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# The Global Fund

To Fight AIDS, Tuberculosis and Malaria

Twenty-Third Board Meeting  
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GF/B23/8  
Board Information

## REPORT OF THE AMFM AD HOC COMMITTEE

### PURPOSE:

This report summarizes the deliberations of the Affordable Medicines Facility-malaria Ad Hoc Committee at its 9<sup>th</sup> Meeting in March 2011. It includes an overview of progress in implementing AMFm Phase 1 and the Committee's recommendations to the Board at its Twenty-Third Meeting.

## PART 1: INTRODUCTION

1.1 The Affordable Medicines Facility-malaria Ad Hoc Committee met in Geneva on 24-25 March 2011 for its 9th Meeting. The acting Chair for the meeting was Kirsten Myhr (UNITAID). The Chair, Minister Leslie Ramsammy (Latin America and Caribbean), was unable to attend the meeting.

1.2 This report includes the following sections.

- i. PART 2: Update On Progress in the Implementation of AMFm Phase 1
- ii. PART 3: Implementing Country Representation on the AMFm Ad Hoc Committee
- iii. PART 4: Status of Work on the Independent Evaluation of the AMFm Phase 1
- iv. PART 5: Issues Concerning Africa-Based Manufacturers of Pharmaceuticals
- v. PART 6: Fixed-Dose Combinations versus Co-Blisters
- vi. PART 7: Scenario Planning for AMFm post-Phase 1

This report also includes two attachments: the Terms of Reference of the Request for Proposal issued in December 2010 (Attachment 1), and the AMFm Independent Evaluation (Attachment 2).

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

2.1 The AMFm Ad Hoc Committee (the “Committee”) recognizes that good progress has been made in the implementation of AMFm Phase 1 and notes that much work remains to be done in all AMFm Phase 1 countries. The innovations in the AMFm are working, showing that in addition to the government and private not-for-profit sectors, which are the traditional channels for development assistance - and which the AMFm also supports, the commercial private sector is a viable channel for getting donor-financed ACTs to people in the countries. First-line buyers are placing orders, the AMFm is making co-payments, medicines are being delivered, and buyers are purchasing subsidized medicines at reduced prices at the retail level. Table 1 shows the eligible orders received as of 21 April and expected deliveries by 30 April and 31 May by sector.

**Table 1.** Status of ACT orders by sector

BUYER TYPE	TOTAL TREATMENTS ORDERED, AS OF 21 APRIL	EXPECTED TREATMENTS DELIVERED BY 30 APRIL	EXPECTED TREATMENTS DELIVERED BY 31 MAY
Private for-profit	75,223,138	38,104,710	49,616,672
Private not-for-profit (NGO)	6,551,110	5,311,530	5,749,110
Public	29,261,515	830,335	11,803,555
COLUMN TOTAL	111,035,763	44,246,575	67,169,337

2.2 The Committee notes that most orders have come from the commercial private sector. The Committee also understands that while public sector entities have started placing orders, their processes are very slow when compared to those of the private sector. The Committee further notes that public sector execution of information and communication campaigns have

been much slower than the placement of private sector orders for co-paid ACTs. This slowness of public sector activities is due to a combination of in-country tender procedures in the public sector and disbursement processes of the Global Fund Secretariat. The Committee urges all parties to move swiftly while maintaining probity and observing due diligence.

2.3 There are indications that retail prices of ACTs are declining at the country level. A few examples illustrate this effect of the AMFm.

- i. Kenya: During its meeting on 24-25 March, the Committee received early results from a formal price survey conducted by a team from the Massachusetts Institute of Technology. Their study, done in November 2010, examined retail prices 3 months after the first AMFm co-paid ACTs reached Kenya. It showed that AMFm co-paid ACTs were generally less expensive than other ACTs. Most outlets sold the AMFm co-paid ACTs at or slightly higher than the Government of Kenya (GoK)-recommended retail price of KSh40 (about US\$ 0.50). This was much lower than the highest recorded retail prices of ACTs that were not subsidized by the AMFm, which cost about US\$ 10.00. Relatively few shopkeepers sold the subsidized ACTs at high prices compared to the GoK-recommended price.
- ii. Ghana: The Committee learned that informal price checks showed that the private sector retail prices of AMFm co-paid ACTs in Accra were around US\$ 0.60 to US\$ 1.20 per adult treatment, and slightly higher in more distant locations. These were sharply lower than the pre-AMFm private sector retail prices of up to US\$ 9.00 per adult treatment, and lower than end user price in the government health centers (US\$ 1.50 - 2.00), as indicated in Ghana's application to the AMFm. The Committee understands that Ghana's government health services are responding by lowering ACT prices in the government clinics to match those achieved through the AMFm in the private sector. In time, AMFm co-paid ACTs will become available through the public sector clinics too.
- iii. Nigeria: ACTs that are not co-paid by the AMFm cost about 1,000 - 1,500 Naira (US\$ 6.70 - 9.50) per adult treatment. The Society for Family Health (SFH), a not-for-profit NGO with expertise in social marketing, is a Nigerian first-line buyer registered with the AMFm. SFH started distribution of AMFm co-paid ACTs in Nigeria in March 2011. Thanks to the vastly reduced purchase price of co-paid ACTs under AMFm Phase 1, a full course of treatment for children aged under five years is expected to be sold in private health facilities and outlets at 30 Naira (US\$ 0.20). The adult course of treatment is expected to sell at 120 Naira (US\$ 0.80).
- iv. Madagascar: Before the AMFm, WHO-recommended ACTs in the private sector sold for US\$8.51-9.36 per adult treatment<sup>1</sup>. Informal price checks in early 2011 showed that the private sector retail price of AMFm co-paid ACTs was about US\$ 0.40 per adult treatment in the capital city of Antananarivo, and about US\$ 0.50 outside the city.

