



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

**Eighteenth Board Meeting
New Delhi, India, 7 – 8 November 2008**

**GF/B18/7
Decision**

REPORT OF THE AFFORDABLE MEDICINES FACILITY – MALARIA AD HOC COMMITTEE

OUTLINE:

1. This paper presents the proposed AMFm policy framework, governance arrangements, implementation plan, and financial requirements for a phased launch of AMFm as requested by the Global Fund Board (GF/B17/DP16).

EXECUTIVE SUMMARY:

1. The Affordable Medicines Facility – malaria (AMFm) is a financing mechanism designed to make artemisinin-based combination therapies (ACTs) more accessible, and by so doing to reduce the use of less-effective treatments. The AMFm involves negotiating a reduced price for ACTs, and then making a co-payment to further lower their sales price to end-users in malaria-endemic countries. These affordable ACTs would then be distributed through providers across the public, private and not-for-profit sectors. By reducing the cost of ACTs available across all providers, the AMFm aims to support countries in scaling up access to ACTs and curtailing emerging resistance to artemisinin brought about by the use of artemisinin-based monotherapies.

2. At its 17th meeting in April 2008, the Global Fund Board agreed that the Secretariat should prepare to host and manage the AMFm as a business line within the Global Fund, subject to the final approval of a policy framework and implementation plan to be presented and approved at its 18th Board meeting (GF/B17/DP16). The Board further decided that the launch of the AMFm would be phased, beginning with a limited number of countries. This first phase (Phase 1) of the AMFm would be assessed via an independent technical evaluation. The findings of this evaluation would be reviewed by the Board in 2010 to decide whether to expand, accelerate, terminate or suspend the AMFm business line.

3. At the request of the Board, working with the RBM AMFm Task Force and under the guidance of the AMFm Ad Hoc Committee, the Secretariat has developed a policy framework and implementation plan for Phase 1 of the AMFm, incorporating the principles outlined in the annex to the decision point (GF/B17/DP16).

4. The original AMFm Phase 1 design covered a 12 month period, with an additional six months of funding, in the event of a Board decision to terminate the AMFm. A key recommendation is to extend the duration of Phase 1 by six months to a total of 18 months, with a similar funding provision for responsible AMFm 'wind down,' if the Board does not approve global roll out. This timetable ensures

that countries will have adequate time to implement the AMFm and better facilitates a scientifically credible independent evaluation of Phase 1. The independent evaluation's findings will be considered by the Board at its meeting in November 2010.

5. The policy framework developed in this paper addresses the key elements of AMFm (Phase 1):

- **Manufacturer negotiations:** Preliminary discussions with manufacturers have resulted in early indications of interest in AMFm. Further negotiations to agree on price and co-payment levels will be undertaken in partnership with UNITAID, which is already leading the development of a demand and supply forecast of ACTs for Phase 1 including an assessment of the availability of the active pharmaceutical ingredient, artemisinin.
- **Country eligibility:** Consistent with recommendations from the Roll Back Malaria AMFm Task Force, country eligibility for Phase 1 has been based on the criteria of (1) high to moderate malaria mortality rates and (2) experience with large-scale ACT programs. The following additional eligibility criteria were also applied to facilitate a credible Phase 1 evaluation: 3) status of private sector distribution levels; 4) strength of country monitoring and evaluation systems; 5) presence of a conducive regulatory environment; 6) previous experience with ACT subsidy schemes. Nine countries¹ met these criteria. The Ad Hoc Committee also recommended that Kenya and Cambodia be considered for AMFm Phase 1. Kenya for reasons of creating a regional East Africa cluster, and Cambodia for fighting emerging artemisinin resistance and its potential threat to spread to other countries.
- **Country access for Phase 1:** Eligible countries will be asked to submit an application that explains how they will implement the AMFm (their national roll-out plan). Guidance will be provided on interventions considered essential, i.e. required for supporting appropriate implementation of the AMFm. The application deadline will be mid-March 2009. The TRP will review applications and send recommendations to the Board for approval at its meeting in May 2009. Following Board approval, countries will be able to place orders for co-paid ACTs.
- **Reaching the poor:** A central goal of the AMFm is to increase access to ACTs by all groups through improving the availability of affordable ACTs through all sectors. Evidence gathered by the RBM Task Force indicates that poorer people seek anti-malarial drugs in both the public and private sectors, and that they often buy drugs that are ineffective (and some that promote resistance). The RBM Task Force has compiled information on 'promising options' for reaching the poorest. This will be made available for countries to draw on, as they will be required to explain how they plan to reach the poor and specific vulnerable populations within their national roll-out plans. Country or multi-country operational research studies will be undertaken to evaluate the effectiveness of different approaches, and socio-economic quintile analyses will be employed to the degree possible as a means to examine this.
- **Quality Assurance:** ACTs subsidized through the AMFm must comply with the Global Fund's policies for quality assurance for pharmaceutical products. In addition, it is recommended that manufacturers that market oral monotherapy artemisinin would not be eligible to participate in the AMFm.
- **Phase 1 monitoring and evaluation framework:** To enable the Global Fund Board to determine whether to proceed to global roll-out of the AMFm, Phase 1 will be assessed through an independent technical evaluation. The purpose of the Phase 1 evaluation is to assess whether the AMFm is meeting its Phase 1 objectives and to examine country experiences and

¹ Benin, Ghana, Madagascar, Niger, Nigeria, Rwanda, Senegal, Tanzania and Uganda

lessons from implementing the AMFm mechanism. The indicators used in the evaluation will also act as potential 'red flags' to identify issues or failures in the design and implementation of the AMFm. The evaluation will be completed and submitted to the Board for its consideration in November 2010. Operational research (including strategies to best reach the poor) will further inform the evaluation through building the evidence base around best practice interventions.

- **Governance:** Governance and oversight of Phase 1 of the AMFm would be the responsibility of the Global Fund Board. It is recommended that the Board requests the Ad Hoc Committee to continue to oversee the pre-launch preparations of AMFm Phase 1 in keeping with its current committee mandate. At the 19th Board meeting, the Board will decide on the governance arrangement to oversee the implementation of AMFm Phase 1. It is recommended that RBM and UNITAID be full members of the committee to reflect their specific interest in the AMFm.

6. The **Implementation Plan** outlines the timetable of key dates and milestones during the launch, implementation and evaluation of Phase 1 of the AMFm. These include:

- AMFm application deadline of 13 March 2009
- TRP review of applications in April 2009
- Board approval of applications and official launch of AMFm by early May 2009
- Baseline data collection for independent evaluation during June/July 2009
- Data collection for independent evaluation completed by end July 2010
- Independent evaluation to be submitted to the Board for its meeting in November 2010.

7. The AMFm Phase 1 Financial Requirements:

- **Resources for co-payment and supporting interventions:** The resources required to finance ACT co-payments in AMFm Phase 1 will be determined principally by the demand forecast for participating countries and the prices and co-payment levels agreed with manufacturers. With the current considerations for country participation in Phase 1, this is estimated at approximately USD 212 million. The UK recently announced a pledge of GBP40 million towards the AMFm and there are indications of support from other key donors. In particular, UNITAID has expressed interest in contributing towards the AMFm financially in addition to supporting forecasting activities and manufacturer negotiations. Essential supporting interventions are estimated to cost in the order of USD 100-125 million. Countries can fund these interventions using their own resources, support from other donors, or by seeking assistance from the Global Fund. To the extent that new Global Fund resources are provided for these interventions, they will be drawn from the existing Global Fund Trust Fund.
- **Resources to manage Phase 1:** In order to fulfill the functions assessed as necessary for Phase 1 of the AMFm, it is estimated that the Secretariat will require an additional 9 Full Time Equivalents (FTEs) at a cost of USD 1.4 million. Other specific AMFm costs including the independent evaluation are estimated to total USD 5.2 million for pre-launch and Phase 1 through to end 2009. The resulting budgetary implications would be approximately USD 6.6 million to end 2009, and USD 14.4 million for the entire Phase 1 period.

8. Policy Fit and Risk Management:

- **Policy fit:** The AMFm design is compatible with the purpose and principles of the Global Fund as described in the Framework Document and the By-laws. It is also consistent at a high level with other aspects of the Framework Document, such as country processes, eligibility criteria, application process, monitoring program progress and fiduciary responsibilities.

- Additions to existing policies or new policies are however needed. It is proposed no adjustments are made to established core Global Fund policies given the experimental nature of AMFm Phase 1. The new AMFm Phase 1 Policy contains all policy elements relevant to the implementation of AMFm Phase 1. This includes the finance policy governing Phase 1, the application of performance based funding and monitoring and evaluation to AMFm, as well as co-payment arrangements and manufacturer and country eligibility criteria. The AMFm Phase 1 Policy is consistent with the principles endorsed by the Board at its 17th meeting.
- Supporting interventions funded by the Global Fund will follow the existing grant-making model and will therefore be subject to the Global Fund's policies in the same way as the Global Fund's other grants.
- **Risk management:** Potential threats to successful global implementation of AMFm and their mitigation were considered in the AMFm business plan, submitted to the PSC at its 9th meeting in March 2008 (GF/PSC9/03). While the types of risk broadly hold true for Phase 1 of the AMFm, the overall risk profile has been reduced by the significantly smaller scope of Phase 1.

