REPORT OF THE TECHNICAL REVIEW PANEL AND THE SECRETARIAT ON APPLICATIONS TO THE FIRST PHASE OF THE AFFORDABLE MEDICINES FACILITY - MALARIA (AMFm PHASE 1)

OUTLINE:

This report presents to the Board the recommendations of Technical Review Panel (TRP) for funding applications to AMFm Phase 1. The report also includes a report of the Secretariat on the application and screening process for AMFm Phase 1 and lessons learned and recommendations from the TRP resulting from AMFm Phase 1.
PART 1: INTRODUCTION

1.1 The Technical Review Panel (TRP) reviewed the technical merit of AMFm Phase 1 applications during its meeting held in Montreux, Switzerland, 24 August to 5 September 2009. The TRP also reviewed the technical merit of Round 9 proposals at this meeting. The Chair of the meeting was Dr Bolanle Oyeledun; the Vice-Chair was Shawn Baker.

1.2 This report is divided into the following sections:
- PART 2: TRP funding recommendations to the Board for AMFm Phase 1 applications
- PART 3: Secretariat report on the application and screening process
- PART 4: TRP review methodology on AMFm Phase 1 applications
- PART 5: Lessons learned and TRP recommendations

1.3 This report should also be read in conjunction with the following Annexes:
- Annex 1: List of eligible AMFm proposals reviewed by TRP (by funding recommendation category)
- Annex 2: List of TRP reviewers for AMFm Phase 1
- Annex 3: Further analysis of AMFm Phase 1 applications
- Annex 4: TRP Review Form and full text of each AMFm Phase 1 application

1.4 Annexes 1, 2 and 3 are provided with this report. Annex 4 is provided on a confidential basis in electronic format as supplementary documentation to Board members.

PART 2: TRP FUNDING RECOMMENDATIONS TO THE BOARD FOR AMFM PHASE 1 APPLICATIONS

2.1 The TRP reviewed 12 applications for AMFm Phase 1. The TRP’s recommendation for funding for each of these applications is listed in Annex 1.

2.2 The TRP recommended 10 applications for funding as follows:
   i.  5 were recommended for funding under Category 1: Recommended for funding with no or some issues identified for the Secretariat to take into account during the process of negotiating the amendment to the ‘host’ grant agreement
   ii. 5 were recommended for funding under Category 2: Recommended for funding, pending TRP satisfaction with further technical information provided by the applicant relating to components of the AMFm application.
   iii. 2 were not recommended for funding, under Category 3.

A more detailed discussion of the funding categories used by the TRP to make recommendations to the Board for AMFm Phase 1 is provided in Part 4 of this report.

2.3 The total budget recommended for funding in Categories 1 and 2 is US$ 126,682,068. Of this, it is estimated that US$ 98,129,257 will be provided through savings gained in the budgets of the recommended countries’ existing Global Fund malaria grants (from the lower price of artemisinin-based combination therapies (ACTs) under AMFm). A further US$ 11,004,397 will be

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1 The TRP and the Secretariat have submitted a separate report to the Board regarding the Round 9 proposals (GF/B20/09).
provided from other sources\(^2\). The total value of requests for *incremental new funding* for AMFm Phase 1 applications recommended by the TRP is US$ 17,548,414\(^3\).

**Decision Point 1: Approval of AMFm Phase 1 Applications**

1. **The Board approves those AMFm applications recommended for approval by the Technical Review Panel (TRP) as ‘Category 1’ and ‘Category 2’, as listed in Annex 1 to the Report of the Technical Review Panel and Secretariat on AMFm Applications (GF/B20/10), subject to paragraphs 2-3 below.** The Board’s approval is for re-programmed and new grant funding (as the case may be) for the full two-year AMFm Phase 1 period for each AMFm application.

2. **The applicants whose applications are recommended for approval as ‘Category 2’ shall:**
   
   i. provide an initial detailed written response to the requested TRP clarifications and adjustments by not later than four weeks after receipt of notification in writing by the Secretariat of the TRP’s funding recommendation; and
   
   ii. conclude the TRP clarifications process, as indicated by the written approval of the Chair and Vice Chair of the TRP, not later than 18 December 2009.

