 1. The Chair of the Technical Evaluation Reference Group (TERG), who attended the 7th AHC Meeting, also received the Inception Report. This report specified the methodology to be employed for the Independent Evaluation of AMFm Phase 1 and included, as annexes study materials, including questionnaires. The AHC endorsed this Report, pending some points of clarification and minor modifications. These revisions were made, and the final version of the AMFm Phase 1 Inception Report was completed in July 2010.

2.12 AMFm Phase 1 Baseline Outlet Survey Work is advancing under the oversight of the AMFm Phase 1 Independent Evaluator (ICF Macro and the London School of Hygiene and

¹ <http://www.theglobalfund.org/programs/amfm/report.aspx>.

² The OAPI trade mark system covers Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Republic of Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo.

Tropical Medicine). Each Data Collection Contractor (*Centre de Recherche pour le Développement Humain*, *Drugs for Neglected Diseases initiative*, and *Population Services International*) is working in accordance with the terms of their contracts. At the 8th AHC Meeting, the Independent Evaluator gave an update on the status of work. This included reports that data collection activities have been completed in Cambodia, Ghana, Madagascar, Niger, Nigeria and Zanzibar and are expected to be finalized in November (Kenya and Tanzania) and before the end of 2010 (Uganda). Work on data entry, cleaning and analysis is progressing, and the Independent Evaluator is providing oversight to assure data quality. Country-specific baseline reports are expected from the Data Collection Contractors before the end of 2010 for some AMFm Phase 1 countries; the remaining reports will be submitted by mid-February 2011. Following this, the Independent Evaluator will be able to complete a comprehensive Phase 1 baseline assessment report.

2.13 In its ‘Position Paper to PSC on the Independent Evaluation of the AMFm’ submitted to the PSC (GF/PSC13/06) and endorsed by the AMFm Ad Hoc Committee at its 6th Meeting, the TERG included several recommendations which were taken into account prior to finalization of the contracts with the Independent Evaluator and the Data Collection Contractors. The TERG also included the following two recommendations: (i) that the evaluation includes studies of the effects of the logo on quality-assured ACTs that do not have the logo; and (ii) in-depth country case studies in a subset of fast-moving countries to understand changes in uptake of AMFm co-paid ACTs at outlets and by people in remote locations. These two recommended studies could not be undertaken within the budget of the Independent Evaluation and the scopes of work of either the Data Collection Contractors or the Independent Evaluator. To respond to these recommendations, which were discussed at the 7th AHC Meeting, in formulating the TERG 2011 workplan and budget, US\$ 220,000 in professional fees was proposed for this work and included in the draft TERG budget. The execution of this work is subject to the preparation by the TERG of clear technical terms of reference and the study design for the work proposed by the TERG, consistent with its Board-mandated role to “...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...” This will help ensure that the additional elements meet the TERG’s technical requirements.

Implementation Research

2.14 There are three key streams of Implementation Research of relevance for AMFm Phase 1; findings from all of which will be summarized in the AMFm Phase 1 Independent Evaluation report to be submitted by the Independent Evaluator for consideration by the AHC. These streams include: (a) research proposed by AMFm Phase 1 countries and funded through Global Fund grants; (b) relevant research funded and implemented by partners, including ACT Consortium and CHAI among others; and (c) research directly supported with Secretariat funds to address key priorities identified by the Committee.

2.15 Collaboration with the World Health Organization’s (WHO) Special Programme for Research and Training in Tropical Diseases (TDR) is ongoing to provide support to AMFm Phase 1 countries for the implementation of research funded through AMFm grants. Initial joint Global Fund/TDR missions have been completed for Ghana, Kenya, Nigeria, Uganda and Zanzibar, and missions are planned for Madagascar and Niger. WHO/TDR has secured funding for a qualitative research skill building workshop, planned for late January/early February

2011. The request for such training was made by participants at the AMFm Implementation Research workshop co-convened by WHO/TDR and WHO/AFRO in Accra in late 2009.