Proposed Decision Point:

The Board refers to its earlier decisions regarding the Affordable Medicine Facility – malaria ("AMFM") (GF/B16/DP14 and GF/B17/DP16).

The Board approves the Policy Framework and Implementation Plan set out in the AMFm Ad Hoc Committee Report to the Board (GF/B18/XX – the "AMFm Report") and reaffirms its decision to host and manage the AMFm for an initial phase ("Phase 1") in a limited number of countries. The Board requests the Secretariat to begin operation of Phase 1 of the AMFm.

The Board requests the AMFm Ad Hoc Committee to continue to oversee the pre-launch preparations of AMFm Phase 1 in keeping with its current committee mandate up to the 19th Board meeting. At the 19th Board meeting, the Board will decide on the governance structure for the oversight and performance monitoring of the implementation of Phase 1.

The Board requests the Secretariat to commission an independent technical evaluation of the roll-out of the AMFm in the AMFm Phase 1 countries. The Board requests the committee with oversight of AMFm Phase 1 to review the findings of such evaluation and to make a recommendation to the Board at its last meeting in 2010, at which time the Board will determine whether to expand, accelerate, terminate or suspend the AMFm business line.

The Board acknowledges the work and support of the RBM Task Force, UNITAID and other partners and requests its partners to continue to support the development and implementation of the AMFm.

The budgetary implications of this decision amount to \$6,600,000 for pre-launch and 2009, which includes an allocation for 9 staff positions. (The cost will be covered by the budget contingency.)

PART 1: INTRODUCTION

1. The Affordable Medicines Facility – malaria (AMFm) is a financing mechanism designed to make artemisinin-based combination therapies (ACTs) a more accessible treatment for malaria² in places where malaria is endemic and other drugs are no longer adequate. The concept and design of the AMFm has been described in-depth elsewhere³⁻⁴. In brief, the AMFm involves making a co-payment towards the cost of ACTs purchased by eligible first-line buyers in malaria endemic countries. These subsidized ACTs will then be distributed through providers across the public, private and not-for-profit sectors. By reducing the cost of ACTs available across all providers, the AMFm aims to serve as a platform for scaling up access to ACTs and curtailing emerging resistance to artemisinin. It is expected to represent one key component in a comprehensive global response to malaria.

2. At its 17th meeting in April 2008, the Global Fund Board agreed that the Secretariat should prepare to host and manage the AMFm as a business line within the Global Fund, subject to the final approval of a policy framework and implementation plan at the 18th Board meeting (GF/B17/DP16). The Board further decided that the launch of AMFm would be phased, beginning with a first group of countries to be agreed at its 18th meeting. The Board agreed that this first phase (Phase 1) of the AMFm would be assessed via an independent technical evaluation. The findings of this evaluation would be reviewed by the Global Fund Board in 2010, to decide whether to expand, accelerate, terminate or suspend the AMFm.

3. The policy framework and implementation plan contained in this document incorporates the principles outlined in the annex to the decision point (GF/B17/DP16) and reflects the guidance of the AMFm Ad-hoc Committee, inputs provided by technical partners (in particular the RBM AMFm Task Force), and consultations held with potential Phase 1 countries.

4. During the process of consultation, the Ad Hoc Committee noted that it is critical for the evaluation of Phase 1 to be based on a credible implementation period. The implementation approach outlined in Attachment 3 to the PSC Report to the 17th Board meeting (GF/B17/4) suggested data for the independent technical evaluation to be collected in early 2010. However, in order to ensure that countries have adequate time for provider training, publicity awareness and the distribution of ACTs, the AMFm Ad Hoc Committee, following the recommendation of the Roll Back Malaria Task Force, proposes to extend the duration of Phase 1 by an additional six months, and so conduct the evaluation from mid-2010. This will enable countries to supply ACTs for up to 10-11 months before the formal data analyses for evaluation purposes commences. This paper then proposes that the Board will consider the evaluation findings at its meeting in November 2010.

5. This paper consists of four parts:

- PART 1: Introduction
- PART 2: AMFm Policy Framework & Implementation Plan
- PART 3: AMFm Financial Requirements
- PART 4: AMFm Policy Fit and Risk Management

² ACTs are recommended by WHO for treating uncomplicated falciparum malaria. ACTs are not recommended for women in their first trimester of pregnancy.

³ Kenneth J. Arrow, Claire B. Panosian, and Hellen Gelband, Editors. Committee on the Economics of Antimalarial Drugs Board on Global Health. Saving Lives Buying Time: Economics of Malaria Drugs in an Age of Resistance. 2004. Institute of Medicines of the National Academies. The National Academies Press, Washington D.C.

⁴ The Global Fund To Fight AIDS, Tuberculosis and Malaria. Affordable Medicines Facility. Submission to the 9th Policy & Strategy Committee Meeting, Geneva, 12-14 March 2008.

More specifically:

The policy framework addresses the following components of the AMFm:

- Manufacturer negotiations and co-payment setting
- Country eligibility criteria for Phase 1 and country processes for accessing the AMFm
- Reaching the poor and vulnerable groups
- Monitoring and evaluation of Phase 1
- Proposed arrangements for the governance of AMFm Phase 1

The implementation plan presented in this paper consists of the timeline and key milestones for launching Phase 1 of the AMFm and conducting an independent technical evaluation.

The financial requirements include a statement of resources available for launch of the AMFm and an outline of the organizational and budgetary requirements for hosting the AMFm within the Global Fund.

The policy fit and risk management section includes:

- The policy compatibility of the AMFm with established Global Fund principles, mechanisms and policies, and an overview of the new AMFm Phase 1 Policy
- An updated analysis of perceived risks and benefits to the Global Fund of the AMFm

PART 2: AMFm POLICY FRAMEWORK

(2a) Manufacturer negotiations and co-payment setting

Negotiations with manufacturers and co-payment setting

1. The approach outlined in this paper builds on earlier work, including the AMFm business plan, submitted to the PSC at its 9th meeting in March 2008 (GF/PSC9/03), and the report from the RBM Task Force working group on Supplier Sourcing. This paper provides an update of work undertaken since then. The approach is compatible with the technical design approved by the RBM Board.

Negotiation roles and responsibilities

2. The Secretariat will be responsible for overall co-ordination of manufacturer negotiations. It will draw on strategic partners and technical experts to provide guidance, and it will contract an external agent to undertake negotiations and establish co-payment levels for AMFm in Phase 1. The roles and responsibilities of these partners are outlined in Annex 1a.

Timeline for negotiations

3. Preliminary discussions with manufacturers have been undertaken in September 2008 to investigate price, production capacity and the supply framework. The Secretariat will seek expressions of interest to participate in AMFm from manufacturers in October 2008. Formal negotiations with manufacturers will be conducted between November 2008 and January 2009 and it is anticipated that contracts will be finalized by February 2009.

4. Preliminary discussions with manufacturers are proceeding as planned. Manufacturers spoken with to date have indicated their interest in supplying ACTs under the AMFm. High level talks between senior management representatives from the Global Fund and manufacturers to discuss expectations and positions are planned to follow the November Board meeting.

AMFm Phase 1 Policy and Contracts

5. The relationship between the Global Fund and manufacturers will be governed by the AMFm Phase 1 Policy (Annex 6b). This policy provides guidance on the scope, nature and implementation of AMFm within the Global Fund. Among other matters, it identifies criteria for 'what' and 'who' the co-payment applies to and the nature of relations between the Global Fund and manufacturers. Importantly, the AMFm Phase 1 Policy also describes the financial policy and rules as applied to AMFm Phase 1 (see Part 4).

6. The new Global Fund Quality Assurance criteria (to be agreed at the 18th Board meeting) will be applied to AMFm. The Quality Assurance standards apply to all manufacturers, whether local or international. Only manufacturers that comply with these quality standards will be eligible to enter negotiations to supply AMFm co-paid anti-malarials. A list of manufacturers included in the AMFm negotiations process and ACTs likely to comply with the harmonized Quality Assurance criteria are provided in Annex 1b. Following the RBM Task Force recommendations of January 2008, technical partners have been encouraged to provide technical assistance to local manufacturers, where required, to support them in reaching these agreed quality assurance standards.

7. In keeping with the AMFm's objective of countering resistance to artemisinin, the Ad Hoc Committee also recommends that in order to supply ACTs through the AMFm, manufacturers must commit to not market oral artemisinin monotherapies.

8. The Global Fund will enter into an agreement with each manufacturer that defines the negotiated manufacturer sales prices, co-payment level (which will be subject to review and possible change during the course of Phase 1), and non-price terms. The maximum duration of these agreements will be the AMFm Phase 1 period⁵.