<sup>1</sup> <http://www.actwatch.info/downloads/results/Madagascar%20Outlet%20Baseline,%20ACTwatch%2012-09.pdf>

2.4 Revised or new grant agreements have been signed for all AMFm Phase 1 countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania, Uganda and Zanzibar. Disbursements under the amended grants for AMFm activities have been made to the following countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria and Tanzania<sup>2</sup>. Implementation of supporting interventions financed by the Global Fund has started in all these countries. AMFm marketing and trade sensitization campaigns are priorities. AMFm launch events have taken place in Ghana, Kenya, Madagascar, Niger and Nigeria. Marketing activities are at different stages of planning and implementation in all pilot countries. As of late March 2011, posters, leaflets, radio and TV spots had been arranged in all countries except Cambodia, Uganda and Zanzibar.

2.5 A meeting involving participants from all AMFm Phase 1 countries took place in Accra, Ghana on 17-18 December, 2010. The meeting was hosted by the National Malaria Control Program of Ghana. The co-conveners were the Roll Back Malaria Partnership and the Global Fund, in collaboration with the Global Health Group of the University of California, San Francisco. This gathering was novel, in that it convened country implementers (including national food and drug regulators, and national marketing firms), manufacturers, representatives of national first-line buyers (private and public), the relevant Principal Recipients of AMFm malaria grants, and a range of technical agencies and partners. The meeting objective was to take stock of early lessons emerging from implementation, particularly experiences related to the delivery and roll out of AMFm co-paid ACTs, the perspectives of manufacturers, first-line buyers, and the initial reported behavior patterns of retailers, in addition to lessons drawn from marketing 'start up' campaigns. The report of the forum is available on the AMFm page of the Global Fund's external website. The Secretariat intends to organize a follow-up meeting later in 2011 to take stock of lessons learned from several months of implementation.

2.6 The Committee would like to acknowledge the work of implementing countries and the role of partners under the leadership of Roll Back Malaria (RBM), 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 in contributing marketing material and providing support to countries on AMFm marketing and other activities to support the roll-out of AMFm Phase 1. The Committee welcomed the briefing from the RBM Partnership on progress at its 9<sup>th</sup> meeting and requests further input and briefings from RBM Partners as Phase 1 progresses. The Committee welcomes the willingness of the Private Sector Constituency to explore the feasibility of pro-bono bulk messages via SMS from mobile phone companies, as part of the public information campaigns.

2.7 In order to keep track of progress, the Committee has requested the Secretariat to produce a quarterly report on progress in all AMFm Phase 1 countries. This report should include information from a variety of sources including updates from RBM partners. This will help illuminate contextual factors to explain how implementing countries are progressing with AMFm Phase 1 and where corrective action may be necessary. The Committee also considers it important to track what is happening to co-paid ACTs beyond customs entry into countries in order to better understand bottlenecks.

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<sup>2</sup> new grant agreement in the case of Madagascar

## Manufacturer Negotiations and Contracting

2.8 The Secretariat has revised co-payment amounts and maximum prices based on recommendations from the AEDES/OTECI consortium, the Secretariat's contracted negotiations agent. AEDES/OTECI recommended increasing the Maximum Prices for all the Artemether-Lumefantrine (AL) formulations to take into account the increase in the price of Artemisinin. No change was recommended for the Artesunate Amodiaquine (ASAQ) Fixed-Dose Combination (FDC) formulation. Regarding the ASAQ co-blister formulation, as there is more demand for the FDC formulation, no change was recommended. Moreover new FDC ASAQ manufacturers are expected to become eligible in 2011 and this should decrease further the market share of the co-blister product. The co-payment amounts were adjusted to reflect the increase in Maximum prices for AL, with the objective to reach even more affordable first-line buyer prices than the ones achieved in the early months of AMFm Phase 1. The co-payment amounts for pediatric formulations have been increased in order to ensure improved affordability of AL for children who access medicines through the private sector. The Secretariat presented the revised Maximum prices and Co-payment amounts to the Committee at its 9<sup>th</sup> meeting<sup>3</sup>. These changes took effect as of 1 March 2011.

