Twenty-Seventh Board Meeting
Geneva, Switzerland, 13-14 September 2012

GF/B27/06
Board Decision

REPORT TO THE BOARD ON THE AMFm

PURPOSE:

1. This report provides context for GF/B27/DPXX: "Transitional Arrangements for the Affordable Medicines Facility-malaria (AMFm)" to extend the Global Fund's mandate to host the AMFm for an additional 12 months (until 31 December 2013) in order to ensure that access to quality-assured ACTs is not disrupted following the Global Fund Board's expected decision on the AMFm in November 2012.

PART 1: INTRODUCTION

1.1 The Strategy, Investment, and Impact Committee (SIIC) met in Geneva on 29-31 August 2012 for its 4th meeting. The Chair was Todd Summers (Private Foundations) and the Vice-Chair was Shaun Mellors (Communities).

1.2 This report is structured into five sections:

i. Part 1: Introduction (Information)
ii. Part 2 : Background on AMFm (Information)
iii. Part 3: Independent Evaluation of AMFm Phase 1 (Information)
iv. Part 4: The Future of AMFm beyond Phase 1 (Information)
v. Part 5: Interim Arrangements for 2013 (Decision)

PART 2: BACKGROUND ON AMFM — Information

2.1 The AMFm is an innovative financing mechanism that is hosted and managed by the Global Fund. The goal of the AMFm is to expand access to affordable artemisinin-based combination therapies (ACTs) in order to reduce malaria-related deaths and delay the onset of widespread resistance to the artemisinin in ACTs. The AMFm has four objectives: (i) increase ACT affordability, (ii) increase ACT availability, (iii) increase ACT use, including among vulnerable groups, and (iv) increase the market share of ACTs relative to less-effective antimalarials.

AMFm provides three inputs:

- Negotiations for price reductions with ACT manufacturers;
- Financing of buyer subsidies through co-payments to ACT manufacturers;
- Financing of supportive interventions at country level to promote appropriate use of ACTs.

2.2 AMFm Phase 1 is currently being implemented through the public, private for-profit, and private not-for-profit sectors in nine pilots in eight countries: Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (mainland and Zanzibar) and Uganda. Implementation of Phase 1 started in mid-2010 with the signing of grant agreements with the Global Fund and the ordering of co-paid ACTs by in-country buyers, and will end on 31 December 2012.

2.3 AMFm Phase 1 is funded from two sources. A co-payment fund of approximately US$338 million, financed by UNITAID, the governments of the United Kingdom and Canada, and the Bill & Melinda Gates Foundation, covers subsidies for ACTs. A further amount of up to US$127 million comes from the extension of existing Global Fund malaria grants to implement supporting interventions to promote appropriate use of ACTs at country level.

2.4 Based on the results of an Independent Evaluation of AMFm Phase 1, the Global Fund Board will decide in November 2012 whether to continue, modify, expand, suspend, or terminate the AMFm.

PART 3: INDEPENDENT EVALUATION OF AMFm PHASE 1 Information

3.1 At the request of the Board, the Global Fund Secretariat commissioned an Independent Evaluation to assess the extent to which AMFm has achieved its objectives. The Evaluation was designed to address the Global Fund Board decision point "*… the Global Fund will only expand from Phase 1 (the pilot phase) of the AMFm to a global scale-up on the basis of evidence gathered during the pilot phase that the initiative is likely to achieve its four stated objectives*" (GF/B20/DP24)

3.2 In 2010 the Technical Evaluation Reference Group (TERG) recommended (GF/B21/07) that the evaluation establish explicit and realistic success metrics. The TERG stressed some of the measurement limitations in the real-world conditions of the country. The TERG recommended the evaluation distinguish:

i. The *upstream* component, with emphasis on the business model of the AMFm as a financing platform; and
ii. The *downstream* component, with emphasis on service delivery to increase access to and use of ACTs, including by the poor. The TERG noted that the downstream part is neither new nor unique to the AMFm

3.3 As per guidance from the TERG, given the short implementation period, the Independent Evaluation has focused on the "upstream" part, with emphasis on the business model of the AMFm as a financing platform; this is assessed through the indicators related to availability, affordability, and market share. The "downstream" part related to ACT use, including among vulnerable populations, will be assessed through an analysis of relevant and available nationally representative secondary data sources from AMFm Phase 1 countries.