Price-setting and terms

9. The negotiation process will begin with seeking expressions of interest from eligible manufacturers. The Global Fund will then issue a request for information to all eligible manufacturers that have expressed interest. This will formally start the negotiation process.

10. The specific strategy and tactics for the negotiations will be advised by the negotiation agent to reflect the best available information about market dynamics, expressions of interest and concerns raised by manufacturers. It is expected that the process will include a competitive component where manufacturers will be asked to submit bids supplemented by a break-down of the cost structure and assumptions behind the bid. Negotiations of final AMFm manufacturer sales prices will be based on this information.

11. It is a principle of the AMFm that manufacturers must agree to sell ACTs under AMFm with a price structure that does not discriminate between private sector and public sector buyers. The agreement to supply ACTs with AMFm co-payment will not set conditions for other legitimate market activities that manufacturers pursue.

Co-payment setting

12. The level of the AMFm co-payment will also be defined as part of the agreements with manufacturers. The co-payment will be set to maximize the likelihood that the end user price is equivalent to or lower than that of less effective anti-malaria drugs currently available on the market (chloroquine and sulfadoxine-pyrimethamine).

⁵ The agreements will also include provisions to protect the Global Fund, such as limitations on liability and indemnities in favor of the Global Fund and cancellation arrangements to cover suspension or termination of the mechanism.

13. The exact structure and level of the co-payments will respond to the information submitted by manufacturers and other market dynamics. It is expected that the co-payment will be applied as a percentage of the agreed manufacturer sales prices to allow potential differences in prices offered by different manufacturers to be reflected in prices offered to first line buyers. The price to first line buyers will also be subject to floor and ceiling prices in order to prevent misuse of the co-payment.

Supply framework

14. The supply framework for the AMFm has been developed to ensure that non-price factors are integrated into manufacturer negotiations and contracts. It also builds on earlier work, as summarized in the AMFm business plan (GF/PSC9/03), which incorporates work conducted by RBM Task Force working groups on Buyer Eligibility and Packaging.

First-line buyer eligibility

15. As outlined in the AMFm business plan (GF/PSC9/03), buyer eligibility requirements determine which first-line buyers can purchase ACTs co-paid through AMFm. These requirements are based on the recommendations of the RBM AMFm Taskforce. They are designed to be transparent and light and will operate within existing national regulatory and commercial systems. To be considered eligible to purchase ACTs under AMFm, first-line buyers must:

- a) Be legally registered with the national drug regulatory authority (NDRA)
- b) Sign a short, standard non-negotiable contract with the Global Fund under which the first-line buyers agree, among other things:
 - To sell co-paid ACTs within AMFm Phase 1 countries only;
 - To follow the aims and spirit of the AMFm⁶;
 - To limit mark-ups in order to pass on the highest possible proportion of the price benefit from co-paid ACTs, via their national supply chains in AMFm Phase 1 countries, to enable an end user price competitive with that of less effective anti-malaria drugs currently available on the market;
 - To allow the Global Fund and its agents access to staff, facilities and records to conduct reviews.

16. In order to minimize administrative burden on the Secretariat, AMFm ACT manufacturers will be required to conduct primary assessments of buyer eligibility, and ensure that the buyer signs a standard, non-negotiable contract with the Global Fund⁷.

Payment of additional costs: Freight, Insurance, Taxes and Duties

17. As recommended in the AMFm technical design, the Global Fund will make co-payments to manufacturers on price terms that include the cost of medicines as well as insurance and freight ("CIF terms"). Separate ceilings may be set for the insurance and freight component to incentivize cost-efficiency.

18. The Global Fund will strongly encourage countries not to levy taxes, customs charges or import duties on AMFm co-paid ACTs, in line with the Global Fund's existing procedures. The Global Fund's prior experience has shown that the majority of countries are willing to adopt such waivers.

⁶ The spirit and aims of the AMFm will be defined around a) Ensuring that people with malaria have access to affordable ACTs, b) Encouraging widespread availability of these affordable ACTs and c) Acknowledging the right of the Global Fund to take remedial action in case of breach by the first line buyer of its obligations, or other evidence, that the goals of the AMFm are not being met in the relevant country.

⁷ The manufacturer is the conduit that provides the contract to the first line buyer and returns the signed 'top copy' to the Secretariat, thus minimizing administrative burden on the Secretariat.

Regulations on AMFm packaging

20. There are a number of objectives in establishing minimum requirements for packaging of co-paid ACTs. These are (i) to maximize appropriate use of the medicine by patients, (ii) to assure the quality of packaging, (iii) to communicate the affordability and effectiveness of ACTs to vulnerable and low income groups in order to generate high demand for these ACTs, and (iv) to facilitate the tracking of subsidized ACTs.

21. The primary responsibility for **assuring appropriate use of medicines** by patients lies with the national authorities. Countries will be expected to indicate in their roll-out plans how they will aim to achieve this objective, including through training and communication campaigns for professionals, retail outlets and the general public. User-friendly instructions on use (consistent with the minimum requirements set by the WHO) and blister packaging will be important elements in meeting this objective. Manufacturers will also be encouraged to apply the user-friendly instructions to packages. AMFm will only co-pay for finished ACT products that are in a fixed dose combination or that are co-blistered. Manufacturers also have an interest in ensuring appropriate use of their products and therefore such minimum requirements will be set out in the manufacturer agreements.

22. The minimum packaging quality requirements for co-paid ACTs will be the packaging standards incorporated into the WHO's good manufacturing practice (GMP), which are included in the Global Fund's quality assurance policy and will be reflected in the manufacturer agreements.

23. A risk for AMFm is the leakage of co-paid ACTs away from the intended markets. It will therefore be important to **monitor the distribution of AMFm co-paid ACTs**. To facilitate this monitoring effort, manufacturers will be required to use an identifier on packaging for all AMFm co-paid products. The identifier may vary and may take any simple form, to be negotiated with each manufacturer. The identifier will not use the Global Fund or AMFm's name or logo and will not be used for communication campaigns. Its sole purpose is to assist in tracing AMFm co-paid ACTs.

24. Effective **communication campaigns will be one of the key means of creating demand for high-quality ACTs**, in addition to training of dispensers and competitive pricing. A tool that is being used in a number of countries to enhance the effectiveness of communication campaigns is a universal, easily-recognizable logo on packaging for quality assured ACT products. The experience of organizations and countries implementing such branding solutions will be shared with AMFm Phase 1 countries through the guidance being prepared by the RBM Harmonization Working Group to help AMFm Phase 1 countries in the development of their communication campaigns.

Administration of co-payment

19. The procedures for processing co-payments, including the invoicing mechanism and payment terms are designed to minimize the administrative burden on the Global Fund Secretariat as well as on manufacturers. It is expected that co-payments will be made through regular (monthly) aggregated disbursements.

20. The Global Fund Secretariat will verify co-payment requests and send payment orders to the Trustee. The Trustee would then transfer funds directly to the manufacturer as specified in the Global Fund payment order⁸. ACT prices will be monitored in country to see that low prices are being passed on to consumers and patients, and these data will indicate where there may be a need for follow up. Additionally, first line buyers agree to spot checks by independent compliance monitors (e.g. Local Fund Agents), appointed by the Global Fund, where required, to assess the integrity and effectiveness of the mechanism.

⁸ To minimize the cost of processing and ensure efficiency, co-payment processing would be automated to the extent possible. A simple online information platform will report on orders and disbursements at frequent intervals.

Market forecasting

21. An accurate demand and supply forecast will be essential for effective manufacturer negotiations and successful roll-out of AMFm. The mix of countries, in conjunction with local market dynamics and the pace of program implementation, will drive AMFm ACT demand during Phase 1. On the supply side, production capacity and availability of the active pharmaceutical ingredient (API), artemisinin, are the key constraining factors. Initial high-level estimates of required volumes (demand) as well as artemisinin availability (supply) will be completed for AMFm Phase 1.

22. As a strategic partner to the Global Fund on AMFm, UNITAID has agreed to lead development of a more detailed forecast of ACT demand and supply for Phase 1. UNITAID will work with manufacturers and technical partners to develop a detailed forecast by the end of 2008 as a key input into the negotiations with manufacturers and the setting of co-payment levels. On the demand side, country-specific factors such as a) size of public and private markets, b) current and expected uptake of ACTs, and c) risk of leakage must be considered. On the supply side, further discussions with manufacturers and experts on artemisinin availability are required. The Roll Back Malaria partnership is also looking into this issue and will provide input to the Global Fund and UNITAID. This forecast would be continuously refined during the course of implementation of Phase 1, for example by incorporating the results of monitoring and evaluation baseline studies.

(2b) Country Eligibility for Phase 1

23. The Global Fund Board agreed at its 17th Meeting that the launch and implementation of the AMFm in endemic countries should be phased, starting with a first group of countries selected according to criteria developed by the Global Fund Secretariat and agreed at the 18th Board Meeting. This section outlines the set of eligibility criteria that were used by the AMFm Ad Hoc Committee to identify Phase 1 countries. In developing these criteria, the Secretariat worked closely with technical partners, in particular the Roll Back Malaria AMFm Task Force Sub-Group which was led by WHO.