3. **For those applications recommended for approval as ‘Category 2’, if the TRP clarification process is not concluded to the satisfaction of the TRP by the deadline stipulated in paragraph 2(ii) above, the AMFm application in its entirety will be deemed not approved.**

4. **The Board declines to approve for funding those applications recommended by the TRP as ‘Category 3’ as indicated in Annex 1 in GF/B20/10.**

*This decision does not have material budgetary implications.*

**PART 3: SECRETARIAT REPORT ON THE APPLICATION AND SCREENING PROCESS**

3.1 **At the Eighteenth Board Meeting, the Global Fund Board, in agreeing to host and manage the AMFm, decided that the launch of the AMFm would be phased, beginning with a limited number of countries (AMFm Phase 1). The Board also decided that AMFm Phase 1 would be assessed by an independent evaluation and that the findings of this evaluation would be reviewed by the Global Fund Board to decide whether to proceed to global roll out of the AMFm (GF/B17/DP8). This decision was reaffirmed at the Eighteenth Board Meeting (GF/B18/DP7). In accordance with these decisions, twelve applicants\(^4\) were invited to apply to AMFm Phase 1, based on consideration of the following criteria:**

   i. Moderate to high malaria mortality rate (defined as >0.1/1000/year by World Health Organization);

   ii. Previous experience of large-scale ACT programs;

   iii. A recommendation to the Board by the AMFm Ad Hoc Committee that a country be invited to participate in Phase 1 based on the following factors:

   a) Strength of country monitoring and evaluation systems

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\(^2\) Other funding sources include existing Global Fund grant funds, other donor funds and domestic resources.

\(^3\) These amounts include budget amounts submitted in Euro (€). The US$ equivalent was calculated according to the official United Nations Exchange Rate of 1 October 2009. These amounts may change according to fluctuations in the exchange rate.

\(^4\) Benin, Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Rwanda, Senegal, Tanzania (mainland), Uganda and Zanzibar
b) Presence of a conducive regulatory environment

c) Effective in-country supply chain management

d) Strength of private sector involvement in malaria treatment distribution

e) In the case of Kenya, to achieve a consolidated cluster approach in East Africa

f) In the case of Cambodia, to counter increasing resistance to artemisinin that has been documented in Cambodia.

3.2 At its 17th meeting the Global Fund Board decided that countries should produce ‘roll-out plans’ for AMFm Phase 1 which should be reviewed for technical soundness by an independent standing technical body, with a particular focus on ensuring sufficient investment in necessary supporting interventions. Accordingly, and in consultation with eligible countries, technical partners and the AMFm Ad Hoc Committee the Secretariat developed the AMFm Phase 1 application form. This application form was submitted to the previous Chair of the TRP for feedback. The primary purpose of the application form was to enable applicants to request access to AMFm co-paid ACTs and it was structured to focus on the critical design elements of AMFm Phase 1. As part of their applications, applicants were required to demonstrate that they either were already or would implement a number of required supporting interventions, designed to ensure safe and broad access to ACTs under AMFm Phase 1. Applicants were also able to propose additional supporting interventions and could request funding from the Global Fund for these interventions. The application form was shorter than standard rounds-based forms as relevant information could be referenced from earlier rounds-based proposals including malaria epidemiological profile, applicant eligibility criteria and national malaria strategies. The call for applications with accompanying application form was issued on 20 March 2009.

3.3 The Harmonization Working Group of the Roll Back Malaria (RBM) Partnership coordinated the provision of technical assistance to applicants during the application development period. The Harmonization Working Group also co-convened a technical workshop to provide applicants with further information on monitoring and evaluation requirements under AMFm Phase 1. This workshop was held in Dar-es-Salaam on 11 June 2009, following the ‘Mock TRP’ meeting organized by the Harmonization Working Group. Global Fund Secretariat staff participated in that workshop with the objective of providing clarifications as needed.

3.4 Applications were received from all eligible applicants by the due date of 1 July 2009. Applications were screened by the Global Fund Secretariat for completeness and applicant eligibility. All twelve applications were submitted to the TRP for review.