2.9 Master Supply Agreements that outline the contractual relationship between the Global Fund and the eligible ACT manufacturers have been amended to reflect the changes in Maximum Prices and Co-Payment amounts. In addition, the agreements are now valid until the end of December 2012 to take into account the decision of the Global Fund Board to extend the phase 1 of AMFm by 6 months.<sup>4</sup>

2.10 The trademark registration of the universal logo in all AMFm Phase 1 countries; also in Switzerland, China, and India; and with the African Intellectual Property Organization (OAPI)<sup>5</sup>, is being processed with the support of Keltie, Patent and Trademark Attorneys, based in the UK. All the applications for registration have been filed in the respective jurisdictions and examinations are in progress. The AMFm logo is now registered in Switzerland, Cambodia and Zanzibar. The logo license agreement that defines the conditions of use of the logo has been shared with the relevant organizations. The local entities in charge of in-country marketing campaigns are obliged to sign the license agreements. As of late March 2011, relevant entities in Ghana, Madagascar, Niger and Zanzibar have signed the logo license agreement.

2.11 The selected laboratories for quality control (NIDQC in Vietnam and SGS Belgium) have received more than 70 requests for inspection, sampling and testing. NIDQC remains the chosen laboratory for ACT inspection with SGS as the backup laboratory. All samples tested were found to be compliant. Starting from May 2011, the laboratories will be requested to review all certificates of analysis for lots skipped due to the quality control randomization scheme applied to the products.

2.12 The Committee discussed the situation regarding Cambodia's selection of ACTs for AMFm Phase 1. Cambodia still needs to procure Dihydroartemisinin-Piperaquine (DHA-PPQ) to

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<sup>3</sup> The revised amounts are available at:

[http://www.theglobalfund.org/documents/amfm/RBM\\_ACT\\_Pricing\\_Fact\\_Sheet\\_en.pdf](http://www.theglobalfund.org/documents/amfm/RBM_ACT_Pricing_Fact_Sheet_en.pdf)

<sup>4</sup> GF/B22/DP13 Affordable Medicines Facility - malaria: Duration Phase 1:

[http://www.theglobalfund.org/documents/board/22/BM22\\_DecisionPoints\\_Report\\_en.pdf](http://www.theglobalfund.org/documents/board/22/BM22_DecisionPoints_Report_en.pdf)

<sup>5</sup> 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.

cover its requirements for the second half of 2011, and there is currently no DHA-PPQ product eligible for procurement under the Global Fund Quality Assurance policy (QA Policy). There is no certainty about when such a product might become available for use in Cambodia.

2.13 As of 21 April 2011, a total of 133 first-line buyers from all AMFm Phase 1 countries (with the exception of Cambodia) have signed a First-Line Buyer Undertaking. Of these, 70 have placed at least one order, of which 61 are from the private (for-profit) sector, the others, from the public or private (not-for-profit) sectors.

2.14 As of 21 April 2011, the Secretariat has received 152 requests for co-payment totaling US\$ 109.9 million dollars. This represents a total of 111 million treatments. The majority of orders (97 percent) are for Fixed-Dose Combinations (FDCs). Twelve percent of the total treatments ordered are for Dispersible Tablets for children.

### **Monitoring AMFm Phase 1**

2.15 An AMFm Co-Payment Summary Report on the Global Fund external website provides information on AMFm co-paid ACT orders that have been confirmed for co-payment.<sup>6</sup> Information is available on the quantities and types of ACTs ordered by first-line buyers from eligible manufacturers, the co-payments committed, and the dates and quantities of deliveries completed. Order data may be exported to Microsoft Excel or Word.

2.16 The Secretariat and partners, including the Roll Back Malaria Harmonization Working Group's AMFm workstream (co-chaired by representatives of WHO and CHAI), continue to collaborate to monitor and support AMFm pilot implementation. This collaboration includes exchanging updates, discussing challenges and proposing actions during regular teleconferences and consultations among partners.