2.16 During its 7th Meeting, the AHC was presented with an overview of relevant research being funded and implemented by ACT Consortium and CHAI, findings from which will be included in the AMFm Phase 1 Independent Evaluation Report. CHAI also shared a description of implementation research projects under consideration which were received in response to a Request for Proposals (RFP) they had issued; the RFP included as an Annex the Global Fund AMFm Phase 1 Implementation Research Priorities document of November 2009, which was informed by the AHC, the AMFm Expert Advisory Group and others.

2.17 An outcome of this discussion at the 7th AHC Meeting was that the AHC identified that a key next step would be for it to review the implementation research priorities and communicate these to the Secretariat, in order to inform how the resources allocated (US\$ 750,000) for this work could best be used to address any outstanding identified gaps. The Committee communicated these revised priorities in August 2010, and the Secretariat is finalizing a Contribution Agreement with CHAI for US\$ 500,000 to leverage their competitive tender and ensure that top priorities communicated by the AHC are addressed within existing budgetary constraints in a priority setting. This work will be designed to improve understanding of treatment-seeking and provider behavior related to use of quality-assured ACTs among key target groups, as well as the reach of IEC/BCC, provider training and packaging to remote areas and their effects (e.g., on knowledge and behavior) and, if possible, implement and evaluate alternative approaches to address identified barriers and improve reach and effect.

Market Dynamics in relation to AMFm

2.18 At its 5th 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 to produce a refined forecast during the early stages of AMFm Phase 1 implementation. The Secretariat subsequently worked with RBM and UNITAID to develop an RFP for the provision of ACT and artemisinin demand forecasting services. UNITAID issued this RFP in April 2010. Bids received for this exercise have been evaluated, and UNITAID is in the final stages of contracting with the entity whose bid was adjudicated as meeting the desired standards.

2.19 Based on technical inputs from the Copayment Technical Advisory Group (CTAG), consultation with RBM partners and subsequent work by the contracted negotiation agent (CHAI), the Secretariat set co-payment amounts in early 2010. These prices vary by formulation and by pack size and were presented to the AHC at its 6th Meeting. The Secretariat also set maximum allowable prices for each formulation by pack size. For some formulations, early orders placed by first-line buyers tended to be priced by manufacturers at the higher end of the price range, but more recent orders are priced lower. First-line buyer prices are expected to trend downwards as more orders are placed and as more manufacturers begin to supply the market. The Secretariat will review prices regularly, and any shifts in the market that may affect the resulting first-line buyer prices will be taken into consideration during reviews of maximum prices and co-payment amounts.

2.20 The Secretariat has a contribution agreement with WHO's Global Malaria Program for the production of a baseline ACT efficacy monitoring report. This report will summarize data

collected by National Malaria Control Programs and other sources prior to the arrival in-country of AMFm co-paid ACTs on the efficacy of ACTs in AMFm Phase 1 countries and in several countries with similar epidemiological profile and treatment policies that are not participating in Phase 1. The report will contribute to a more detailed review of first-line malaria treatment efficacy for first-line drugs in AMFm countries and serve as a helpful reference point against future drug efficacy findings that may become available over time.

2.21 The Secretariat has engaged a consultant to produce a technical paper that can frame and inform initial policy discussions of the relative merits of alternative approaches to financing expanded (including universal) access to malaria treatment using ACTs. The exercise will include: (a) the development of a conceptual framework for comparing the cost-effectiveness of alternative approaches to financing expanded (including universal) access to malaria treatment using ACTs; and, (b) a concise review of the literature on the cost-effectiveness of approaches to financing expanded (including universal) access to therapeutic health technologies in low-income settings.

Supply Chain Management

2.22 The Committee welcomes initiatives undertaken by the Secretariat, working with and through partners, to improve supply chain management through the AMFm. These include:

- i. A contractor developing a framework for Supply Chain Performance improvement for both public and private sectors, with the participation of Tanzania and Niger; information collected from these countries will be used to customize the framework to address the needs of ACT supply chains in AMFm Phase 1 pilot countries;
- ii. A contribution agreement with INTERPOL to: develop customized materials for campaigns on dangers of counterfeit antimalarials with emphasis on AMFm co-paid ACTs; produce a criminal analytical report on the situation of counterfeit antimalarial products; and, map the routes of counterfeit and diverted antimalarials with emphasis on AMFm co-paid ACTs; and,
- iii. A contract with MIT/Zaragoza to perform modeling of ACT prices, availability and distribution chain structure, and to document factors that may influence price and availability.