3.5 Six countries eligible to apply for AMFm Phase 1 also submitted malaria proposals under Round 9. One country also submitted a National Strategy Application. The TRP’s funding recommendations following their review of these proposals are provided in the respective report of the TRP and the Secretariat.

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5 Required interventions were: i) Public awareness and education interventions; ii) Provider training, supervision and ongoing support; iii) Activities to ensure appropriate national drug monitoring (including pharmacovigilance, drug quality surveillance and resistance monitoring); iv) Strengthening national policies and regulations to ensure effective supply and broad distribution of ACTs; v) Interventions to expand ACT access to poor people and other vulnerable groups.

6 Additional supporting interventions could include, but were not limited to, introducing or expanding the use of diagnostics. Scaling-up the use of diagnosis was not included as a required supporting intervention for AMFm Phase 1, based on the guidance of the RBM Harmonization Working Group. Where an applicant did not have experience in scaling-up the use of diagnostic tests in the private sector, they were encouraged to undertake operational research in this area.
PART 4: TRP REVIEW METHODOLOGY OF AMFM PHASE 1 APPLICATIONS

4.1 AMFm Phase 1 applications were reviewed by the TRP during its meeting held 24 August to 5 September 2009. A subset of the TRP was constituted to review AMFm Phase 1 applications. This subset was comprised of six malaria experts and six cross-cutting experts. Membership of the TRP subset is set out in Annex 2.

4.2 In advance of the meeting, the Secretariat provided TRP members with background material on AMFm Phase 1. The Harmonization Working Group submitted specific briefing on the technical assistance provided to applicants during the application development process. The Global Fund Secretariat presented briefings on AMFm Phase 1 to the TRP before the three days of AMFm review sessions.

4.3 Each AMFm Phase 1 application was reviewed by a team of two malaria experts and two cross-cutting experts. Each application and funding recommendation was then discussed by the twelve AMFm reviewers in a parallel plenary session, prior to joining the full TRP plenary for Round 9. This process allowed members to consider the technical merits of each application in more detail and to ensure consistency of funding recommendations across all applications in this new initiative. The AMFm Phase 1 parallel plenary session was chaired by Shawn Baker, one of the Vice-Chairs of the TRP. The recommendations were then presented to the full TRP plenary where final recommendations were endorsed.

4.4 The TRP were requested to review AMFm Phase 1 applications according to the standard technical criteria of soundness of approach, feasibility, and potential for sustainability and impact and with regard to the stated objectives of AMFm Phase 1.

4.5 The TRP was requested to review each AMFm Phase 1 application as a whole. However, in keeping with their terms of reference, the TRP was advised that they may recommend modification or elimination of weak elements in an otherwise strong application, where those weak elements are not a required supporting intervention or any other essential component of the application.

4.6 In accordance with the AMFm implementation plan approved at the Eighteenth Board meeting (GF/B18/DP7), the TRP was advised that there would be no formal TRP clarifications process for AMFm Phase 1 applications. This proposal had been discussed with the previous chair of the TRP in advance of the Eighteenth Board Meeting. However, during the TRP meeting, members strongly recommended that a clarifications period be introduced for AMFm Phase 1, to enable the TRP to access information from the applicant after their review and prior to final approval for funding. As implementing this recommendation required amending the AMFm implementation plan, the Secretariat advised that they would need to seek the approval of the AMFm Ad Hoc Committee.

4.7 As an interim measure, the TRP review form was revised to incorporate a clarifications process and the TRP developed the following three categories for their funding recommendations, pending AMFm Ad Hoc Committee approval of the clarifications process:

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7 Increasing ACT availability, affordability, use and market share compared with undesirable antimalarial treatments.
### Category and description of recommendation

| Recommendation for funding | 1. Recommended for funding with no or some issues identified for the Secretariat to take into account during the process of negotiating the amendment to the ‘host’ grant agreement |
| Not recommended for funding | 2. Recommended for funding, pending TRP satisfaction with further technical information provided by the applicant relating to components of the AMFm application |
| 3. Rejected |

4.8 Following the TRP meeting, the AMFm Ad Hoc Committee approved the introduction of a clarifications period for AMFm Phase 1. In order to avoid delays to the implementation timeline for AMFm, the clarifications process will begin immediately following the release of this report to the Board and is intended to be completed by mid-December 2009.