24. The initial criteria recommended by Roll Back Malaria for selecting countries for Phase 1 of the AMFm were high to moderate malaria mortality rates and previous country experience of large-scale ACT programs. These criteria were selected to provide conditions that will enable high impact against malaria morbidity and mortality via the successful implementation of Phase 1. The application of these criteria yielded an initial group of 25 countries⁹.

25. It was agreed that this list of 25 countries should be further reduced because simultaneous implementation in 25 countries was considered extremely complex, and would not comply with the AMFm phase-in approach agreed by the Global Fund Board. Furthermore, there is still a potential threat of a shortage of artemisinin due to seasonal production periods of the plant *A. Annua*.

26. The AMFm Ad Hoc Committee considered additional parameters to reduce the list from 25 to a more manageable number of countries. These included:

- a) The status of private sector distribution levels, given the AMFm is more likely to achieve wider coverage and access to ACTs in countries that have established private sector involvement in malaria treatment distribution¹⁰
- b) Strength of country monitoring and evaluation systems

⁹ Angola, Benin, Burundi, Comoros, DRC, Ethiopia, Gabon, Ghana, Guyana, Kenya, Liberia, Madagascar, Myanmar, Namibia, Niger, Nigeria, Rwanda, Sao Tomé and Príncipe, Senegal, Sudan, Suriname, Tanzania, Togo, Uganda, Zambia

¹⁰ Though no comprehensive data exists for all malaria endemic countries, anecdotal evidence can be collated to indicate countries with higher relative private sector involvement.

- c) Presence of a conducive regulatory environment, including ACTs as either 'over the counter' medicines, or ACTs deployed at community level
- d) Previous experience with ACT subsidy schemes to facilitate scale-up

The full list of eligibility criteria are listed in Annex 2a.

27. Nine countries were found to best satisfy these eligibility criteria. The Ad-Hoc Committee decided that Kenya should also be considered eligible for Phase 1 in order to achieve a more consolidated cluster approach in East Africa. It was also decided that Cambodia should be considered eligible, in order to counter increasing resistance to artemisinin that has been documented in Cambodia, and threatens to spread to other countries. Thus 11 countries¹¹ are recommended by the Ad Hoc Committee as eligible to apply for Phase 1.

28. Countries not selected for participation will continue to be eligible to seek Global Fund support through the existing rounds-based system.

Consultations with Countries

29. Country interest in participating in AMFm Phase 1 is a fundamental requirement. To this end, the Secretariat is undertaking a series of consultations with short-listed countries to inform key stakeholders of the AMFm and its implications, and to assess interest in the AMFm. These consultations will continue up to and beyond the Board meeting in November and will involve direct meetings with CCMs, PRs and national stakeholders. This will allow countries the opportunity to decide whether they wish to apply to Phase 1 of the AMFm.

(2c) Country Access

30. This section describes how countries wishing to access the AMFm during Phase 1 will submit applications; how these applications will be assessed; and how funding for essential supporting interventions will reach countries. The process is designed to be simple and efficient in order to meet Board timelines and adapts the process for country access and financing of supporting interventions outlined in the AMFm business plan (GF/PSC9/03).

AMFm Application

31. Countries considered eligible to apply for the first phase of the AMFm will be invited to submit a simplified application form that explains how they will implement the AMFm (their national roll-out plan). The Secretariat will provide guidance to countries on the application process based on RBM Task Force input. This will include guidance on the interventions that are considered essential, i.e. that are required for appropriate implementation of the AMFm and the areas that need to be addressed in the application, such as reaching vulnerable populations and the poor. In order to assist countries in the application process, technical assistance in developing applications will be provided. The RBM AMFm Task Force recommends that technical assistance be coordinated through its Harmonization Working Group.

32. As outlined in the AMFm business plan (GF/PSC9/03) (based on Task Force guidance) and further refined through consultation with countries and external partners, roll-out plans would be required to include:

- A budgeted plan with funding source(s) for essential supporting interventions, including

¹¹ Benin, Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Tanzania, Uganda

- Public education and awareness campaigns to support the scale-up of subsidized/free ACTs and market the products
 - Provider training, monitoring and supervision to ensure patient safety
 - Monitoring and evaluation framework for the implementation of the AMFm
 - Planning for national policy and regulatory preparedness
 - Planning for monitoring of drug quality
 - Additional interventions to reach vulnerable populations and the poor, as well as operational research activities to further investigate best ways for AMFm implementation
- A statement of preparedness, including:
 - List of eligible first line buyers
 - Named focal point for national drug quality monitoring
 - The nominated Principal Recipient of the grant funding for the roll-out plan
 - A link with holistic national plans, including
 - Explanation of how AMFm fits with the national malaria control strategy
 - Explanation of how the national malaria control strategy seeks to ensure that ACTs reach women, children and the poor, especially the poorest quintile.
 - An advance disbursement request to facilitate quick disbursement of funds after Board approval to start implementing supporting interventions, including:
 - The most recent version of a relevant existing grant agreement that will be amended to enable rapid disbursement, including the summary budget and indicators
 - A summary budget and indicators for the advance funds
 - A consolidated new summary budget and indicators of the existing grant plus the advance funds

Financing for supporting interventions

33. The AMFm business plan (GF/PSC9/03) outlined an integrated process for countries to apply to the AMFm and to apply for supporting interventions financing. This approach was affirmed in the Decision Point principles approved by the Board¹². The recommendation remains that the Global Fund's grant financing mechanism would play a key role in financing these supporting interventions for which other sources of funding are not available. A summary of the application process is set out below (a more detailed description of the process is set out in Annex 2b to this paper).

Proposed process for countries to access AMFm Phase 1

34. Following a positive Board decision in November, the Secretariat will solicit AMFm applications from all eligible countries to participate in AMFm¹³. The submission deadline will be 13 March 2009.

35. A subset of the Technical Review Panel (TRP) with relevant expertise will review AMFm applications, along with the RCC Wave 6 applications in late April. The TRP subgroup will make a recommendation to the Board either to fund or not to fund an application. In doing so, the TRP would also identify matters for the Secretariat to take into account in further negotiations with the country. However, there would be no TRP clarification process.

36. The Board will vote on the TRP's recommendations for funding at the subsequent 19th Board meeting in the first week of May 2009. The Board's decision on an AMFm application is final and not subject to appeal. At the same time, the Secretariat will present to the Board a statement of

¹² "Resource mobilization for supporting interventions will be part of ongoing resource mobilization for Global Fund grant making and should be integrated into the Global Fund resource mobilization strategy"

¹³ All countries participating in AMFm must submit an application even if the funding for the roll-out plan is being provided by another source.

resources available for funding of the estimated co-payment need for the full AMFm Phase 1 period, based on confirmed pledges.

37. Due to the tight timeline for Phase 1, it will be important for countries to start implementing roll-out plans as soon as possible after Board approval of their AMFm applications. Where funding for country supporting interventions is secured from the Global Fund, following Board approval of its AMFm application, an existing grant agreement will be amended to allow a portion of the approved funding (up to the amount budgeted for the first quarter) to be disbursed to the nominated Principal Recipient to start their AMFm supporting intervention activities. The Secretariat will then negotiate grant documentation with the nominated Principal Recipient for the remainder of the approved funds (either as an amendment to the existing grant agreement or as a new agreement if the PR so chooses).

38. According to the timelines requested by the Board, AMFm Phase 1 will open for receipt of ACT orders from end of May 2009, with ACTs expected to arrive in country a minimum of two months after order. Supporting interventions will be implemented from May 2009, in preparation for the arrival of the first co-paid ACTs.

(2d) Reaching the Poor and Vulnerable Groups¹⁴

39. A central goal of the AMFm is to increase access to ACTs by all groups through availability of affordable ACTs in the public, not-for-profit and private sectors. The Secretariat, in conjunction with external partners, in particular an RBM AMFm Task Force Sub-Group focused on this issue, has worked to identify practical solutions to reaching the poorest, who shoulder a high proportion of the disease burden. The Secretariat has designed the proposed implementation of Phase 1 of the AMFm accordingly.

40. The RBM Task Force conducted a thorough literature review between February and July 2008, to determine what is known about the malaria treatment-seeking behavior of the poor, with a view to informing how the AMFm mechanism can best reach them. Accrued evidence demonstrates that poor people seek anti-malarial drugs in both the public and private sectors with some studies even showing that wealthier people use the public sector more than the poor. Knowledge gaps were found in a number of important areas. For example:

- There is limited data examining the issue of treatment quality by socio-economic groups. The evidence that is available suggests that wealthier people experience higher quality care by using more effective anti-malarials and being more likely to undergo a full course of treatment.
- Many countries want to scale up the use of ACTs and increase the comparatively lower rates of access and use amongst their poor and children. Yet, it was shown there is much to learn about what works best where, and under what conditions.