2.23 In addition to these activities, the Secretariat is participating in planning for a multi-stakeholder consultation led by the African Leaders Malaria Alliance (ALMA) to discuss the challenges faced by Africa-based manufacturers of antimalarials. The Minister of Health of Kenya has offered to host the consultation. A consultant has been hired to collect information on technical, regulatory and economic issues affecting the manufacture of antimalarials in Africa. This will be used to prepare a background paper for the forum, which will be held in May 2011. The forum will convene: representatives of relevant government agencies; Presidential Office focal points; regional economic communities; Africa based manufacturers; potential investors; and technical partners.

2.24 As part of partnership development activities for the uptake of AMFm co-paid ACTs, the Secretariat participated in a meeting organized by the Ecumenical Pharmaceutical Network (EPN) at which the AMFm approach to increasing access to antimalarials was discussed and opportunities for EPN/Global Fund collaboration at the country level were

explored. These options include: eligible EPN members becoming first-line buyers; improved understanding of in-country markets and supply chains; and, strengthening Information Education and Communication (IEC) and Behavior Change (BCC) activities that promote demand for effective anti-malarial treatment in the EPN.

Resource Mobilization

2.25 The Secretariat has received all contributions to the AMFm Co-payment Fund, from UNITAID, the United Kingdom Department for International Development (DFID) and the Bill and Melinda Gates Foundation. Total resources received for co-payment are approximately US\$ 216 million. The Secretariat would like to express its sincere gratitude for the funds received and the vision and commitment shown by these partners to the AMFm.

Founders Forum

2.26 The Executive Director of the Global Fund briefed the Committee on his intention to convene a forum of the ‘founders’ of the AMFm. The ‘founders’ refers to the heads of agencies who took the decision in October 2007 to invite the Global Fund to host and manage the AMFm. This forum, which will be for the heads of the relevant agencies and the leadership of the AMFm Ad Hoc Committee, will be an opportunity to discuss progress on the AMFm and an opportunity to place AMFm in the wider malaria control context. Further details on the forum will follow.

PART 3: DEFINING AND JUDGING THE SUCCESS OF AMFm PHASE 1

Information

3.1 At its Twentieth Meeting in November 2009, the Board decided as follows:

“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.” (GF/B20/DP24: ‘AMFm Implementation’.)

At its 6th Meeting and as reported to the Board (GF/B21/07), the Committee endorsed the technical findings of the TERG in its Position Paper to the PSC on the AMFm (GF/PSC13/06) and adopted as a basis for further work the TERG’s recommendations to establish, ex-ante, realistic success metrics for AMFm Phase 1 within the current constraints of time and resources committed to AMFm Phase 1. At its 7th Meeting in June 2010 the Committee discussed these metrics of success. To provide information and evidence that would help the Committee reach decisions on how to judge success of AMFm Phase 1, the Committee developed a scope of work, with input from the TERG. The scope of work included a review of experience to define success against the four key parameters of the AMFm, within the timescale of AMFm Phase 1, and the identification of an approach for bringing together the results across the different parameters, recognizing that the AMFm may perform better on some parameters than others, and in some countries than others. In response to the

Committee's request, the Secretariat contracted the supplier that the Committee identified for this work, the Evidence-to-Policy initiative (E2Pi).

3.2 At its 7th Meeting, the Committee discussed a draft report of evidence compiled by E2Pi that it had received in advance of the meeting. Thereafter, E2Pi produced a second draft of the report, which included additional evidence gathered and additional interviews with key informants conducted, based on specific suggestions provided by meeting participants, which included the TERG. This second draft was then submitted to an expert peer review process, with nine reviewers providing comments by the requested deadline. E2Pi summarized reviewers' comments and suggested an approach for responding to what were in some cases conflicting recommendations for the next draft of the paper. The Committee leadership endorsed the proposed approach.