### PART 5: TRP REPORT ON LESSONS LEARNED AND RECOMMENDATIONS

5.1 Following its review of the applications to AMFm Phase 1, the TRP has observed common strengths and weaknesses of these applications. The TRP has also noted a number of lessons learned and made a series of recommendations to the Board and Secretariat for any future expansion of the AMFm.

#### Strengths and weaknesses of AMFm Phase 1 applications

5.2 Overall, applications to AMFm Phase 1 were strong. Including those applications recommended for funding in categories 1 and 2, the success rate of AMFm Phase 1 applications was 83 percent. This is significantly higher than the success rate of Rounds-based proposals and Rolling Continuation Channel (RCC) proposals. The TRP emphasizes that the categorization system for funding recommendations used for AMFm Phase 1 does not directly correspond to that used for the Rounds-based channel or RCC.

**Supporting interventions**

5.3 In general, applications to AMFm Phase 1 addressed all required supporting interventions, in accordance with the AMFm design and as prompted by the structure of the application form.

5.4 Applicants were requested to explain all existing activities currently being undertaken under each required supporting intervention and, if necessary, to propose additional activities in these areas. Several applicants provided an excellent analysis of current activities and proposed new activities that were clearly complementary and additional to this existing work. Many of these applications also clearly demonstrated the evidence base for undertaking new activities, including describing where proposed activities were extensions of programs already in place or were based on pilots or operational research.

5.5 However, some applicants did not clearly explain how the proposed activities would build on existing programs and in some areas activities appeared to be duplicated. Furthermore, in some

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8 The cumulative success rate for Rounds-based proposals over Rounds 1-8 was 40 percent and the cumulative success rate for RCC over Waves 1-6 was 58 percent.
cases, applicants did not provide a sound evidence base for undertaking particular activities, such as describing the impact of previous activities or explaining how approaches would be pre-tested prior to large-scale implementation.

5.6 As with the Rounds-based channel, the TRP strongly recommends that AMFm applicants demonstrate how newly-proposed activities complement existing work and provide detailed evidence for the implementation approach.

5.7 The TRP was pleased to note that some applications clearly articulated how AMFm will align with and support the broader national malaria control program.

5.8 Many applications provided good analysis of the existing supply chain for anti-malarials across different sectors and proposed activities to improve these where necessary. Some applications also gave a very good description of how the private sector will be engaged in AMFm implementation; however, a lack of clarity on this point was a weakness in other applications.

5.9 The TRP was pleased to note that some applications proposed strong and innovative approaches to increase coverage to poor and remote populations, in line with the objectives of AMFm Phase 1.

Feasibility and coordination
5.10 However, some proposed activities were not feasible within the time period for AMFm Phase 1 and were not aligned across the demand and supply sides of ACT scale-up (such as not matching the proposed increase in behavior change communication campaigns with increased training for providers). Some proposals also did not demonstrate adequate capacity to undertake the proposed activities within the timeframe of AMFm Phase 1.

5.11 Several applicants proposed utilizing coordination ‘task forces’ within the CCM for AMFm. The TRP supported the introduction of these groups, under the existing forum of the CCM, but warned against the establishment of parallel coordination mechanisms.

Rapid diagnostic tests and ACT procurement
5.12 The majority of applicants proposed the introduction or expansion of rapid diagnostic tests to support ACT scale-up, including undertaking operational research where needed to inform scale-up in the private sector. The TRP welcomes this as a sound approach to malaria case management.

5.13 Some applicants proposed to purchase additional ACTs with ‘excess’ savings expected in their existing Global fund malaria grants. In some cases, applicants provided a clear quantification for this additional request, including taking into account recent changes in the malaria epidemic within their country. However, in some cases applicants did not provide detailed analysis to justify the additional procurement. The TRP recommends that in the future, the application form should explicitly prompt applicants to provide detailed quantification of ACT need for any additional procurement.