2.17 The Secretariat continues to complement data on implementation from grant reports and formal partner updates with the following: information gathered first-hand during visits to AMFm Phase 1 countries; tracking of media coverage; proactive and reactive outreach to country-based partners for relevant qualitative and quantitative information; and information gathered by the Independent Evaluator and Data Collection Contractors.

### **Implementation Research**

2.18 Collaboration with WHO/TDR is ongoing to provide support to AMFm Phase 1 countries for Implementation Research funded through AMFm grants. From 31 January - 4 February 2011, WHO/TDR led a qualitative research skills building workshop in Yaoundé, Cameroon for research teams of francophone countries, including Cambodia, Madagascar and Niger. The Global Fund Secretariat participated in the workshop, facilitating planning by country teams that included representatives of research institutions and national malaria control programs. WHO/TDR will convene a second qualitative research skills building workshop for Anglophone AMFm countries in May 2011. Countries have been encouraged to contribute their research results for consideration by the Independent Evaluator in 2012.

2.19 To address the AMFm Ad Hoc Committee's updated implementation research priorities communicated to the Secretariat in August 2010, a Contribution Agreement for an amount of

<sup>6</sup> Accessed at: <http://www.theglobalfund.org/programs/amfm/report.aspx>

US\$ 500,000 was concluded between the Secretariat and CHAI. A request for proposals (RFP) was issued in November 2010 as a result of this Global Fund-CHAI collaboration. Researchers were requested to propose work that would improve understanding of the following: treatment-seeking and provider behaviors related to the use of quality-assured ACTs among key target groups; the reach of information and education and behavior change campaigns (IEC/BCC); provider training; and packaging. Researchers were encouraged to implement and evaluate alternative approaches that would address identified barriers and improve the reach and effect of co-paid ACTs. The research is proposed to take place in Ghana, an AMFm Phase 1 country which is proceeding with implementation relatively quickly.

## **Comparative Effectiveness and Cost Effectiveness**

2.20 At its 8<sup>th</sup> meeting in October 2010, the Committee discussed the issue of the second part of the relevant Board decision relating to the evaluation of AMFm Phase 1, namely the comparative effectiveness and cost-effectiveness of AMFm in relation to other similar financing mechanisms. The text of the Board Decision follows:

*“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.)<sup>7</sup>*

2.21 On the basis of its discussion, facilitated by draft TORs produced by the Secretariat, the Committee requested that the Secretariat commission a two-part study of comparative effectiveness and cost-effectiveness of the AMFm. The first step of this study would address the technical and institutional feasibility of the analyses. The second step, contingent upon and informed by findings from the first, would be the actual analyses and reporting.

2.22 The Secretariat duly issued a Request for Proposals (RFP) in mid-December 2010 and solicited applications from over 100 institutions, organizations and companies with relevant skills and experience. The Terms of Reference in the RFP are attached as Attachment 1. The deadline for applications was 24 January 2011. By this deadline, only one proposal had been received. Given the importance of this study, the RFP was re-issued for another month to allow potential bidders additional time to submit their proposals. In addition to posting the RFP on the Global Fund’s external website, the Secretariat sent direct notices to the heads of a number of academic and research institutions with strong track records in health economics and quantitative modeling. The extended period ended on 7 March 2011. The Secretariat is currently considering proposals.

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

2.23 At its 5<sup>th</sup> meeting, the Committee requested that a working group be established to review the ACT demand forecast for AMFm and to produce a refined forecast during the early stages of AMFm Phase 1 implementation. A consortium led by Boston Consulting Group (BCG) was selected through a competitive process, managed by UNITAID. To ensure technical quality of the service towards meeting the needs of the contractual services, a Steering

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<sup>7</sup> 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.

Committee composed of representatives from lead institutions (UNITAID, RBM, WHO's Global Malaria Program and the Global Fund) was established. The Steering Committee held its first meeting in January 2011 and agreed with BCG on the proposed methodology and steps forward. The first deliverable, a draft report on the initial ACT forecast for AMFm, was produced by the consortium in late February 2011. This report forecasts ACT demand of 261 million treatments in 2011 (74% public, 26% private) and 271 million treatments in 2012 (70% public, 30% private). The Committee would like to emphasize that these are projections not predictions. The forecast is highly sensitive to disbursement delays, pricing assumptions, variation in the ACT share of funding and buyers' decisions about the timing and quantities of orders. The consortium will produce quarterly updates.