3.3 In advance of its 8th Meeting, the Committee received the revised draft version of the 'Estimating Thresholds of Success in the AMFm Phase 1' report for review and discussion. The Committee discussed the report and charged a sub-Committee to work with the consultants to prepare a refined draft that would be considered by all Committee members, and then finalized. Work was in progress as of mid-November.

PART 4: COMPARATIVE EFFECTIVENESS AND COST-EFFECTIVENESS

Information

4.1 At its Twentieth Meeting in November 2009, the Board determined the following:

"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)." (GF/B20/DP24: 'AMFm Implementation').³

This work requires quantifying the effectiveness and cost-effectiveness of both AMFm Phase 1 and comparator financing models that aim to achieve similar objectives solely or largely through the expansion of public sector services. The key comparator is the grants-based finance model of the Global Fund. Other potential comparators are bilateral and multilateral finance models with a multi-country scale of operations. The cost-effectiveness of the grants-based finance model of the Global Fund is unknown with reference to the four objectives, and the Committee is not aware of similar information, in the public domain, for any of the large bilateral or multilateral financing models that may be used as comparators. In order to address this request of the Board, the Committee tasked the Secretariat to produce draft Terms of Reference (TORs) for a consultant to look at comparative effectiveness and cost-effectiveness of the AMFm versus other large-scale financing models. The Committee reviewed the draft TORs and discussed the issue at its 8th Meeting.

4.2. The Committee considers that the task of producing an analysis of comparative effectiveness and cost-effectiveness may not be straightforward, for technical reasons. In addition, it might indeed not be possible for institutional reasons because a full and proper

³ Objectives are; (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.

analysis would require non-Global Fund comparator financing models to provide data on both their costs and their effectiveness, and for such data to be analyzed by independent assessors and made available in the public domain. Given the potential difficulties, the Committee considers it useful to take a two-step approach. The first step will address the technical and institutional feasibility of the analyses. The second step, contingent upon and informed by findings from the first, will be the actual analyses and reporting. The Secretariat will structure its approach to take account of the Committee's findings.

PART 5: APPROPRIATE DURATION OF AMFm PHASE 1

Decision

5.1 At its Twentieth Meeting the Board stated that:

“The Board notes that, in addition, it may decide to extend the pilot phase beyond its first meeting in 2012, if necessary. Any such extension would be subject to available funding and the Board reiterates that AMFm Phase 1 is currently funded as a 24-month program and countries should plan accordingly.” (GF/B20/DP24: ‘AMFm Implementation’.)

As outlined in Part 1 of this report, implementation of AMFm Phase 1 has started later than anticipated in most AMFm Phase 1 countries and inconsistently across countries. Although seven out of nine grant amendments have now been signed, countries are only now beginning to implement relevant AMFm supporting interventions. The first Phase 1 countries to receive co-paid drugs were Ghana and Kenya. These first deliveries were in early August 2010, and drugs are currently on sale in outlets. The other AMFm Phase 1 countries were yet to receive AMFm co-paid ACTs as of end October 2010. For countries that have signed grant amendments, and where first-line buyers have placed orders, ACTs are due to arrive from November 2010. The Committee acknowledges that the delay in starting implementation is mostly due to the complex standard grant negotiation and amendment processes, rather than AMFm-specific issues. Given this shift in the starting point of AMFm Phase 1, the Committee believes the current timeline for evaluating AMFm Phase 1 would not provide a sufficient evaluated implementation period and is no longer appropriate. The Committee recommends that the end point data collection be pushed back by six months. This would mean that the end point data collection for AMFm Phase 1 would be completed by the end of November 2011. The Committee would report to the Board with its recommendation at the Board's second meeting in 2012, which is expected to be in November 2012.