Budgets
5.14 In some cases, applicants provided lump sums in their budgets instead of disaggregated cost estimates. This makes it difficult for the TRP to assess the appropriateness of the funding request. Some applicants also proposed excessive budgets, including excessive unit costs and unnecessary requests for additional funding, given grants already in place in the country. To ensure the submission of sound and reasonable budgets for review, the TRP recommends that applicants provide detailed budget requests, disaggregated to include unit costs.
5.15 In some cases, applicants did not provide sufficient detail of the proposed activities to inform the subsequent resource allocations. In order to enable the TRP to assess the appropriateness of a proposed resource allocation, applicants are encouraged to provide full detail of the activity, including quantifying the scale of the program (such as the number of health professionals to be trained).

Design of AMFm Phase 1

5.16 The TRP recognizes the importance of the fundamental elements of the AMFm design. In particular, the TRP supports advocating for significant price reductions in the cost of ACTs and using these savings to facilitate robust malaria control programming, including the active involvement of the private sector.

5.17 However, the TRP is concerned that the use of diagnosis was regarded as an additional, rather than required, supporting intervention. The TRP strongly recommends that countries are supported to quickly scale-up access to appropriate case management, which includes access to both medicines and diagnosis.

5.18 The TRP is also concerned about the limitations of behavior change and communication campaigns that are focused exclusively on ACTs. The TRP encourages a robust BCC approach focused on all measures to improve prevention and treatment of malaria and not limited to ACTs alone.

Lessons learned regarding the application and review process for AMFm Phase 1

5.19 The TRP recognizes that as this was the first application process for the AMFm, some minor ‘teething problems’ were to be expected. However, the TRP regrets that it was not more closely involved with the development of the application and review process, including in the development of guidelines and additional documentation regarding design assumptions and approaches. The TRP found the AMFm Phase 1 applications process duplicative of the Rounds-based channel and confusing at times.

5.20 The TRP strongly recommends that the Secretariat consults extensively with the TRP when developing application processes in the future. The TRP was concerned that there were limitations in the AMFm Phase 1 application form and that it did not always direct applicants to provide the level of detail expected by the TRP in assessing a funding proposal.

5.21 The TRP also recommends that the existing funding recommendation system should be applied to AMFm proposals in the future, or that any changes to this system should be agreed with the TRP in advance of any subsequent review.

5.22 The TRP also strongly recommends that a clarifications process should be introduced for AMFm Phase 1 and any future AMFm applications. The clarifications process is a core element of the TRP review and is productive to both the TRP and the quality of a country’s application. It enables the TRP to fully understand the approaches proposed in an application prior to their final approval and allows the TRP to provide feedback to applicants regarding issues to take into account for the implementation of activities.

5.23 The TRP feels that the review process for AMFm Phase 1, including the decision to remove the clarifications period, was too rigidly defined by the Global Fund Board. While the TRP is highly respectful of the Board and of its recommendations, the TRP believes that from a technical standpoint it is important that its own independent structure and role be respected and preserved.
5.24 Ultimately, the TRP believes it was not the appropriate mechanism to review applications to the first, ‘proof of concept’ phase of AMFm, as it is not currently structured to work with experimental approaches. The TRP recommends that it be involved in deciding the appropriate review mechanism for all future pilot approaches so as to generate the evidence necessary to design the scale-up process that should be implemented through the rounds-based channel.
List of eligible AMFm proposals reviewed by TRP (by funding recommendation category)

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9 Rwanda submitted a total budget for supporting interventions of US$9,796,263. The TRP recommended an upfront budget reduction of US$6,938,511. The total upper ceiling budget for supporting interventions recommended by the TRP for Rwanda is US$2,857,752.
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Annex 3

Further analysis of AMFm Phase 1 applications

1. As part of the application, applicants were requested to provide a budget for their proposed AMFm activities (including supporting interventions, operational research and monitoring). They were also requested to estimate the savings that would be gained through their existing Global Fund malaria grants\textsuperscript{10}, as these savings would be used in the first instance to fund the cost of AMFm activities. In addition, applicants were requested to provide details of other funding sources for AMFm activities. The estimated savings in existing grants were not a funding ceiling for AMFm activities and, if needed, applicants were able to request additional, new funding from the Global Fund.