3.4 The Preliminary Report of the Independent Evaluation of AMFm Phase 1 was released on 19 July 2012. The Final Report is expected to be released before the September 2012 Board meeting.

3.5 **AMFm has been described by the Independent Evaluator as a "game changer" for the private for-profit sector.** The private sector plays an important role in the treatment of malaria: between 40% and 97% of antimalarial treatments are sourced from this sector in AMFm Phase 1 countries The Independent Evaluation showed that significant quantities of quality-assured ACTs have been quickly and widely distributed through pre-existing private sector networks, reducing or closing rural-urban gaps in a very short period.

3.6 The main results according to TERG questions and established 1st year benchmarks are summarized as follows:

i. **Availability:** The benchmark of increasing by 20 percentage points the availability of quality ACTs was met in both urban and rural outlets in **five of the eight** pilots.
ii. **Price:** The affordability benchmark of reducing the price of quality ACT to less than one third of the most popular non-quality ACT was met in **five of eight** pilots. (There is a particular reason for Ghana but we need to adhere to the benchmark)
iii. **Market share:** The benchmark of increasing by 10 percentage points the market share of quality ACTs in outlets carrying antimalarials was met in **four of eight** pilots.
iv. **Use:** The benchmark of increasing by 10 percentage points the use of quality ACTs to manage uncomplicated malarial fevers within 24 hours among the poorest quintile was not reported as data are not yet available. The Independent Evaluator plans to issue a

"late-breaker" addendum to the Final Report in October 2012, incorporating analyses on ACT use based on available household survey data from AMFm Phase 1 countries.

3.7 The degree to which success benchmarks were met depended on the duration of the implementation of the full AMFm model, including supporting interventions (particularly mass communication campaigns and a recommended retail price). Sub-optimal implementation of the components of the AMFm model limited the achievement of some success benchmarks in certain contexts. Contextual factors, including the political climate within a country and key regulatory steps, facilitated implementation of the AMFm model.

3.8 There are a number of issues and limitations to the study, internal and external validity and the short period of implementation which was assessed. A sub-Committee of the TERG was set up to conduct a technical review of the Independent Evaluation of the AMFm. The sub-Committee presented the outcome of its deliberations to the TERG at its 20th meeting.

3.9 The TERG plans to present a report on the AMFm Phase 1 Independent Evaluation to the SIIC at its October 2012 meeting. In addition to analysing the internal and external validity of the Independent Evaluation results, the TERG will also be looking at ways for the Global Fund to institutionalize the learning from the AMFm Phase 1 Independent Evaluation, to inform strategic investments in the broader Global Fund malaria grant portfolio.

PART 4: THE FUTURE OF AMFm BEYOND PHASE 1 **Information**

4.1 The Global Fund's hosting mandate for the AMFm ends on 31 December 2012. The Board plans to take a decision on the future of AMFm beyond Phase 1 at its November 2012 meeting. The SIIC has established the AMFm Working Group (AMFm WG) of the Market Dynamics Advisory Group (MDAG). This group has been tasked with recommending options for future hosting or other support of the AMFm based on the results of the Independent Evaluation and other appropriate analyses of its risks, benefits, and impact. To inform this recommendation to the Board, the AMFm WG will: consider evidence from the independent evaluation and other studies; consult with implementing countries, manufacturers, donors, and other stakeholders; and carry out in-depth analyses of several potential future options.

4.2 The Roll Back Malaria (RBM) Partnership Board recently established an AMFm Task Force to look at broader strategies to improve access to high quality diagnosis and treatment in the commercial private sector. Both groups are chaired by Alan Court, Senior Advisor in the Office of the United Nations' Secretary General's Special Envoy for Malaria. The RBM Task Force includes all AMFm WG members plus several other members. To ensure that the eventual recommendation of the AMFm WG is in step with global malaria control activities, the two groups have, in effect, been merged.