## **ACT Price Tracking**

2.24 AMFm Phase 1 is already resulting in reductions in the retail prices of ACTs that meet the Global Fund's QA policy (i.e. AMFm co-paid ACTs). Against this backdrop, the Secretariat has engaged Health Action International (HAI) on a 12 month ACT price tracking study. Price tracking will be conducted using a standardized method co-developed by WHO and HAI and adapted to the needs of AMFm. Data collection will take place in a total of 300 outlets (i.e. 60 per country) in the informal and formal private sectors of five AMFm Phase 1 countries. The selected countries are Ghana, Kenya, Madagascar, Nigeria and Tanzania. Progress reports will be sent to the Secretariat bi-monthly. The findings of this work will inform discussions by implementers, technical partners and the Secretariat as they explore options for ensuring that retail prices of AMFm co-paid ACTs move in the preferred direction.

2.25 The Secretariat notes that implementation of AMFm Phase 1 will continue throughout 2012 after the endpoint data collection in late 2011 (in parallel with data entry, cleaning, analyses, preparation of draft reports and reviews by the Committee before the Board makes its decision in late 2012). In order to better understand price trends during 2012, the Secretariat is also planning for price-tracking surveys to be continued until late 2012. Information from these price-tracking surveys will complement those from the relatively detailed end-point data collection in the independent evaluation.

## **Supply Chain Management and Improvement**

2.26 A tool for supply chain performance improvement developed under AMFm was finalized on 20 December 2010. The tool is based on context-specific supply chain information collected from two AMFm Phase 1 countries: Tanzania and Niger. Core modules included in the tool are: business process reengineering, performance benchmarking, and supply chain improvement through the implementation of best practices. The tool has three variations that have been customized for public sector central and zonal/regional levels, and private sector. The tool allows users to input performance data for selected performance measures, automatically calculating performance levels. It also allows users to establish performance targets and easily identify potential areas for improvement with a stop-light (Red, Yellow, Green) system of indicators that compare actual performance with established targets. Although use of the tool is not a requirement for supply chain actors in AMFm Phase 1 countries, the Secretariat and technical partners will support further customization of the measures included in the tool and its use by supply chain actors in Phase 1 countries who choose to adopt it.



2.27 Under a contribution agreement with the Global Fund, INTERPOL will produce criminal analytical reports on situations and mapping of routes of counterfeit and diverted antimalarial products in the context of AMFm. The first report of enforcement actions carried out in August 2010, one month after co-paid ACTs arrived in Ghana and Kenya, included three AMFm countries: Tanzania, Uganda, and Kenya. The report did not find counterfeit or diverted AMFm co-paid products in these countries. The Secretariat will continue to provide information regarding co-paid ACTs to INTERPOL for use during subsequent enforcement operations. In addition, INTERPOL is working on audio and video materials that will be used for campaigns on the dangers of counterfeit and substandard pharmaceutical products. These materials will include language on the benefits of using AMFm co-paid ACTs.

### **PART 3: IMPLEMENTING COUNTRY REPRESENTATION ON THE AMFm AD HOC COMMITTEE** **Information**

3.1 The Committee would like to raise to the Board's attention the absence at AMFm Ad Hoc Committee meetings of representatives from implementing country constituencies. The Committee understands that the Secretariat has made every effort it can to secure representation of implementing country constituency members. The concern of the AMFm Ad Hoc Committee is that the Committee does not have representatives from any of the affected countries, and only one representative from a region affected by malaria. The Committee would like to express its concern that this leads to a situation in which the Committee is making recommendations and giving guidance to the Secretariat on an important line of business without potentially fully considering the views of implementing countries. The Committee calls on the Board to take measures to ensure that all constituencies fulfill their functions as members of Board committees.

### **PART 4: STATUS OF WORK ON THE INDEPENDENT EVALUATION OF AMFm PHASE 1** **Information**

#### **AMFm Phase 1 Independent Evaluation**

4.1 A summary of Board Decisions, Committee Decisions, TERG Recommendations and Secretariat Actions on the Independent Evaluation of AMFm Phase 1 is attached as Attachment 2. Following the Board Meeting in Sofia, the report submitted by the Evidence-to-Policy Initiative (E2Pi) "Estimating Success Benchmarks for AMFm Phase 1" was made available on the AMFm page of the Global Fund's external website. This exercise addressed only the first part of the most recent Board decision on the independent evaluation of AMFm Phase 1 (GF/B20/DP24: "AMFm Implementation").<sup>8</sup> The second part of the same Board decision, on comparative effectiveness and cost-effectiveness, is being addressed separately (see paragraphs 2.20 - 2.22).

4.2 As part of a Global Fund-financed contribution agreement with WHO's Global Malaria Program, a report was submitted to the Secretariat in December 2010 which summarized 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 both in AMFm Phase 1 countries

<sup>8</sup> [http://www.theglobalfund.org/documents/board/20/GF-BM20-DecisionPoints\\_en.pdf](http://www.theglobalfund.org/documents/board/20/GF-BM20-DecisionPoints_en.pdf)

(except Niger) and in several countries with similar epidemiological profile and treatment policies that are not participating in AMFm Phase 1.