2. The total budget for AMFm activities across all applications recommended for funding was approximately US $126.6 million. As shown in Figure 1, 77 percent (US $98.1 million) of this funding is estimated to be provided through savings in existing grants. A further 9 percent (US $11 million) of funding required is expected to be provided through other funding sources. Finally, 14 percent (US $17.5 million) of funding required has been requested as new funding from the Global Fund.

![Figure 1: Sources of funding for AMFm Phase 1 activities in applications recommended for funding](image)

3. After AMFm activities had been budgeted, applicants were encouraged to return to the Global Fund any ‘excess’ savings in their existing Global Fund malaria grants. Alternatively, applicants were able to propose to use these ‘excess’ savings, firstly, to fund additional ACT procurement and secondly, to fund additional activities to strengthen the health system as relevant to the scale-up of ACTs.

4. Within those applications recommended for funding by the TRP, four applicants estimated that they would have ‘excess’ savings remaining in their existing malaria grants, after AMFm activities had been funded\textsuperscript{11}. The cumulative value of these ‘excess’ savings across these applicants was

\textsuperscript{10} Including unsigned Round 8 grants, but not including proposals to Round 9.
\textsuperscript{11} Due to budget cuts recommended by the TRP, it is expected that Rwanda will now also have ‘excess’ savings in its host grant. The detail of how these savings will be used will be determined during the grant amendment process in accordance with the priorities outlined in paragraph 3 above.
estimated to be approximately US$ 12 million. All four applicants proposed to utilize ‘excess’ savings to purchase additional ACTs and one of these applicants also proposed to undertake additional health systems strengthening activities.

5. As shown in Figure 2, applicants proposed to use 30 percent (approximately US $3.5 million) of these ‘excess’ savings for additional ACT procurement and 23 percent (approximately US $3.5 million) for additional health system strengthening activities. It is expected that 47 percent of ‘excess’ savings (approximately US $3.5 million) will be returned to the Global Fund.

Figure 2: Proposed use of ‘excess’ savings in AMFm Phase 1 applications recommended for funding

6. The total budget for AMFm activities across all applications recommended for funding (not including funding from other sources) is approximately US$ 115.7 million. As shown in Figure 3, of this amount, 33 percent of funding (US$ 36.9 million) has been budgeted towards communication material, 24 percent (US$ 28 million) has been budgeted for training and 18 percent (US$ 20.3 million) has been budgeted for monitoring and evaluation costs.
7. Applicants to AMFm Phase 1 were required to demonstrate that they either were already or would introduce activities to expand access to ACTs for poor people and other vulnerable groups. Applicants proposed a number of new activities under this supporting intervention, including: targeted BCC, training, supervision and procurement of ACTs for community health workers, introducing wholesaler incentives, market creation at the retailer level, supporting PSM in rural and remote areas, and encouraging the involvement of non-government organizations in ACT distribution.

8. Introducing or expanding the use of diagnosis was not a required supporting intervention under AMFm Phase 1. However, applicants were able to propose this as an additional supporting intervention. Where an applicant did not have experience in scaling-up the use of diagnostic tests in the private sector, they were encouraged to undertake operational research in this area.

9. Of those applications recommended for funding by the TRP, seven included a funding request for procurement of rapid diagnostic tests (RDTs). Five of these applicants proposed to undertake operational research into the expansion of RDTs in the private sector.
10. Applicants were requested to nominate which ACT combination(s) they request to be co-paid under AMFm Phase 1. The ACT combinations nominated in applications recommended for funding by the TRP are listed in Figure 4.

**Figure 4: ACT combinations requested for copayment in applications recommended for funding**

<table>
<thead>
<tr>
<th>ACT</th>
<th>Number of applicants requesting ACT</th>
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<tbody>
<tr>
<td>Artemether-lumefantrine (AL)</td>
<td>8</td>
</tr>
<tr>
<td>Artesunate + amodiaquine (AS+AQ)</td>
<td>8</td>
</tr>
<tr>
<td>Dihydroartemisinin-piperaquine (DHA-PIP)</td>
<td>3</td>
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