5.2 The Committee believes the cost implications of a six month extension to be minimal because it is essentially a shift in the start of implementation (see para 5.1). Therefore, the cost of additional co-payment funding requirements, if any, should be minimal. The projected demand under AMFm Phase 1 will become clearer once the UNITAID-funded demand forecasting contractor has reported its findings (see para 2.18). UNITAID are confident that the consultant will make its first report by the end of February 2011. The rising cost of the artemisinin Active Pharmaceutical Ingredient (API) is a concern to the Committee. Should this cause manufacturer sales prices to increase the Secretariat could raise co-payments to compensate, thereby keeping the price to end-users low. This would result in a quicker drain on the Co-Payment Fund. The Committee will monitor this situation as it develops and recommend remedial action where necessary. The Committee did discuss extending AMFm Phase 1 by 12 months; however, given major uncertainty over cost implications, particularly relating to the Co-Payment Fund, the Committee considered this not to be a prudent course of action at this stage.

5.3 Other costs of an extension of AMFm Phase 1 by six months include the cost of the AMFm Unit of the Secretariat. Based on the current AMFm Unit budget, a six month extension would cost an additional US\$ 1.6 million, apart from costs of the Independent Evaluation. The Committee also considered the costs to partners of supporting implementation. A rough estimate of likely costs was presented to the Committee by the RBM Harmonization Working Group AMFm workstream co-chairs. This figure is estimated to be US\$ 1.25 million for six months support to countries. There is a potential increased cost to the Independent Evaluation of up to US\$ 1.2 million. This includes a small increase in labor costs and inflation. However, the more significant factor is the potential inability to leverage data collection work commissioned by a separate financier on this proposed timeframe. In this scenario, there would be a potential need to commission separate data collection activities for up to four AMFm Phase 1 countries under this proposed timeframe. Should it prove possible to leverage the separate financier's funded work for AMFm Phase 1, there is likely to be a reduction in the funds needed for the end-point data collection. This will become clearer once the Secretariat has contracted the end-point data collection firms.

5.4 Consideration was given to the cost of AMFm supporting interventions should there be an extension of AMFm Phase 1 by six months. It is impossible to predict at this stage whether each of the Principal Recipients participating in AMFm Phase 1 will have grant monies left over at the end of AMFm Phase 1 under current timelines to fund AMFm supporting interventions to cover the six month extension period, or what interventions countries might wish to implement during a six month extension. The Committee, whilst not wishing to rule out the possibility of countries applying for funding for additional interventions of relevance to the implementation of AMFm Phase 1, does not consider that funds held in the general account with the trustee should be earmarked for AMFm supporting interventions and therefore proposes that there be no earmarked funds for AMFm Phase 1 activities in the nine implementing countries during a six month extension of AMFm Phase 1. Countries would be able to apply for additional grant funds for AMFm supporting interventions using the appropriate Rounds-based channel.

5.5 The Committee also considered the programmatic implications of an extension of six months of AMFm Phase 1, particularly the impact this would have on implementing countries. The Secretariat will look into the implications for countries in terms of grant management and any necessary grant extensions and report back to the Committee. In order to lessen the procedural burden on implementing countries of grant extensions, the Committee recommends that the Secretariat be given full responsibility and authority to work with relevant countries and Principal Recipients, and to extend the relevant grants, and to make any other consequential amendments to those grants as a result of the extension of AMFm Phase 1 by six months. The Committee recommends the following Decision Point for approval by the Board.

Decision Point: Duration of AMFm Phase 1

The Board refers to its earlier decision regarding the evaluation of Phase 1 of the Affordable Medicines Facility - malaria ("AMFm") (GF/B20/DP24), and notes that AMFm Phase 1 is currently funded as a 24-month program.

The Board recognises the shift in the start of the implementation of AMFm Phase 1 and the need to ensure an evaluation that can inform a decision on the future of the AMFm

as a business line. Accordingly, the Board decides to extend the implementation period of AMFm Phase 1 by six months and requests the AMFm Ad Hoc Committee to present a recommendation to the Board at its second meeting in 2012 on whether to expand, accelerate, modify, terminate or suspend the AMFm business line.

The Board grants the Secretariat the authority to work with relevant countries and Principal Recipients to extend the relevant grants and to make any other consequential amendments to those grants as a result of the extension of AMFm Phase 1. The Board further decides that there are no additional funds earmarked for financing AMFm Phase 1 Supporting Interventions, and countries and Principal Recipients should plan accordingly.