41. For this reason, the RBM Task Force compiled information on promising options for reaching the poorest and lessons learnt in their application¹⁵. This information will be made available to countries as a resource of possible ideas to draw upon when they are completing their AMF application form.

¹⁴ For the purposes of this analysis, the poor are considered, as those living on less than \$2 (purchasing power parity) per day (World Bank definition), which includes the majority of the population in most countries in Sub Saharan Africa. In relative poverty terms, the poor are defined as the lower three socio-economic status (SES) quintiles while the poorest are within the lowest SES quintile. Children under 5 and pregnant women are particularly vulnerable to malaria. There are potentially also specific vulnerable population groups at country level, for example based on their living conditions or ethnicity.

¹⁵ Prepared by the AMFm Task Force Sub-Group on Reaching the Poor. Options for Reaching the Poor with Malaria Treatment.

These ideas are not prescriptive, and countries will be encouraged to develop strategies that fit their context, and to promote operational research aimed at identifying the best strategies for reaching the poor, including the poorest quintiles.

42. Countries will be required to explain how they plan to reach the poor and specific vulnerable population sub-groups as part of their national 'roll-out' plans (for example, through information, education and communication materials, other supporting intervention activities and distribution strategies). In addition, the RBM Task Force will coordinate technical assistance to support proposal writing and the development of supporting interventions (including those for reaching the poor).

43. Finally, the extent of population access to and coverage of ACTs will be a principal area of data analysis for the independent evaluation of Phase 1 implementation (see Section 2e). This will build the evidence base regarding the most effective interventions to achieve better access and use among vulnerable populations and the poor. Socio-economic quintile analyses will be conducted to the degree feasible, particularly in operational research focused on examining access, coverage and uptake by vulnerable and poor populations. These studies may be country or multi-country in nature.

44. While the AMFm will thus make a strong effort to reach the poorest through the public and not-for-profit sector, donors can also fund free distribution programs outside the Global Fund grant structures. Recipients in Phase 1 countries could still purchase ACTs at reduced cost, as long as they meet buyer eligibility criteria.

(2e) Phase 1 Monitoring and Evaluation Framework

45. To enable the Global Fund Board to determine whether to proceed to global roll-out of the AMFm, Phase 1 of the AMFm will be assessed through a continuous process of monitoring and an independent technical evaluation. The purpose of monitoring and evaluation in Phase 1 is to assess whether the AMFm is meeting its Phase 1 objectives, to examine country experiences and lessons from implementing the AMFm mechanism and provide recommendations for moving forward, including global scale up. The indicators and targets used in the monitoring and evaluation will be used to identify and signal 'red flags' in the design and implementation of the AMFm.

46. The monitoring and evaluation approach to AMFm Phase 1 consists of three components:

- In-country monitoring and evaluation (including supporting interventions)
- Operational research (single country and multi country studies)
- Independent evaluation

Guidance will be provided to countries by the Global Fund Secretariat about the respective roles, contributions and implementation arrangements for these different components.

47. The process for designing the monitoring and evaluation system flows from the objectives of Phase 1 of the AMFm. Acknowledging that Phase 1 of the AMFm is experimental, the purpose of Phase 1 is to assess the potential of AMFm in meeting its objectives. These are defined as:

- To increase access to high quality, affordable ACTs, including by the poor, and
- To drive less effective treatments out of the market, including crowding out artemisinin monotherapies.

48. From these objectives, the key evaluation questions for the evaluation of Phase 1 can be defined and from this the design of the monitoring and evaluation system can be developed. The initial set of monitoring and evaluation questions includes the following:

- Has the ACT cost to patient been reduced at point of distribution (public health centers, pharmacies, NGOs and faith based organizations dispensing centers) to a price comparable to that of chloroquine and sulfadoxine-pyrimethamine?
- Has the proportion of ACTs relative to all anti-malarial treatments increased in the public and private sectors?
- Has the AMFm mechanism helped increase anti-malarial treatment access for the poor?

These questions will be further refined in consultation with Global Fund monitoring and evaluation experts, the RBM MERG and the GF Board Committee which will maintain oversight of the AMFm Phase 1. In this process, other areas of investigation may be added to the evaluation.

49. Scope of the Phase 1 Monitoring and Evaluation

- *Breadth of assessment* – Indicators for monitoring and evaluation will include the inputs, processes, outputs and outcomes of Phase 1 of the AMFm. Although the Phase 1 implementation period has been extended by six months from the original proposal, time constraints will restrict data analysis to trends. In order to make an assessment of ‘impact on malaria’, a longer implementation period would be necessary to build a more definitive evidence base.
- *Identification of ‘red flags’* – ‘Red flags’ will be used to indicate a major fault or failure of the AMFm Phase 1 mechanism, as well as significant bottlenecks in implementation. These ‘red flags’ will reflect the objectives of the AMFm Phase 1, as expressed through the key evaluation questions, and will be derived from the monitoring and evaluation indicators, and specified in the monitoring and evaluation plan.
- *Timeframe for the evaluation* – Pending a positive Board decision, a request for proposals for the independent evaluation will be issued in November 2008 with a Board decision in early May 2009. Baseline data for the independent evaluation will then begin. The first ACTs are expected to arrive in country in the summer of 2009. Given the proposal to extend the implementation period by six months, data collection for the evaluation of Phase 1 is planned to be completed by June/July 2010, to enable the Board to consider the independent evaluation findings at its meeting in November 2010.

50. Monitoring and evaluation will be guided by the following principles:

- *Country leadership*: As part of their AMFm ‘roll out’ plans, countries will formulate monitoring and evaluation plans that address how the proposed data and indicators will be collected and managed within their country contexts. Through partners, technical assistance for the development of these plans will be available upon request. It is important to note that country-level monitoring systems, particularly regarding drug resistance, drug quality, and surveillance of counterfeit drugs, may need to be developed and supported over the course of Phase 1.
- *Strengthening of country monitoring and evaluation systems*: Efforts will be made to facilitate and contribute to the strengthening of Phase 1 countries’ capacity for monitoring, evaluation and operational research. This will be undertaken with Global Fund partners, including the World Bank, Roll Back Malaria and PMI, where they exist in these country contexts. AMFm provides a unique opportunity – particularly with its overarching public and private sector focus – to build and strengthen country systems in new ways.
- *Independence of evaluation*: The Secretariat, under the oversight of the Committee overseeing Phase 1 implementation (see proposed governance arrangements below), will issue a call for

proposals for a suitably qualified organization (or consortium) to undertake an independent evaluation of this multi-country initiative. Applications will be assessed based on technical expertise, organizational capacity and proven track record to conduct large scale evaluations.

- *Capitalize on current activity:* For reasons of feasibility, reduction of country burden and avoiding duplication, it is vital that opportunities for collaboration and partnership between different country and international ACT initiatives are optimized. This will involve sharing data, exploring opportunities for adding AMFm related questions to already planned surveys (e.g. ACT watch surveys), and also investigating overlap between AMFm Phase 1 countries and those participating in the wider Global Fund Five Year Evaluation (e.g. examining the availability in health facilities of different anti-malaria drugs).
- *Importance of realistic expectations:* Given the short evaluation period, it is important to consider what data is feasible to collect across multiple countries as well as practical factors (such as the seasonality of malaria) which will determine when evaluation activities can be undertaken.

51. Lessons learning & identification of best practices from operational research activity:

Monitoring and operational research to be conducted at the individual country and multi-country level will build and further inform AMFm stakeholders, at of the evidence base around best practice interventions. Countries will develop their own monitoring and evaluation plans, as well as operational research agendas and submit these as part of their national roll-out plans. Monitoring and operational research are intended to underpin countries' internal review and 'problem-solving' processes and will inform assessments of AMFm supporting interventions, such as community awareness campaigns and efforts to reach the poor and vulnerable groups¹⁶.

Cross-country analyses will also be commissioned to further inform our understanding of best practice interventions.

(2f) Governance

52. At its 17th meeting, the Board requested the Secretariat develop recommendations regarding the ongoing governance of the AMFm. The recommendations proposed below build on those presented in the AMFm business plan (GF/PSC9/03) and maximize the use of existing structures within the Global Fund Board.

53. The Global Fund Board would retain overall governance and oversight of the AMFm. In this role, it would be responsible for strategic and high-level policy decision making, approving resource requirements and monitoring the performance of Phase 1 of the AMFm. As has already been agreed (GF/B17/DP16), the Global Fund Board would also decide whether to proceed to global roll-out, adjust, terminate or suspend the AMFm following the independent evaluation of Phase 1.