4.3 With oversight from the AMFm Phase 1 Independent Evaluator (a consortium of ICF Macro and the London School of Hygiene and Tropical Medicine), data collection activities for the AMFm Phase 1 Baseline Outlet Surveys have been completed in all countries, and each Data Collection Contractor (Centre de Recherche pour le Développement Humain, Drugs for Neglected Diseases initiative, and Population Services International) is making progress in accordance with the terms of its contract. The Independent Evaluator will be able to complete a comprehensive AMFm Phase 1 baseline assessment report by mid-2011.

4.4 In 2010 the Secretariat decided that it would be appropriate to ask the firms that collected baseline data to also collect the endpoint data, subject to satisfactory performance and institutional due diligence. Informed by feedback provided by the Independent Evaluator that all three contractors have acquired the experience and skills needed to conduct the end point assessments effectively, the Secretariat has conducted internal due diligence, the outcome of which informed a decision to initiate negotiations with the same firms for the endpoint data collection.

4.5 In its Position Paper on the AMFm Independent Evaluation submitted to the Policy and Strategy Committee (PSC)<sup>9</sup> and endorsed by the AMFm Ad Hoc Committee at its 6th meeting, the Technical Evaluation Reference Group (TERG) included several recommendations which could be taken into account prior to finalization of the contracts with the Independent Evaluator and the Data Collection Contractors. The TERG recommended that the evaluation include the following: (i) studies of the effects of the logo on quality-assured ACTs that do not have the AMFm logo on packaging; and (ii) in-depth country case studies for selected fast-moving countries to understand changes in uptake of AMFm co-paid ACTs at outlets and by people in remote locations. These two studies could not be undertaken within the 2010 budget of the Independent Evaluation, and the scopes of work of either the Data Collection Contractors or the Independent Evaluator.

4.6 To respond to these recommendations, which were discussed at the 7th Ad Hoc Committee 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. In its report to the 22nd Meeting of the Global Fund Board in Sofia, the Committee noted that the execution of this work was contingent upon the preparation by the TERG of clear technical terms of reference (TORs) and the study design, 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.”<sup>10</sup> The purpose was to help ensure upfront that the additional elements would meet the TERG’s technical requirements.

4.7 In order to ensure that the work was done independently and in a timely fashion, on 5 February 2011 the leadership of the AMFm Ad Hoc Committee asked the TERG Chair to provide the technical TORs. As of mid-April, the leadership of the AMFm Ad Hoc Committee had received no response from the TERG Chair. To ensure the technical integrity of the exercise, as well as timeliness within the Board-mandated schedule for the independent

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<sup>9</sup> GF/PSC/13/06

<sup>10</sup> Global Fund Board Decision Point GF/B20/DP24, accessed at:  
[http://www.theglobalfund.org/documents/board/20/GF-BM20-DecisionPoints\\_en.pdf](http://www.theglobalfund.org/documents/board/20/GF-BM20-DecisionPoints_en.pdf)

evaluation, the Secretariat asked the Independent Evaluator to write technical workplans for those studies. This recourse was specified in the request from the leadership of the AMFm Ad Hoc Committee to the TERG Chair. These workplans have now been received and are being considered by the Secretariat.

## **Cambodia and the evaluation of AMFm Phase 1**

4.8 The Committee has decided that progress in Cambodia should not be assessed as part of the evaluation of AMFm Phase 1. This is because of prolonged delays before the start of implementation and uncertainties about when implementation can start in the country. There is currently no DHA-PPQ product eligible for procurement by Cambodian first-line buyers under the Global Fund Quality Assurance policy (QA Policy). As far as the Committee is aware there is no imminent product in the pipeline and therefore first-line buyers, including the relevant PR, will be unable to procure ACTs under the AMFm with sufficient time before the proposed end-point data collection for any meaningful data to be collected. There does not therefore seem to be any point in paying for end-point data collection. The Committee does not recommend excluding Cambodia from AMFm as any savings would be modest, and even a few months of implementation can provide some valuable lessons before the end of AMFm Phase 1. Therefore, Cambodia will be in a position to benefit from AMFm co-paid ACTs once a drug becomes eligible but prior to the Board decision on AMFm, expected in November 2012. Relatively simple price tracking studies can be used to learn from the period of implementation, which is expected to be short.