In order to support the six month extension, the activities of the AMFm Unit shall be extended by six months. At current budgetary rates, not including the Professional Fees for the Independent Evaluation, an additional US\$ 1.6 million will be required in 2012.

The six month extension is expected to result in an increase in Professional Fees in 2012 for the Independent Evaluation of US\$ 108,000 to cover additional labor costs, inflation and wage increases.

The six month extension will likely mean a reduction in 2011 Professional Fees expenditure for the end-point data collection contracts. However, any expenditure saved in 2011 would correspondingly be incurred in 2012. The actual costs of end-point data collection will be known when the contracts for the data collection firms are finalized. The Board notes that this could result in an additional cost or a saving to the estimated US\$ 3.9 million budget for the end-point data collection. Any additional cost to the end-point data collection budget will be presented to the Board for approval.

This decision does not have material budgetary implications for the 2011 Operating Expense Budget.

PART 6: THE INTERFACE BETWEEN AMFm AND DIAGNOSTICS FOR MALARIA Information

6.1 Before the November 2008 Board Decision to implement AMFm Phase 1 (GF/B18/DP7), the technical parameters of the design were informed by the work of the RBM Task Force on the AMFm. In March 2009, the Global Fund invited a set of countries to apply to participate in AMFm Phase 1. Countries could request funds for diagnostic tests. On the application form,⁴ applicants were “encouraged to include additional supporting interventions to improve malaria case management, such as introducing/expanding the use of diagnostics and introducing patient-friendly packaging on co-paid ACTs.” According to the Technical Review Panel (TRP) report,⁵ which the Board approved in November 2009: “The majority of applicants proposed the introduction or expansion of rapid diagnostic tests to support ACT

⁴ Available at <http://www.theglobalfund.org/en/amfm/documents/>

⁵ Report of the Technical Review Panel and the Secretariat on applications to the First Phase of the Affordable Medicines Facility-malaria (AMFm) Phase 1. GF/B20/10. November 2009. Page 7. Available at http://www.theglobalfund.org/documents/board/20/GF-BM20-10_Report_of_TRP_and_Secretariat_on_AMFm_Phase_1_Applications.pdf

scale-up, including undertaking operational research where needed to inform scale-up in the private sector. The TRP welcomes this as a sound approach to malaria case management.”

6.2 Subsequently, in the new Guidelines for the Treatment of Malaria 2010, WHO recommended 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 suspicion should be considered only when a parasitological diagnosis is not accessible.

6.3 As of 2010, parasitological diagnosis is not accessible in many places. In resource-poor settings with weak health infrastructure, most malaria treatment is currently based on presumptive diagnosis, and most antimalarial treatments are purchased directly by patients or caregivers in the private sector. In the Democratic Republic of Congo, for example, the private sector dominates the market, selling 85 percent of all antimalarials taken in the country. In Nigeria, the private sector accounts for an even higher percentage, about 95 percent, of all antimalarials.⁶ These two countries alone accounted for more than one-third of all estimated malaria cases in the WHO Africa Region in 2006.⁷

6.4 Through its grants-based architecture, the Global Fund is currently the largest financier of diagnostic tests for malaria. As a responsible and learning investor in the fight against malaria, the Global Fund initiated and, with WHO, co-convened a ‘Consultation on the Economics and Financing of Universal Access to Parasitological Confirmation of Malaria’ to consider the economic and financial implications of WHO’s recommendation for universal access to parasitological confirmation of malaria, including potential investments in diagnostics. The consultation included experts in economics, financing, epidemiology, biotechnology, product development and service delivery in resource-poor settings (public and private sectors). Professor Dean Jamison (University of Seattle) and Professor David Schellenberg (University of London) co-chaired the meeting, which was held in Geneva 31 May-1 June 2010.⁸ The objectives of the consultation were to examine and discuss the following questions:

- i. What are the economic implications of expanded (including universal) access to the parasitological confirmation of malaria?
- ii. What are the current costs of RDT use and their probable future evolution, considering the marginal cost of production, packaging and distribution, and the cost of use in terms of provider skills required and costs of alternative actions if the RDT is negative for malaria?
- iii. What are the best options for financing expanded (including universal) access to the parasitological confirmation of malaria?