54. It is recommended that the AMFm Ad Hoc Committee continues to oversee the pre-launch preparations of AMFm Phase 1. At its 19th meeting, the Global Fund Board will decide on the governance structure to oversee the implementation of AMFm Phase 1 and monitor its performance. This committee could be stand-alone or integrated into the Global Fund committee structure. As was originally proposed in the AMFm business plan (GF/PSC9/03), this Committee would oversee the independent evaluation, and consider its findings, to subsequently advise the Board on its decision to pursue global roll-out, suspension or termination of the AMFm. Finally, the Committee would advise the Board on permanent governance arrangements for the AMFm, should the Board decide to

¹⁶ Emerging lessons from existing private sector ACT distribution programs describe the importance of addressing knowledge gaps on private ACT distribution - see Sabot et al.: Distribution of artemisinin-based combination therapies through private sector channels: Lessons from four country case studies.

proceed to global roll-out. The Committee overseeing the implementation of AMFm Phase 1 would continue to work with the existing committees, including through the participation of its Chair and Vice Chair in the established meetings of committee chairs/vice chairs.

55. It is recommended that the Committee overseeing Phase 1 implementation be comprised of a balanced representation from the donor and implementing blocs. It is recommended this Committee be small in size (four members from each bloc) and that its members have relevant expertise. It is also recommended that UNITAID and RBM be members of the Committee.

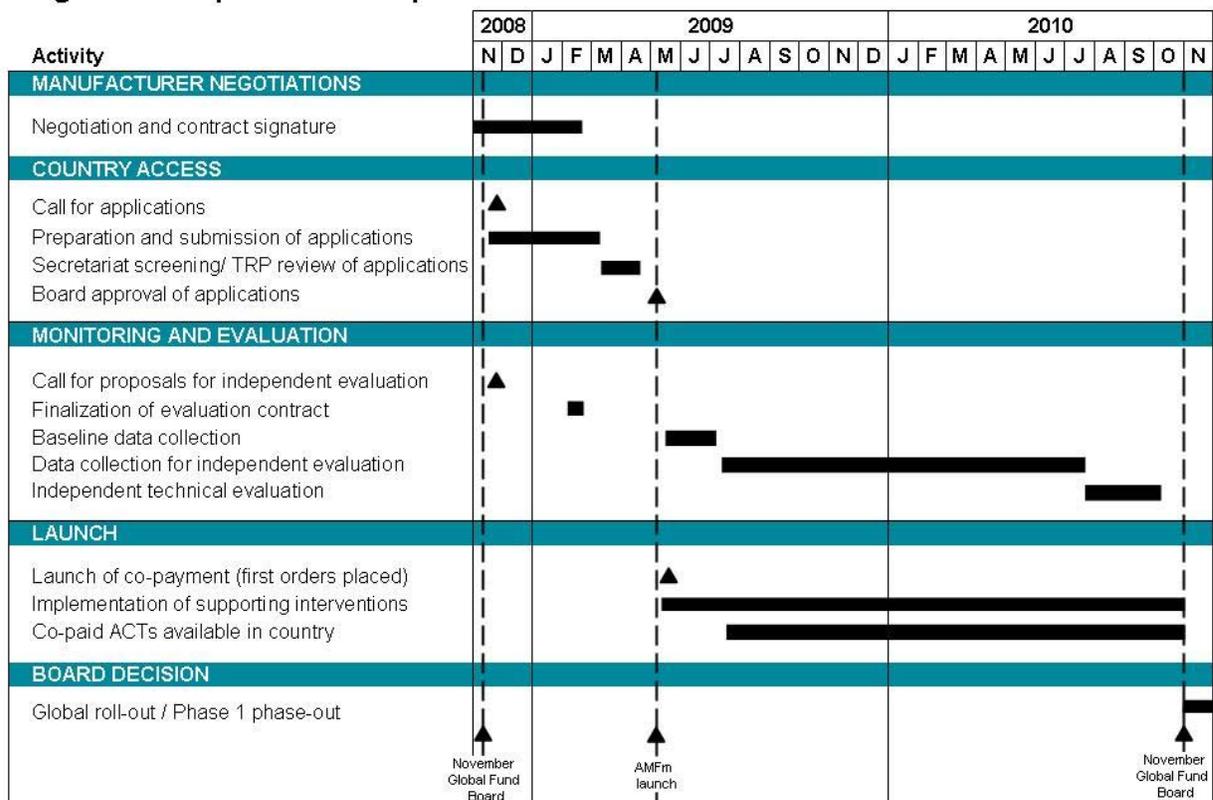
56. A description of the proposed delegation of authority, advisory function and terms of reference for the Committee overseeing the implementation of AMFm Phase 1 is presented in Annexes 3a-3c.

(2g) Implementation Timeline

57. The implementation plan outlined in this paper provides the timetable of key events during the launch, implementation and evaluation of Phase 1 of the AMFm. It is based on the approach outlined in the AMFm business plan (GF/PSC9/03); however adjustments have been made to reflect the extension of the Phase 1 timeframes by six months following feedback received from the AMFm Ad Hoc Committee and consultations with the RBM AMFm Task Force and potential Phase 1 countries.

58. An overview of the recommended implementation plan for Phase 1 is provided below in Figure 1. The target launch period for the AMFm would be early May 2009 and the Board, at its meeting in November 2010, would decide whether to expand, accelerate, terminate or suspend the AMFm.

Figure 1: Implementation plan for Phase 1 of the AMFm



PART 3: AMFm FINANCIAL REQUIREMENTS

(3a) Statement of resources available for launch

1. This section discusses how resources for Phase 1 of the AMFm will be managed within the Global Fund, estimates of resource requirements for Phase 1 and the approach to resource mobilization.

2. As was discussed in the AMFm business plan (GF/PSC9/03) presented at the 17th Board meeting, resources for AMFm co-payments will be held in a new AMFm Trust Fund held with the Trustee (the "AMFm Co-Payment Fund"). This will enable direct receipt of funds dedicated to AMFm co-payments and strict separate management of these resources. Grants to finance essential AMFm supporting interventions will be funded from the existing Global Fund Trust Fund.

3. The resources required to finance ACT co-payments in AMFm Phase 1 will be determined by the number of countries participating, by the demand forecasts for these countries and by manufacturer sales prices and co-payment levels. With the current considerations for country participation in Phase 1, this resource requirement is estimated at USD 212 million (see Annex 4a). This includes the 18-month Phase 1 period and a further 6 months of 'phase-out' funding, should the AMFm be terminated by the Board¹⁷. The assumptions that underpin this estimate are provided in Annex 4b.

4. The cost of supporting interventions for Phase 1 of the AMFm is estimated in the order of USD 100-125 million. Essential supporting interventions included by countries in their roll-out plans for AMFm in Phase 1 may be financed through grants in line with regular Global Fund procedures or through finance provided by other donors. It is expected that a significant portion of the finance required for supporting intervention grants would come from reprogramming grant resources which would be released as PRs get access to co-paid ACTs. The assumptions that underpin these estimates are provided in Annexes 4c and 4d.

5. Consistent with the previous board decision, resource mobilization for the AMFm co-payments will occur separately from and in addition to ongoing resource mobilization for the Global Fund's grants-based operations. Resource mobilization efforts to date have resulted in support from key donors. The United Kingdom has pledged GBP 40 million¹⁸ to the AMFm, subject to approval of AMFm Phase 1 by the Global Fund Board. UNITAID has also expressed strong interest in contributing towards the AMFm Co-payment Fund.

(3b) Resource, budget and organization

6. At the 17th meeting of the Board, the Secretariat presented the budgetary requirements for managing the AMFm as a new business line within the Global Fund. Following the Board decision to proceed with a phased approach to the launch of the AMFm, the Secretariat has reworked its proposal to reflect the different scale of Phase 1 of the AMFm.

7. The functions assessed as necessary for launching and managing Phase 1 of the AMFm include (see full description provided in Annex 5a):

- i. Overall management of AMFm Phase 1 and partner coordination
- ii. Manufacturer negotiations and setting of co-payment levels
- iii. Coordination of the process for countries to access the AMFm and essential supporting interventions finance

¹⁷ This is proposed in order to meet ethical obligations to Phase 1 countries and to avoid sudden market distortions, should the Board decide to terminate the AMFm following Phase 1.

¹⁸ Currently USD 73.5 million

- iv. Processing of co-payments and management of relations with the Trustee
- v. Monitoring and Evaluation of AMFm Phase 1
- vi. Analysis of ACT market data and forecasts
- vii. Resource mobilization and communication

8. Staffing requirements to cover these functions in the pre-launch phase and first year of operation (November 2008 – end 2009) of the AMFm are estimated as 9 Full Time Equivalents (FTEs) to cost USD 1.4 million. Other specific AMFm costs total USD 5.2 million (see full description in Annex 5b).

9. The resulting budgetary implications for pre-launch and Phase 1 through to end 2009 would be approximately USD 6.6 million. The budget required to manage the entire Phase 1 of the AMFm is currently estimated at USD 14.4 million (see full description in Annex 5c).

10. The Global Fund Secretariat will continue to work with partners to deliver specific elements of the AMFm. This would include:

- i. Building country level capacity with the Harmonization Working Group of RBM
- ii. Refining monitoring and evaluation arrangements in coordination with the MERG and other partners
- iii. Ongoing collaboration with UNITAID and potentially other strategic partners on negotiations with manufacturers and the setting of co-payment levels.