## **Judging the success of AMFm Phase 1**

4.9 The Committee has discussed further the independent evaluation of AMFm and how to measure its success. The Committee welcomes the Board's decision to extend the period of evaluation by six months<sup>11</sup> but notes that the evaluated implementation period is still short. The Committee discussed this issue with representatives of the Independent Evaluator (a consortium of ISF Macro and the London School of Hygiene and Tropical Medicine) at its 9th meeting in order to establish how long the evaluated implementation period could be before end-point data collection take place. The Independent Evaluator has advised the Committee that in order to ensure the Independent Evaluation Report on AMFm Phase 1 is ready for the Board meeting at the end of 2012, the end-point data collection needs to be completed by the end of November 2011. The Committee has tasked the Secretariat with contracting the Data Collection Firms to conduct the end-point data collection with due regard to the need to complete the work by end November 2011.

4.10 The timing of the end-point data collection means that only a small number of AMFm Phase 1 countries will have had ACTs available for purchase in-country for more than 12 months. The Committee notes that considerable wisdom and realism will be required to judge the success of AMFm Phase 1 in view of this short time-frame, bearing in mind a conclusion of the 5 Year Evaluation of the Global Fund, that:

“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.

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<sup>11</sup> GF/B22/DP13 Affordable Medicines Facility - malaria: Duration Phase 1:  
[http://www.theglobalfund.org/documents/board/22/BM22\\_DecisionPoints\\_Report\\_en.pdf](http://www.theglobalfund.org/documents/board/22/BM22_DecisionPoints_Report_en.pdf)

Investments of both new resources and new approaches require time to take root and bear fruit.<sup>12</sup>”

4.11 To this end, the Committee will continue to examine prudent ways to judge the evaluation of AMFm Phase 1. The Committee will be in contact with other Board constituencies in order to solicit their input, provide information on how AMFm implementation is progressing in-countries and discuss the Committee’s perspectives. The Committee intends to bring its findings to the Board at its Twenty-Fourth Meeting later in 2011.

## **PART 5: ISSUES CONCERNING AFRICA-BASED MANUFACTURERS OF PHARMACEUTICALS**

**Information**

5.1 The Committee recognizes the concerns of Africa-based pharmaceuticals manufacturers regarding the eligibility of their products under the Global Fund QA policy and the cost competitiveness of their products. This concern has arisen in the case of Quality Chemicals, Uganda which manufactures an ACT that is eligible for co-payment under the Global Fund QA policy but does not manufacture an ACT that is price competitive. The Committee understands that the Secretariat has a responsibility to spend donors’ money cost-effectively, particularly in the current resource-constrained environment. The Committee recommends that the appropriate body or bodies examine the question of a price preference for locally based manufacturers of ACTs that meet the Global Fund’s QA policy. The Committee is not expressing a view, but is acknowledging the concerns of locally based manufacturers and would like the appropriate body or bodies to explore the issue and propose an acceptable solution to all parties.

5.2 The Secretariat is participating in preparations for a forum that will examine the challenges faced by Africa-based manufacturers of pharmaceuticals and other malaria products. The forum will be co-convened by the African Leaders Malaria Alliance Secretariat (ALMA), the Global Fund, the Roll Back Malaria partnership, the Office of the UN Secretary General’s Special Envoy for Malaria, Medicines for Malaria Venture and the UN Industrial Development Organization (UNIDO). The meeting will be hosted by the Government of Kenya, in Nairobi, on 30 - 31 May 2011.

5.3 This high-level forum will bring together key stakeholders with interests in the future of the pharmaceutical industry in Africa to consider how the industry may address current bottlenecks to development of the industry. The forum will address three specific areas currently identified as hampering the development of an Africa-based pharmaceutical manufacturing capacity: (a) regulation, quality standards and material sourcing; (b) market and economic issues; and (c) challenges specific to generic manufacturers. The forum will conclude by making recommendations to African Heads of State on opportunities to create a conducive investment climate for the continued development of the African-based pharmaceutical industry. With support from the Secretariat, TropMed Pharma Consulting has prepared a background paper that is a neutral and fact-based summary of the current situation of the pharmaceutical industry in sub-Saharan Africa. The paper is intended to

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<sup>12</sup> The Five-Year Evaluation of the Global Fund to Fight AIDS, Tuberculosis and Malaria. Synthesis of Study Areas 1, 2 and 3. March 2009. Page viii.

serve as a starting point for discussions at the meeting, using antimalarial drugs (and ACTs specifically) to illustrate the situation.