4.3 The AMFm WG has noted several important changes to the malaria landscape since the Global Fund agreed to host and manage AMFm Phase 1 in 2008.

i. **Malaria endemicity is falling.** Due to the scale-up of malaria prevention efforts over the past several years, malaria endemicity has fallen significantly, potentially reducing the probability that a fever is caused by malaria.
ii. **World Health Organization (WHO) recommends parasitological diagnosis before treatment** for everyone regardless of age or transmission intensity**.** Current guidance from WHO recommends that parasitological diagnosis (when accessible) should take place before treatment with an ACT for all age groups. Countries have begun to scale-up access to diagnosis, including the use of rapid diagnostic tests (RDTs), in the public sector. Access to diagnosis in the private sector is still very limited.
iii. **International funding for malaria is declining.** International funding for malaria declined in 2011 for the first time in a decade, reflecting an overall challenging financial climate for global health financing.
iv. **Resistance to artemisinin has been detected.** Resistance to artemisinin has been detected in Southeast Asia, and there have been strong efforts to reduce the availability of oral artemisinin monotherapies in many countries through regulatory intervention.

Any successor to AMFm Phase 1 will need to take these developments into account.

4.4 The AMFm WG has already been able to make some initial conclusions:

i. Given changes to the malaria landscape, AMFm WG will not be recommending AMFm be continued without modification;
ii. Future successor model(s) must ensure more sustainable funding;
iii. Quality-assured ACTs must be available to support implementation of regulatory interventions to limit availability of artemisinin monotherapies; and
iv. Future successor model(s) should be flexible enough to account for different country circumstances.

4.5 The AMFm WG is looking into options to modify the subsidy model to allow for a more targeted approach that includes diagnosis – potentially including a subsidy for RDTs and additional training/support in the private sector. The increased emphasis on malaria diagnosis raises questions about the Global Fund's role in the treatment of non-malarial fevers. Further, the SIIC and the AMFm WG recognize that the at-scale transition from the status quo (presumptive treatment) to consistent use of and adherence to an RDT, especially in the private sector, will take time.

4.6 Another option being considered by the AMFm WG for the recommendation to the Board is to maintain the subsidy only in areas that meet the following three criteria: (i) a high level of malaria mortality; (ii) the majority of malaria treatment sought in the private sector; and (iii) a high proportion of fever expected to be caused by malaria.

4.7 The AMFm WG is also reviewing modified models where the funding of AMFm is integrated into core Global Fund grants. In this case, Global Fund Principal Recipients will then have to allocate part of available resources to a private sector malaria component, including the costs of RDT and ACT subsidies.

4.8 In the event that resources are inadequate to make this sustainable, two possible alternatives are also under consideration: (i) reducing the level of subsidy; (ii) prioritizing countries according to factors such as malaria burden and income level; and (iii) targeting the subsidy only to paediatric dosage forms.

4.9 The fully costed options are planned to be available for the October 2012 SIIC meeting and the November 2012 Board. In all cases there will be a need for a transition period to the next phase for each AMFm Phase 1 country.

PART 5: INTERIM ARRANGEMENTS FOR 2013 **Decision**

5.1 The hosting mandate and current funding for AMFm Phase 1 end on 31 December 2012, six weeks after the Global Fund Board is expected to take a decision on the future of AMFm beyond Phase 1. AMFm has markedly altered the private-sector antimalarial market in Phase 1 countries and the global ACT supply market. Although the ACT requirements for the public sector in 2013 are covered by the traditional Global Fund grants, an abrupt termination of ACT supplies to the private sector may have serious consequences:

i. **Reversal of the gains made during AMFm Phase 1**, including decreased availability and increased retail prices of quality-assured ACTs and the return of less-effective or undesirable antimalarials (including through local production);
ii. **Criticism of the Global Fund** for any resulting short- or medium-term distortions to the global ACT supply market and/or disruption of country health services;
iii. **Loss of credibility** of the Global Fund, donors/partners, and country-level implementers in Phase 1 countries – particularly since AMFm has met the success benchmarks the TERG indicated were most meaningful; and
iv. **Inability to provide the gradual phase-out contemplated in the legal agreements between the Global Fund and AMFm first-line buyers.**