The Committee notes the following:

⁶ ACTwatch Group. Availability, volumes, price and use of antimalarials in 7 malaria-endemic countries. 2009. Presentation at the 2009 MIM Conference in Nairobi, Kenya. Also available online at: <http://www.actwatch.info/home/home.asp>

⁷ World Health Organization. World Malaria Report 2009. World Health Organization, Geneva.

⁸ The final report of the meeting is available on the Global Fund website.

- i. The meeting did not revisit WHO's new guidelines, which deal with the "what" of diagnostics. Instead, the meeting dealt primarily with the "how" of financing and delivery.
- ii. Participants reaffirmed the need to progress from the status quo to universal access to diagnostics as rapidly as possible. They recognized the complexities of financing and delivery, and that achievement of universal access to diagnostics will not happen overnight.
- iii. When a test indicates that a patient does not have malaria, proper compliance requires (a) not using ACTs and (b) ensuring appropriate management of non-malaria febrile illnesses.
- iv. In order to achieve universal access to diagnostics, it is essential to ensure full access to diagnostics at service delivery points in the private sector, where most presumptive treatments of malaria take place. Yet, the private sector, particularly the less formal parts thereof, will be the most challenging sector.
- v. The optimum architecture of financing an expansion of diagnostics from the status quo to universal access is unknown. The consultation recognized the limited knowledge on this point, and participants reached no conclusion on the topic.
- vi. Most studies of RDT use are in the public sector, and there is very little rigorous knowledge of how to finance expanded access to RDTs in the private sector in a way that is both scalable and rapid. Researchers in a recent randomized trial⁹ in Kenya found that vouchers led to increased use of RDTs, but only marginal improvement in the targeted use of ACTs; and, people bought ACTs regardless of the results of RDTs. This indicates that progress to universal use of RDTs, and compliance with test results, will come through persistence over years.
- vii. Implementation research during AMFm Phase 1 provides opportunities to learn about scalable approaches to the expansion of diagnostics in the private sector. These can be applied to the design and implementation of a potential global phase of AMFm, a matter that depends on future Board decision.

6.5 At least ten implementation research projects have been identified that are addressing the issue of scaling-up access to malaria diagnostics through the use of rapid diagnostic tests (RDTs). In addition, four AMFm Phase 1 countries have proposed research, to be funded through their AMFm host grants, related to scaling-up access to malaria diagnostics in the private sector. These include: Ghana (private sector), Madagascar (through community-based agents), Nigeria (both public and private sectors) and Zanzibar (private sector). In addition to implementation research projects, a total of US\$ 25.6 million has been requested by AMFm Phase 1 countries for diagnostics through their host malaria grants.

⁹ Cohen and others, 2010. Presentation at the Consultation on the Economics and Financing of Universal Access to Parasitological Confirmation of Malaria. The report of the meeting is available on the Global Fund website.

PART 7: THE MARKET DYNAMICS AND COMMODITIES AD-HOC COMMITTEE'S PROPOSED DECISION POINT ON FIXED DOSE COMBINATIONS **Information**

7.1 The Market Dynamics and Commodities Ad Hoc Committee (MDC) Chair requested input from the AMFm Ad Hoc Committee on its proposed decision point to the Board that recommends the phasing out of Global Fund-supported procurement of co-blistered ACT formulations in favor of Fixed Dose Combination ACTs (FDCs). The Committee discussed the proposal and was unanimous in its support for the MDC's recommended decision point. The Committee noted that the advantage of FDCs over co-blistered forms lay in greater compliance, not drug efficacy. The Committee confirms that the proposed Board decision would, for timing and ACT combination availability reasons, not have a large impact on AMFm Phase 1, but would further align the AMFm with good public health principles. The Secretariat confirmed that the timing and actions proposed will not have a negative impact on its contractual agreements with the manufacturers of Quality Assured ACTs currently supplying first-line buyers under AMFm Phase 1. Provisions exist for the phase-out of co-payments for co-blistered ACT formulations in these contracts.