PART 4: AMFm POLICY FIT & RISK MANAGEMENT

1. At its 17th meeting in April 2008, the Global Fund Board requested the FAC to work with the AMFm Ad-hoc Committee to review the AMFm design and business plan with regard to the Global Fund's fiscal management policies and processes (GF/B17/DP16). The Board also requested the FAC and the PSC to provide analysis on elements of the AMFm policy framework, implementation and business plan that may potentially change the Framework Document and By-laws.

2. The phased AMFm approach described here remains broadly compatible with the analysis of business and policy 'fit' with the Global Fund that was described in the AMFm business plan (GF/PSC9/03). This is also true for the earlier assessment of risk to the Fund of this new venture.

3. Established core Global Fund policies that need to accommodate the AMFm are listed below. Identified 'policy gaps' (areas requiring new policy development) are also highlighted. In terms of the earlier risk assessment of AMFm for the Fund (outlined in the AMFm business plan (GF/PSC9/03)), some identified potential risks are now reduced by the controlled roll out of Phase 1. This is explained below.

(4a) Global Fund & AMFm: Policy 'Fit'

4. The AMFm design is compatible with the purpose of the Global Fund as described in the Framework Document and the By-laws. The AMFm is expected to attract, manage and disburse additional resources, to make a sustainable and significant contribution to the reduction of illness and death, caused by malaria in endemic countries thereby contributing to poverty reduction, as part of the Millennium Development Goals.

5. The AMFm does not necessitate any changes to the By-laws and is compliant with the principles of the Global Fund as outlined in the Framework Document (for more details see Annex 6a)

6. At a high level, the AMFm is also consistent with other parts of the Framework Document, such as country processes, eligibility criteria (disease burden), application process, monitoring program progress and fiduciary responsibilities. However, operational detail is clearly different because the AMFm is different from the established Global Fund modus operandi for grants to countries (AMFm supporting interventions notwithstanding). The AMFm is also in keeping with the spirit of the Global Fund's Strategy, *Accelerating the Effort to Save Lives*. In particular, the AMFm is a new financing mechanism through which the Global Fund may tackle themes central to this strategic approach, namely 'growing to meet demand' within implementing countries and 'innovating for greater impact' against malaria.

7. Particular care has been taken in the design of the AMFm as a business line within the Global Fund to ensure that it remains true to the core principles of the Global Fund, to operate as a financial instrument, not an implementing entity and to ensure national ownership of program implementation. Managing the AMFm necessarily involves the Global Fund entering into new relationships with the participants in the AMFm, including national public health bodies, manufacturers and first line buyers. However, its role in those relationships is as a responsible *funder*, not an implementer. The implementers of the AMFm are national stakeholders themselves: through the development of roll-out plans by CCMs, through the implementation of approved roll-out plans by Principal Recipients of grants; and through the procurement of co-paid ACTs by first-line buyers (and through them distributors, retailers and others in the supply chain). The Global Fund does not dictate to implementers how to implement the AMFm in their countries. However, in the same way as for grant operations, the Global Fund does stipulate some minimum requirements or guidance to ensure that, to the extent possible, implementers understand and commit to the goals of the AMFm, and Global Fund resources are used effectively. For example, roll-out plans are required to include training and communication campaigns, but the design of those campaigns is at the discretion and control of the country applicant.

8. The Global Fund's country grant approach clearly shapes current core institutional policies and practice. The development of the AMFm, which is strongly defined by a co-payment component, means that relevant policies (particularly finance policies) need to evolve to reflect the requirements of this co-payment mechanism.

9. Two policy 'gaps' were identified and areas for new policy development were recognized. Table 1 provides details of these.

Table 1: New Policies Required for AMFm

New Policy	Policy Content
AMFm Phase 1 Policy (Annex 6b)	<ul style="list-style-type: none"> • Description of the co-payment mechanism, including payment arrangements, ordering ACTs and fiduciary arrangements; • Finance policy for co-payment, including resource mobilization; • Eligibility criteria for the country, manufacturer and first line buyer; • Roles and responsibilities of involved parties; • Nature of contractual requirements; <i>and</i> • Performance-based funding and audit/reporting requirements, as applied to AMFm Phase 1. • Monitoring & Evaluation • Reporting
Country Guidance ¹⁹	<ul style="list-style-type: none"> • Overview of the AMFm concept and principles; • Country eligibility criteria (for Phase 1); • Country access process, including guidance on access to technical assistance; • Requirements for supporting interventions; • Roles of other existing Global Fund-related bodies as they pertain to AMFm, e.g. the Country Coordinating Mechanism, Principal Recipient and Local Fund Agent.

10. For the purposes of Phase 1, the “AMFm Phase 1 Policy” is the overarching document providing guidance on core elements of AMFm Phase 1 – principally finance, co-payment, country eligibility, performance based funding, monitoring and evaluation and reporting requirements. Where AMFm Phase 1 policy differs from existing policies (e.g. Policy on Restricted Financial Contributions), these differences should be viewed as temporary exceptions which will be reviewed and aligned pending a Global Fund Board decision on global roll out. This is particularly relevant for the Comprehensive Funding Policy and the Policy for Restricted Financial Contributions. Table 2 summarizes how core Global Fund policies (finance and performance-based funding) apply or are customized to AMFm Phase 1 within the AMFm Phase 1 Policy.

Table 2: Application of Core Global Fund Policies within AMFm Phase 1 Policy

Core Global Fund Policies	As Applied Within AMFm Phase 1 Policy
Comprehensive Funding Policy	<ul style="list-style-type: none"> • AMFm resource mobilization, separate trust fund management, asset definition/requirements
Global Fund Policy for Restricted Financial Contributions	<ul style="list-style-type: none"> • The establishment of a discrete trust fund for the AMFm, out of which co-payments for ACTs will be paid. Restricted financial contributions for the AMFm co-payment will be open to all donors. Donors will not be permitted to further restrict contributions within the AMFm trust fund.
Guidelines for Performance-Based Funding	<ul style="list-style-type: none"> • AMFm country supporting interventions are bound by the same performance-based funding rules as other Global Fund country grants. • The performance management of manufacturers and country ‘first line buyers’ is described in the new AMFm Phase 1 Policy

11. As AMFm is a pricing and financing instrument with the co-payment of ACTs at its core, the finance policy for AMFm co-payment is centrally important and warrants singling out for attention. It reflects the principles endorsed for AMFm at the Board's 17th Meeting:

¹⁹ Guidance currently under development

- AMFm Phase 1 will not become operational until sufficient funds have been contributed to cover estimated co-payment costs for the full first phase of roll-out.
- Resources mobilized by the Global Fund Secretariat for the AMFm copayment should be additional to and separate from resources raised for ongoing Global Fund grant making.
- Resource mobilization for supporting interventions should be part of ongoing resource mobilization for Global Fund grant making and should be integrated into the Global Fund resource mobilization strategy.
- AMFm co-payment funds should be held in a separate account with the Trustee. No funds should be transferred from the Global Fund's "general" account with the Trustee to support AMFm co-payments.
- The Global Fund should not make contractual commitments with manufacturers unless the necessary funds are available in the co-payment account with the Trustee.

12. The two key Global Fund policies governing resource mobilization and funding for Global Fund grants are the Comprehensive Funding Policy and the Policy on Restricted Financial Contributions. These policies do not contemplate any form of support other than grant-making operations. Since AMFm supporting interventions can be funded via the Global Fund's grant-making mechanisms, these policies will continue to govern resource mobilization and funding for AMFm supporting interventions. However these policies need to be expanded to accommodate resource mobilization and funding for AMFm co-payment.

13. The financial rules and arrangements for AMFm Phase 1 described in the AMFm Phase 1 Policy are consistent with the principles underlying the Comprehensive Funding Policy. The AMFm Co-Payment Fund shall only be used for AMFm co-payments. Funds from the Global Fund's "general" account with the Trustee (the "Global Fund General Fund") shall not be used to support AMFm co-payment commitments. It is also proposed that *all* donors (including Official Development Assistance or new public mechanisms) may restrict contributions to this AMFm Co-payment Fund. However, no further restriction on contributions (e.g. to region or country) will be permitted. This is an AMFm Phase 1 temporary exception to the Policy for Restricted Financial Contributions, i.e. the latter limits restricted contributions to private donors and a limited number of public mechanisms.

14. The financial rules for AMFm co-payment require that a forecast of resources available for AMFm Phase 1 co-payment, based on confirmed pledges, should be announced by the Secretariat at the time that AMFm applications are submitted to the Board for approval. In line with the Board's normal practice, the Board may then approve funding for AMFm Phase 1 co-payments, based on the forecast co-payment need for the full duration of Phase 1, up to the amount of funds available, based on confirmed pledges for AMFm co-payments²⁰.