The AMFm WG and the Global Fund Secretariat have developed estimates for interim arrangements including supporting interventions:

i. **Orderly Phase-Out Scenario:** In the event that the Global Fund Board decides to *Terminate* all AMFm pilots in November 2012, there is a need for an orderly phase-out period of 12 months (seven months of full approval followed by a gradual reduction in co-payment through the end of 2013) to allow countries, the Global Fund, and partners to mitigate the effects of a Termination decision. This would cost **US$129 million.**
ii. **Responsible Transition Scenario:** In the event that the Global Fund Board decides to *Continue* or *Modify* all AMFm pilots in November 2012, there is a need for a responsible transition period of 12 months to allow time for AMFm Phase 1 countries to bridge to any new Global Fund funding opportunities. This would cost **US$171 million.**

In both cases, the Global Fund would continue to host AMFm during a 12-month transition period. These indicative estimates are for discussion and cautious planning purposes and do not yet reflect the modification scenario being assessed by the Working Group, which could likely involve both modification and termination, depending on country context. The final agreed estimates will be presented in November.

5.2 At the current rate, existing funding for AMFm Phase 1 will run out in December 2012; resources for the *Orderly Phase-Out* or *Responsible Transition* scenarios described above may need to be mobilized. Current donor contributions to the AMFm are limited to the pilot phase. Three donors (UNITAID, and the governments of the United Kingdom and Canada) have recently contributed US$120 million to a 2012 Phase-1 Cost-Extension. To date, resource mobilization efforts by the Secretariat have been limited by the fact that there is no decision by the Global Fund Board to continue hosting the AMFm beyond 31 December 2012.

5.3 Several constituencies have indicated potential support for funding AMFm activities through the traditional grant mechanism. The estimated cost for the *Responsible Transition*

scenario has been included in the Global Fund Forecast of Uncommitted Assets (01 July 2012 – 30 June 2015). However, there are currently two barriers prohibiting the support of AMFm co-payments from Global Fund grant resources:

i. **Board Decision Point GF/B17/DP16**: This decision stipulates that "no funds can be transferred from the Global Fund's 'general' account with the Trustee to support AMFm co-payments."
ii. **US authorization for 2009-2013 contribution to the Global Fund:** The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 stipulates that:

> *The Global Fund should not support activities involving the 'Affordable Medicines Facility-Malaria' or similar entities pending compelling evidence of success from pilot programs as evaluated by the Coordinator of United States Government Activities to Combat Malaria Globally.*

5.4 To ensure that there is adequate Secretariat capacity to respond to any Board decision regarding the future of the AMFm, the SIIC discussed and agreed to recommend the following decision point to the Board.

Decision Point GF/B27/XX: Transitional Arrangements for the Affordable Medicines Facility-malaria

The Board refers to its earlier decision regarding the duration of Phase 1 of the Affordable Medicines Facility – malaria ("AMFm") (GF/B22/DP13) and notes that Phase 1 will end on 31 December 2012.

The Board recognizes the importance of an orderly transition for those countries that are part of the Phase 1 pilot following its decision expected in November 2012 on whether to expand, accelerate, modify, terminate or suspend the AMFm business line. In order to support an orderly transition towards implementing the outcome of the November decision, the Global Fund will continue to host AMFm during a twelve-month transition period, and the Board will approve the details of the transition in November.

In order to support the transition period, the activities of the AMFm Unit shall be extended by twelve months (until 31 December 2013). The Board requests that the Secretariat include the appropriate budgetary implications of the extended mandate of the AMFm Unit in the 2013 Operating Expenses Budget.

The incremental budgetary implications of this decision point for the 2013 Operating Expenses Budget amount to approximately US$2.5 million to allow the AMFm Unit to support an orderly transition following the Board's expected decision in November 2012.