## **PART 6: FIXED-DOSE COMBINATIONS VERSUS CO-BLISTERS**

**Information**

6.1 The Committee discussed again the issue of co-blistered versus fixed-dose combination ACTs, and reiterated its preference for fixed-dose combinations on public health grounds, and recognized that co-blistered formulations in fact constitute a small fraction of orders placed under the AMFm. The Committee recognizes that WHO is the body with responsibility for setting guidelines and norms in this field. The Committee also recognizes that the AMFm is a financing mechanism, not a procurement agency, and that as long as co-blistered formulations are eligible for purchase under WHO guidelines and Global Fund policies, the AMFm should not be the mechanism that decides what first-line buyers, including PRs, should buy. The Committee understands that the Market Dynamics and Commodities Ad-Hoc Committee (MDC) discussed this issue at its 4th meeting in April 2011, including the demand and availability of suitable formulations that comply with the Global Fund's QA policy, and will propose a Decision Point for a preferential funding policy for fixed-dose combination ACTs to the Board.

## **PART 7: SCENARIO PLANNING**

**Information**

7.1 As part of its oversight functions, the Committee is preparing scenarios for AMFm post-Phase 1. The idea behind this work is to ensure that adequate preparation is in place at both the global and country level to ensure a transition as seamless as possible in implementing the Board's decision on the future of AMFm beyond Phase 1. In taking this forward, the Committee requested, at its 8th meeting in October 2010, that the Secretariat send to the Committee Chair and Vice-Chair draft TORs and a workplan for a sub-Committee on scenario planning. The Committee leadership considered this input from the Secretariat and decided that the level of effort required to undertake the "Scenario Planning" work was unlikely to be met by a sub-Committee of the AMFm Ad Hoc Committee. The Secretariat suggested an alternative approach, in which: (a) the Committee would oversee the process and comment on draft products; (b) the Secretariat would commission appropriately skilled partners and consultants to provide inputs where needed; and (c) the Secretariat would provide direct inputs into and manage the process. The Committee leadership endorsed this modified approach.

7.2 In February 2011, participants at the first meeting of the Institutional Initiators of the AMFm also considered, in very broad terms and on a preliminary basis, potential scenarios that may arise at the end of AMFm Phase 1.

7.3 With regard to the importance of this topic and the request from the Committee, the Secretariat has established a workstream for 2011, with the following deliverables:

- i. Initial Scoping Paper on "AMFm Phase 2: Strategic Options and Responsibilities": - This was presented to the Committee at its meeting on 24-25 March. The immediate purposes were to elicit feedback from Committee members on the scope and parameters of the exercise, and to ensure general consensus on questions to be explored.

- ii. Draft paper on "AMFm Phase 2: Strategic Options and Responsibilities": This will be shared with the Committee in the last quarter of 2011.

7.4 The Committee discussed the Initial Scoping paper at its 9th meeting. The paper included various considerations and scenarios to address the parameters of the Board's decision on AMFm (i.e. to expand, accelerate, modify, terminate or suspend AMFm). The Committee broadly welcomed the approach outlined in the Scoping Paper and requested that the Secretariat present a draft of the proposed full paper to the Committee at its 10th meeting, expected to be in October 2011. The paper will include input from those who will be affected by the Board's decision: representatives of beneficiaries at the country level, technical experts and stakeholders, including RBM and the Institutional Initiators of AMFm (i.e. the organizations that proposed that the Global Fund be invited to host and manage the AMFm).

This document is part of an internal deliberative process of the Global Fund and as such cannot be made public until after the Board meeting.

## GUIDANCE ON LOCATION OF FURTHER INFORMATION

The below table indicates where further information on items dealt with in this report can be found:

Where indicated documents are available on the Governance Extranet:

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

Item:	Further information available:
1. ACTwatch - Outlet Survey Report (Baseline) Madagascar	<a href="http://www.actwatch.info/downloads/results/Madagascar%20Outlet%20Baseline,%20ACTwatch%2012-09.pdf">http://www.actwatch.info/downloads/results/Madagascar%20Outlet%20Baseline,%20ACTwatch%2012-09.pdf</a>
2. Updated ACT prices (March 2011)	<a href="http://www.theglobalfund.org/documents/amfm/RBM_ACT_Pricing_Fact_Sheet_en.pdf">http://www.theglobalfund.org/documents/amfm/RBM_ACT_Pricing_Fact_Sheet_en.pdf</a>
3. AMFm Co-payment Summary Report	<a href="http://www.theglobalfund.org/programs/amfm/report.aspx">http://www.theglobalfund.org/programs/amfm/report.aspx</a>
4. Five Year Evaluation Synthesis Report	<a href="http://www.theglobalfund.org/en/terg/evaluations/sr/">http://www.theglobalfund.org/en/terg/evaluations/sr/</a>
5. Attachment 1	Terms of Reference of the Request for Proposal issued in December 2010 <b>Available on the Governance Extranet</b>
6. Attachment 2	AMFm Independent Evaluation <b>Available on the Governance Extranet</b>