15. In the same way as for grant agreements, the Secretariat will only make a financial commitment to pay for co-paid ACTs if there are sufficient assets (as defined in the Comprehensive Funding Policy) in the Trustee's AMFm Co-payment Fund to meet the full amount of such commitment. A financial commitment is made by the Secretariat each time that it accepts a first-line buyer's order for co-paid ACTs presented to it by a manufacturer, with the order specifying the maximum of the co-payment commitment. The Secretariat will only accept such an order if the level of uncommitted funds in the Trustee's AMFm Co-payment Fund can cover the full amount of the co-payment due under such order.

²⁰ An "AMFm Phase 1 co-payment commitment" is a commitment by the Global Fund to a manufacturer under a framework manufacturer contract to pay the co-payment portion of an order placed by a first-line buyer. Such commitment is concluded at the time the Global Fund "accepts" the order.

(4b) Risk Identification & Management

16. Potential challenges to successful global implementation of AMFm, along with their potential impact on the Global Fund, were considered in the AMFm business plan (GF/PSC9/03). Whilst this risk profile holds true for Phase 1 as well, it is important to note that the scale of risk has been reduced in most cases due to the phased roll out.

17. Failure of AMFm to reach its objectives: The AMFm is a new, innovative financing mechanism that has no direct parallel elsewhere in the global health architecture. Its on-going success will be based on its ability to make ACTs affordable to a vastly greater number of end-users and thereby positively impact malaria mortality/morbidity and the onset of ACT resistance. Failure to reach these objectives could result in loss of donor confidence and reputational damage to the Global Fund.

18. Mitigation of this risk was a key focus of the technical design by RBM, and the development of the business plan for managing the AMFm within the Global Fund. Supporting interventions to ensure that the price-reductions are passed on to end-users, and that broad access to co-paid ACTs is achieved, play a critical role in this context. This is why access to the AMFm for all countries is dependent on a financed roll out plan (either through the Global Fund, other donors or national resources) which includes these supporting interventions. Additionally, Monitoring & Evaluation activities during AMFm Phase 1, coupled with learning lessons from operational research findings from countries, where national ACT subsidy schemes are already ongoing, will maximize opportunities to learn about emerging challenges and permit corrective action, to the extent that is possible.

19. Furthermore, the rationale for introducing the AMFm in a select number of countries means that lessons can be learnt to inform and shape the nature of global roll out. For instance, AMFm performance in reaching the poor and vulnerable groups, as well as other key areas of function can be examined. In this way, a 'proof of concept' approach with a planned independent evaluation enables a balanced consideration of evidence before making a larger commitment – i.e. by the Global Fund itself, along with the wider international donor and development community.

20. Insufficient Funding: The resources required for the full Phase 1 period are estimated at US\$212 million AMFm co-payment and US\$100-125 million for AMFm supporting interventions. Since AMFm Phase 1 will not be launched unless there are sufficient contributions to cover the estimated AMFm need for the full Phase 1 period and since these amounts are small compared to the sums the Global Fund is accustomed to mobilizing and disbursing, this risk is relatively low. Given an increased global community response to malaria control and eradication, and the interest by some donors it is likely that resource requirements for AMFm Phase 1 can be met.

21. Limited Country participation: Lack of country interest in AMFm Phase 1 due to cumbersome access procedures would undermine the reach and impact of AMFm. However, early country consultations have indicated that countries are interested and willing to participate. Considerable efforts have also been made to address matters that may deter or hinder eligible countries decisions to participate in Phase 1. For example:

- Efforts are underway, including by the RBM Harmonization Working Group, to ensure the provision of technical assistance (where required), to develop country roll out plans, including supporting interventions. This additional, focused technical support is aimed to support successful applications and minimize transaction costs on busy country work schedules;

- The early release of a limited amount of approved funding to allow countries, without other sources of funding, to move ahead with their supporting interventions.

Additionally, country demand for ACTs via the Global Fund grant system further indicates that scaling up effective malaria treatment interventions remains high on country agendas.

22. Diversion of drugs: Unlike the risks above, when compared with a global roll out, there is an increased risk in Phase 1 of co-paid ACTs being diverted to countries that are not participating in AMFm. This is because there are greater incentives and opportunities for agents in the supply chain to profit from the subsidized ACTs. Measures adopted to detect and control leakage will include:

- Where first line buyers are identified abusing the system, they will be struck off the list of eligible buyers, so that they cannot access any further co-paid ACTs
- The use of an identifier on packaging that is unique to AMFm co-paid ACTs will facilitate monitoring efforts to track the movement of drugs across borders
- A whistle-blowing system

23. Limited Stock: In addition to these risks, concerns have been expressed about the size and availability of global raw material stocks for ACT manufacturing. With a sudden increase in ACT demand (i.e. generated by AMFm Phase 1, but also the substantial increase in demand from Round 8), the risk of ACT stock outs could rise. Steps to safeguard against this are:

- The number of countries selected to participate in AMFm Phase 1 will be predicated upon demand/supply forecasts that take the volume of available raw material stock into account.
- Negotiations with eligible manufacturers will gather information on their knowledge and access to raw material stocks.

24. Legal Risk: By taking responsibility for managing the AMFm and financing co-paid ACTs, the Global Fund may be deemed to have a limited duty to potential patients, and other parties, to use reasonable care in establishing a system that delivers co-paid ACTs in a safe and reliable manner. While the risks of successful claims against the Global Fund may be remote and can to an extent be mitigated, the consequences for the Global Fund in the event that patients, or others, suffer damages or injury could still be significant (including financial and reputational risk).

- These risks can, to an extent, be mitigated by documenting key relationships through contractual arrangements (grant agreements to finance country roll-out plans, agreements with manufacturers, and standard terms and conditions with first-line buyers)²¹. These agreements will need to be carefully drafted, but they do not, in themselves, create or increase the liability risks to the Global Fund. Rather, they serve to manage the Global Fund's risks and to minimize the liability of the Global Fund.
- In addition, these legal risks may be mitigated to some extent by the Global Fund using reasonable efforts to limit the likelihood of potential patients suffering injury as a result of co-paid ACTs. Measures to mitigate such risks are incorporated in the AMFm design and implementation plan, for example, by ensuring a reasonable process for the selection of participating manufacturers and only co-paying for ACTs that meet the Global Fund's quality assurance policy.

²¹ The purpose of these agreements is to clarify the roles and responsibilities, to obtain commitments to the principles of the AMFm (including quality assurance and pricing), to set out the conditions of participation, to provide a legal basis for monitoring, access rights and to provide protection for the Global Fund, through limitation of liability and indemnity provisions.

- The Global Fund should be able to rely on its immunity from legal process in the United States and Switzerland, such that any judgment obtained in another jurisdiction is unlikely to be enforceable against the Global Fund's assets. However, for reputational and other reasons, consideration would still need to be given to defending claims brought against the Global Fund.

25. **AMFm withdrawal:** Participating in AMFm will change national malaria planning and public and private sector markets for ACTs. Specific attention has been paid, through the planning of supporting interventions, to make the introduction of AMFm a carefully managed process. If the Board decides not to continue with AMFm after Phase 1, consideration will need to be given as to how to exit in a gradual and ethically responsible way from Phase 1 participating countries, and minimize the impact on global and local anti-malarials markets during the re-adjustment of ACT prices. The AMFm Phase 1 implementation plan includes a 6-month period to phase-out AMFm if this scenario should occur, and also includes provisions for financing supporting interventions for additional consumer and provider communication to support the transition.

26. **Organizational Capacity:** The Global Fund Secretariat is still growing and is currently undergoing a re-structuring of its organization to accommodate the increased size of its operations. In addition, the Global Fund is currently working on the implementation of its own administrative arrangements. This raises the question whether taking on the AMFm as a further major project would overstretch organizational capacity. Whilst this concern is real, three factors should help to mitigate this risk. Firstly, the AMFm will not be launched until the second quarter of 2009, which will allow the new structures to bed-down and new financial and administrative arrangements to be implemented prior to the launch of AMFm operations. Secondly, a limited number of additional Global Fund Secretariat staff resources will be required to deliver this expanded area of work, within the Fund's corporate portfolio of activity. Thirdly, AMFm Phase 1 is based on a select number of countries which is more manageable than an immediate global roll out.

27. The Global Fund has a **well-established risk management framework** through its fiduciary arrangements for grant recipients, its core structures at the Secretariat and the Office of the Inspector General, its policies, guidance and grant agreements. The risk management framework continues to evolve and it is intended that a detailed description will be presented to the Finance and Audit Committee next year. The AMFm design builds on the existing Global Fund assurance framework and also incorporates a monitoring system that is specifically designed for the AMFm. The Secretariat will take into consideration the specific risks associated with AMFm in the continuing development and enhancement of the Global Fund's risk management framework.

28. To conclude, as with any new venture, the phased launch of AMFm contains risks, yet these risks have to be compared to the consequences of further delays in accessing essential medicines for malaria. Moreover, many of the AMFm related risks can either be managed or measured. AMFm Phase 1 is a way to minimize these risks by allowing a 'road testing' of the approach to determine if the potential large scale treatments benefits sought, can be achieved in a way that risks (described above) are acceptably controlled or minimized.