PART 8: CONSIDERATIONS AND IMPLICATIONS POST-PHASE 1 **Information**

8.1 The Committee notes that the Board decision (GF/B20/DP24) and Secretariat workplan provide for a finite AMFm Phase 1 duration of two years. There is no provision for a transition from AMFm to other financing mechanisms should the Global Fund Board decide to terminate AMFm at the end of Phase 1. This has multiple implications for affected countries. For example, depending on local contexts at the end of AMFm Phase 1, citizens might face sudden and unknown jumps in the prices of ACTs, as well as sudden reductions in the availability of ACTs. Governments might face strong backlash from country-based manufacturers of ACTs, especially where such manufacturers have discontinued production of ACTs that did not meet the Global Fund's quality assurance criteria. Ministries of Health could lose credibility among local partners who deliver services. Local NGOs, who would have benefited from subsidized ACTs, would need to start buying again at potentially higher prices. Similarly, there is no explicit plan for a full range of options to be considered by the Board if it decides to expand AMFm beyond Phase 1. This leaves the possibility of a long, but avoidable, gap between the end of AMFm Phase 1 and the start of a global phase.

8.2 The AMFm Ad Hoc Committee considers it prudent to define and start preparing for plausible scenarios. This is in the interest of populations in implementing countries and in the interest of the Global Fund as a responsible investor. The Committee will establish a sub-Committee to perform the task with support from the Secretariat and solicited contributions from persons or institutions with deep knowledge and skills in topics of interest to the sub-Committee. It will pay particular attention to the perspectives of representatives of implementing countries and implementing partners in AMFm. The sub-Committee will be headed by Minister Leslie Ramsammy, Chair of the Committee.

8.3 The sub-Committee will consider scale, content, funding, governance, management and technical support for potential scenarios after AMFm Phase 1.

Scale

8.4 Based on current knowledge, there are two main scenarios for the AMFm following completion of Phase 1:

Expansion of AMFm to other malaria endemic countries:

- Immediate expansion to global scale on the basis of preparations already made during Phase 1
- Phased expansion to global scale on the basis of preparations made during Phase 1, including all or only some components of AMFm
- Expansion to a sub-global level, perhaps regional or sub-regional, based on criteria that are compatible with the rationale for and goals of AMFm
- Continuation of AMFm in current Phase 1 countries alone while plans are made for global expansion

Suspension or termination of AMFm:

- Immediate termination AMFm work by the Global Fund following a Board Decision in 2012
- Gradual winding down of AMFm to enable a transition by countries to other financing mechanisms (or combination of financing mechanisms)

Content of a potential global phase

8.5 A concurrent consideration is that of content. AMFm Phase 1 is expected to yield many lessons that will inform decisions on the contents of a potential global phase. These may include the relevance and feasibility of various supporting interventions, new technical guidelines such as expanded use of diagnostics, and lessons learned about effects of country regulatory frameworks on maximum achievable levels of access.

Funding levels and sources

8.6 In any of the above scenarios, particularly the expansion to a global phase, levels and potential source(s) of funds need to be clear. The AMFm Co-payment Fund for Phase 1 is separate from regular Global Fund finances. In the event that AMFm Phase 1 succeeds, the rationale for that separation will need to be revisited.

Governance, management and technical support

8.7 Subject to Global Fund Board decision(s), business needs of scale, timeline and content will, among other factors, determine the most appropriate functions of the Global Fund Secretariat in managing AMFm after Phase 1. Those functions, in turn, will determine the appropriate governance, internal management structure for a global phase, as well as the configuration, source and levels of funding.

8.8 The Committee will discuss scenarios based on input from the sub-committee and report back to the Board during its second meeting in 2011.

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>

Item:	Further information available:
1.	Consultation on the Economics and Financing of Universal Access to Parasitological Confirmation of Malaria. Part 6 of the Report. http://www.theglobalfund.org/documents/amfm/AMFm_EconFinanceDiagnostics_Report_en.pdf